

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Comments of Safer Chemicals Healthy Families and NRDC
on Proposed Restrictions on Trichloroethylene Vapor Degreasing Uses under
Section 6 of the Amended Toxic Substances Control Act

Submitted via Regulations.gov (May 19, 2017)

Docket ID EPA-HQ-OPPT-2016-0387

Safer Chemicals Healthy Families (SCHF) and the Natural Resources Defense Council (NRDC) submit these comments on the Environmental Protection Agency's (EPA's) proposed rule to restrict use of trichloroethylene (TCE) in vapor degreasing under section 6 of the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).¹

SCHF is a coalition of national, state and local organizations committed to assuring the safety of chemicals used in our homes, workplaces and in the many products to which our families and children are exposed each day. SCHF and its partners took a leadership role during the LCSA legislative process, advocating the most protective legislation possible to reduce the risks of toxic chemicals in use today.

The Natural Resources Defense Council (NRDC) is a SCHF coalition partner. NRDC is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC submits these comments on behalf of our over two million members and online activists. SCHF and NRDC do not have any financial interest in the topic of these comments.

LCSA is the first major overhaul of the 1976 Toxic Substances Control (TSCA) and a potentially important step forward in evaluating and reducing the risks of chemicals to health and the environment in the US. If EPA takes forceful and proactive steps to implement the new law, it can deliver significant health and environmental benefits to the American people. However, if EPA rolls back the protections mandated by Congress, the law's promise will not be realized and the threats that chemical risks now pose to our communities and the environment will continue unchecked. SCHF and NRDC will engage constructively with EPA on an implementation path that maximizes the health and environmental protections of LCSA but will hold EPA accountable if it fails to carry out the law as enacted by Congress.

The following organizations have endorsed and are supporting the SCHF and NRDC comments:

¹ 82 Federal Register 7432 (January 19, 2007).

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
Asbestos Disease Awareness Organization
Bayou St John Conservation Alliance
Breast Cancer Action
Breast Cancer Prevention Partners
Center for Environmental Health
Citizens for a Clean Pompton Lakes
Clean and Healthy New York
Clean Production Action
Clean Water Action
Clean Water for North Carolina
Earthjustice
Ecology Center
Environmental Health Strategy Center
Healthy Legacy
Ithaca-SHIP.org

League of Conservation Voters
Learning Disabilities Association
Maryland PIRG
Midwest Environmental Justice Organization
MountainTrue
NC Conservation Network
Oregon Environmental Council
Physicians for Social Responsibility
POWER Action Group
Safer States
SCA Associates
Science and Environmental Health Network
Toxics Free Future
U.S. Public Interest Research Group (PIRG)
Utility Workers Union of America
VPIRG
WE ACT for Environmental Justice

SUMMARY OF KEY POINTS

This proposed rule – coupled with two companion EPA proposals – represents the first use of LCSA’s strengthened authorities for regulating unsafe chemicals. Congress overhauled section 6 of TSCA in direct response to the abysmal history of existing chemical control under the old law. Over a 40 year period, only a handful of existing chemicals were addressed under section 6. EPA’s most ambitious effort – the phase-out of several uses of asbestos, a uniquely dangerous chemical responsible for hundreds of thousands of deaths – was overturned by a court of appeals for failing to satisfy TSCA requirements.² Through LCSA, Congress eliminated the roadblocks to effective regulation under the old law and replaced them with a more flexible and protective framework intended to encourage more forceful EPA action to eliminate unacceptable chemical risks.

Although EPA’s TCE risk assessment was completed before the new law took effect, section 26(l)(4) of amended TSCA specifically authorizes EPA to use its expanded section 6 rulemaking powers to provide protection against the risks identified in that assessment. Since it will be several years before EPA is able to regulate the initial set of chemicals undergoing risk evaluations under the LCSA, early action on TCE is essential to demonstrate immediate and tangible progress in meeting the law’s risk reduction goals.

The case for immediate action on TCE use in vapor degreasing is compelling. TCE is a dangerous chemical that has been shown to have numerous harmful effects on human health, including cancer, risks to unborn fetuses and infants, effects on reproduction, liver and kidney damage and harmful effects on the nervous system. The vapor degreasing operations targeted by the EPA proposal are largely uncontrolled. As a result of these uses, tens of thousands of workers– including men and women of child-bearing age at risk of effects on fertility and reproduction -- are exposed to TCE at levels that are unsafe under established benchmarks for risk management. Banning TCE use in vapor degreasing is the only way to provide meaningful protection against these risks because lesser remedies will be

² *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

ineffective. A ban on these uses would follow the precedent of several states and other countries that have prohibited uses of TCE.

If the new TSCA law cannot be used to address such compelling and clear risks, it will be a dead letter before it is implemented. TSCA section 6(c)(1) requires EPA to publish a final rule on chemicals presenting unreasonable risks within one year of proposal. This deadline applies to the TCE rulemakings under the terms of TSCA section 26(l)(4). We urge EPA to finalize the TCE rule as proposed within this timetable.³

We will show below in these comments that:

➤ **EPA HAS CORRECTLY APPLIED THE RISK MANAGEMENT FRAMEWORK IN THE NEW LAW**

The TCE proposal represents the first application of the new section 6 requirements and will set an important precedent for future rulemakings on chemicals determined to present an unreasonable risk of injury to health or the environment. EPA has correctly recognized that:

- The determination of unreasonable risk under section 6 is strictly health-based and excludes consideration of cost or other non-risk factors.
- The restrictions imposed under section 6(a) must be sufficient to provide full protection against the unreasonable risk, without consideration of economic factors. Regulatory alternatives that do not eliminate the unreasonable risk – including for vulnerable subpopulations -- cannot lawfully be adopted.
- The “regulatory actions” analyzed in the required “statement” under section 6(c)(2)(A)(iv) should only include those restrictions that fully protect against the unreasonable risk. EPA should not analyze regulatory alternatives that fail to eliminate the risk.
- Similarly, the analysis of costs and benefits in the required EPA statement cannot override the obligation to provide sufficient protection against unreasonable risks, without regard to costs or other non-risk factors.

³ As EPA works toward finalizing this proposed rule, Nancy Beck, Deputy Assistant Administrator, must be recused from any involvement in the Agency’s deliberations and decision-making process. Dr. Beck’s former employer, the American Chemistry Council (ACC), filed comments on EPA’s earlier TCE proposal and will presumably submit comments on this TCE proposal. Dr. Beck herself earlier filed comments for ACC on the TCE risk assessment that forms the basis for the two TCE proposals. TCE is manufactured by a small group of companies who are members of ACC. The TCE rules will have direct and significant impacts on the financial and other interests of these companies. Paragraph 6 of the Trump Administration ethics pledge bars appointees for two years from participating “in any particular matter involving specific parties that is directly and substantially related to [the appointee’s] former employer or former clients, including regulations and contracts.” Because of its significant impacts on a discrete group of ACC members, the TCE rulemakings are “particular matters involving specific parties” and are “directly and substantially related to” ACC, Dr. Beck’s ex-employer, by virtue of ACC’s submission of comments on the proposed rules and Dr. Beck’s role in preparing ACC comments on the TCE risk assessment. If she participates in the deliberative process on these rulemakings, she will be violating applicable ethical requirements and EPA actions reflecting her influence will be unlawful and an abuse of discretion.

- Under section 6(c)(2)(C), EPA must consider the availability of substitutes for banned or restricted uses but this does not change the Agency’s obligation to select restrictions sufficient to protect fully against the unreasonable risk.

➤ **TCE USE IN VAPOR DEGREASING PRESENTS AN UNREASONABLE RISK**

The record amply supports EPA’s determination that the TCE uses it proposes to ban present an “unreasonable risk of injury to health or the environment” requiring restriction under TSCA section 6(a):

- TCE’s adverse health effects are well-documented, have been confirmed in multiple peer reviewed studies and include cancer, harm to male and female reproduction and heart abnormalities and other damage to unborn fetuses and newborn infants.
- Tens of thousands of workers breathe and/or have dermal contact with TCE in largely uncontrolled settings from vapor degreasing operations.
- EPA has determined that TCE exposure levels within this large population are significant based on valid and peer-reviewed models that are adequate and reliable for TSCA risk evaluations.
- The EPA-calculated Margins of Exposure (MOEs) for TCE’s non-cancer effects are well below the benchmark MOEs that the Agency has historically used to determine low risk for these endpoints, confirming that TCE exposures are widely occurring at levels that are unsafe and unacceptable.
- Using established risk extrapolation methods, EPA determined that the cancer risk for a large segment of the TCE-exposed population is within a range (10^{-2} - 10^{-3}) that EPA and other authoritative bodies have historically deemed unacceptable and to warrant regulation.
- EPA’s risk estimates for non-cancer effects and cancer are understated because EPA did not take into account the contribution of exposure to TCE by the dermal route.
- The risks of TCE to vulnerable populations from the targeted uses (including large numbers of pregnant women and members of environmental justice communities) are significant and well defined and require special protection under TSCA.

➤ **EPA’S ANALYSIS DEMONSTRATES THAT A BAN ON THE TARGETED USES IS THE ONLY RESTRICTION UNDER SECTION 6(a) THAT WILL ADEQUATELY PROTECT AGAINST THE UNREASONABLE RISK**

After determining that TCE vapor degreasing uses present an unreasonable risk of injury, EPA’s next task was to examine the list of authorized restrictions in section 6(a) and select requirements that would assure that the chemical “no longer presents such risk.” It concluded that a ban on this TCE use is the only remedy that would reliably achieve that goal. This conclusion is fully explained and justified in the preamble to the proposal and the administrative record:

- EPA correctly focused on options that could provide exposed workers with sufficient protection against TCE-related non-cancer and cancer risks and further screened these options to determine whether they would in fact be effective and reliable in eliminating these risks.

- Applying these criteria, EPA rejected label warnings and instructions under TSCA section 6(a)(3) on the ground that they are not uniformly read, comprehended or followed and thus provide limited protection, particularly in small businesses with high employee turnover.
- EPA also evaluated whether continued TCE use might be made safe by reducing the concentration of TCE in degreasing formulations and/or by requiring local exhaust ventilation at TCE-using facilities. However, it found that, after taking these measures, TCE exposures remained too high – by orders of magnitude – “to achieve the target MOE benchmarks for non-cancer end-points for acute and chronic exposures and standard cancer risk benchmarks for chronic exposures.”
- EPA also determined that, either alone or in conjunction with other measures, respirators could reduce exposures to levels that are protective against non-cancer and cancer risks. However, it rejected this remedy because the many drawbacks of respirator programs limit their ability to provide consistent, reliable protection against exposure in practice.
- Under the well-established “hierarchy of controls” applied by OSHA and the industrial hygiene community, respirators are the least preferred workplace protection strategy, to be implemented only if more effective measures like chemical substitution are not feasible. Here, EPA correctly found that substitution of other solvents for TCE in vapor degreasing will fully protect against the unreasonable risk and, consistent with long-standing OSHA policies, will be more effective and reliable and significantly less costly than respirators in safeguarding TCE-exposed workers.
- EPA and OSHA determined that the workplace exposure limit for TCE is not sufficiently protective of worker health.

➤ **EPA’S DETERMINATION THAT ITS BENEFITS GREATLY EXCEED ITS COSTS STRONGLY SUPPORTS THE PROPOSED RULE**

The use bans proposed by EPA would both achieve benefits significantly larger than the costs and achieve risk reductions far more cost-effectively than other alternatives.

- As required by section 6(c)(2)(A), EPA’s proposed rule is accompanied by a statement comparing its costs and benefits. While this comparison cannot justify compromising the protectiveness of the selected remedy, it provides an important overall perspective on the proposal’s contribution to societal well-being.
- EPA found that the total costs of the proposed rule would be \$30-46 million annualized over 20 years. This is less than the benefits of the rule (\$32 to \$447 million annualized over 20 years) even excluding non-monetizable benefits of avoided non-cancer health effects, which are at least as significant as the reductions in cancer risk that EPA was able to monetize.
- EPA also examined the relative costs and benefits of the principal regulatory alternative it considered – requiring air-supplied respirators and some process controls – and concluded that it would be less protective and produce smaller benefits but result in comparable costs (between \$32 and \$47 million annualized over 20 years).

➤ **EPA’S ANALYSIS OF SUBSTITUTES DEMONSTRATES THAT A WIDE RANGE OF EFFECTIVE, LOW HAZARD TCE REPLACEMENTS IS AVAILABLE**

As required by section 6(c)(2)(C), EPA considered to the extent practicable the availability, costs, technical and economic feasibility and risks of chemicals that could be substituted for TCE in vapor degreasing operations. The EPA analysis demonstrates that a wide range of effective, economical and safer substitutes is available. The availability of adequate substitutes is also demonstrated by experience under TCE bans in several states and the EU. As industry transitions away from TCE, EPA must play a critical role in encouraging substitutes that are truly “reduced risk” and avoiding replacements like N Propyl bromide (nPB) which have serious adverse health effects.

➤ **THERE IS NO BASIS FOR REFERRING RISKS RELATED TO TCE USE IN VAPOR DEGREASING TO OSHA UNDER SECTION 9(a) OF TSCA**

Section 9(a) of TSCA creates a mechanism by which EPA may refer a chemical presenting an unreasonable risk to another agency for action under its governing authority in lieu of rulemaking under section 6(a) of TSCA. Since workers comprise the bulk of the population exposed to TCE vapor degreasing products, EPA considered whether to refer the unreasonable risks presented by these products to the Occupational Safety and Health Administration (OSHA) under section 9(a). However, EPA properly decided against this course after comparing its authority to eliminate these risks to that of OSHA, concluding that “with the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce” risks from these uses of TCE.

➤ **WHILE THE “GOOD SCIENCE” CONSIDERATIONS OF TSCA SECTION 26(h) ARE NOT APPLICABLE TO THE TCE RISK ASSESSMENT, IT IS FULLY CONSISTENT WITH THESE CONSIDERATIONS**

Section 26(h) of amended TSCA sets out general “standards” for using science in decision-making under the new law. Since the TCE risk assessment was developed under the old law, the provisions of section 26(h) are not “applicable” requirements that the assessment must meet under section 26(l)(4). In any case, the science standards in section 26(h) are straightforward, flexible and generally consistent with current and past agency practice. EPA’s transparent and fully documented TCE risk assessment, based on peer-reviewed data, methods and findings, would easily meet section 26(h)’s “good science” benchmarks, assuming they are applicable to the assessment in the first instance.

➤ **EPA’S THREE-PHASE IMPLEMENTATION FRAMEWORK IS APPROPRIATE BUT EPA SHOULD ADOPT A FASTER SCHEDULE FOR TCE ELIMINATION IN VAPOR DEGREASING OPERATIONS**

EPA proposes to impose its prohibitions on TCE use in vapor degreasing by placing separate requirements on upstream manufacturers, processors and distributors and on downstream users and by requiring written notification of these prohibitions at all levels in the value chain. This is a sound and comprehensive approach that maximizes the likelihood that these products will be removed from the stream of commerce.

EPA is also proposing an implementation schedule under which the requirements of its rule will take effect within 18 months of its publication date for upstream manufacturers and processors and within 24 months for downstream degreasing operations. The immediacy of the risk and large

exposed population heavily favor the most expedited compliance schedule feasible. We believe that the evidence cited by EPA indicates that it can shorten its implementation schedule for end users by six months. We agree that some modest delay in compliance might be appropriate for those users who commit to convert to aqueous or other non-toxic leaning systems. However, any across-the-board extension for such firms should be limited (no longer than 6 months) and further delays in compliance to enable conversion to non-toxic processes should be granted only through the section 6(g) exemption process based on a particularized showing of need.

I. EPA HAS CORRECTLY APPLIED THE RISK MANAGEMENT FRAMEWORK IN THE NEW LAW

The TCE proposal represents the first application of the new section 6 requirements and will set an important precedent for future rulemakings on chemicals determined to present an unreasonable risk of injury to health or the environment. We believe the risk management framework on which the TCE proposal is based is compelled by the language and intent of LCSA and provides a strong foundation for future rules targeting unsafe chemicals.

Under section 26(l)(4), EPA may issue rules under section 6(a) of the new law based on pre-enactment risk assessments even if these assessments did not address all potential risks and conditions of use. Congress provided this authority to EPA on the understanding “that, rather than reexamine and perhaps broaden the scope of these assessments, it is better to proceed with proposed and final rules on the covered chemicals to avoid any delay in the imposition of important public health protections that are known to be needed.”⁴

These rules must be “consistent with the scope of the completed risk assessment and consistent with other applicable requirements of section 6.” Thus, the TCE proposal must conform to the requirements of section 6 except where they are inapplicable.⁵

As EPA has concluded, several elements of section 6 should govern the TCE rulemaking:

A. The Determination of Unreasonable Risk under Section 6 is Strictly Health-Based and Excludes Consideration of Cost or Other Non-Risk Factors.

Because EPA did not conduct a risk evaluation on TCE under the old law, the critical predicate for risk management under section 6 – a determination that TCE presents an unreasonable risk of injury – must be part of its section 6(a) rulemaking. Under section 6(a)(4)(A), such determinations must be made “without consideration of costs or other non-risk factors.” In addition, EPA must examine not just risks to the general population but whether the chemical presents an “unreasonable risk to a potentially exposed or susceptible population . . . under [the chemical’s] conditions of use.”

⁴ Congressional Record – Senate 3519 (June 7, 2016).

⁵ For example, because EPA is proceeding directly to rulemaking based on an existing risk assessment, the prioritization provisions of section 6(b)(1)-(2)) are inapplicable. Similarly, since the risk assessment was completed before the new law took effect, the science “standards” in section 26(h) and (i) would be inapplicable. To incorporate these considerations in the risk assessment would require reopening and revising it. Congress obviously did not intend this because it described carryover risk assessments as “completed” in section 26(l)(4). Moreover, the “applicable” requirements EPA must comply with under this provision are those in section 6, not other portions of the law.

The exclusion of all factors other than the nature and magnitude of the risk represents a conscious departure from the old law and is intended to assure that only health and environmental factors – and not economic considerations – will drive EPA’s judgments of unreasonable risk. While “unreasonable risk” had previously been viewed as requiring a weighing of risk and economic considerations, the LCRA legislative history is clear that Congress wanted to eliminate any such “balancing test.”⁶

B. EPA Must Initiate and Complete Rulemaking by Prescribed Deadlines Under Section 6(a) Where It Makes a Determination of Unreasonable Risk

Under section 6(c)(1), a determination of unreasonable risk obligates EPA to propose and finalize a rule restricting the chemical under section 6(a). Since EPA’s determination for TCE is part of its proposed rule, the timetable for initiating rulemaking in section 6(c)(1)(A) does not apply. However, once EPA proposes a rule for a chemical presenting an unreasonable risk, section 6(c)(1)(B) requires EPA to finalize the rule within one year from proposal except where EPA extends this deadline under paragraph (1)(C).⁷ This requirement would be “applicable” to the TCE rulemaking under section 26(l)(4). Thus, SCHF and NRDC expect EPA to promulgate a final TCE rule by January 19, 2018, a year after it published its proposal.

C. The Restrictions Imposed Under Section 6(a) Must be Sufficient to Provide Full Protection Against the Unreasonable Risk

Section 6(a) provides that, upon determining that a chemical presents an unreasonable risk, EPA must examine the list of permitted remedies and select the requirements it considers best to address the risk. In making this selection, EPA must restrict the chemical “to the extent necessary so that the chemical no longer presents such risk.” This directive replaces a discredited requirement under the old law to impose the “least burdensome” restrictions. In addition, because Congress eliminated any risk-cost tradeoff in the definition of unreasonable risk, the adequacy of a remedy depends strictly on its effectiveness in eliminating the risk. EPA has no ability to compromise this level of protection based on economic considerations or to impose restrictions insufficient to protect against the risk in order to reduce costs. Regulatory alternatives that do not provide full protection cannot lawfully be adopted under section 6(a) and should not be considered in the formulation of EPA’s rule.

D. The Required “Statement of Effects” that EPA Must Publish on the Economic Consequences of the Rule Must Only Consider Regulatory Alternatives That Would Pass Muster Under Section 6(a)

Under section 6(c)(2)(A)(iv), EPA must “publish a statement based on reasonably available information with respect to” four issues, including “the benefits of the chemical substance for various uses” and “the reasonably ascertainable economic consequences of the rule.” In addressing the latter issue, EPA must describe “the costs and benefits of the proposed regulatory action and of the one or more primary regulatory actions considered by the Administrator” as well as the “cost effectiveness” of these actions.

⁶ Congressional Record – Senate 3516 (June 7, 2016).

⁷ Such extensions cannot exceed 2 years. Where the subject chemical is on EPA’s Workplan List, as is the case for TCE, an extension can only be granted if EPA provides an “adequate public justification, following the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.”

Congress limited the burden on EPA in conducting this analysis by providing that it must be based on “reasonably available information” and focus on those economic impacts that are “reasonably ascertainable.”

Since only options that will assure that the chemical “no longer presents [an unreasonable] risk” can be considered by the Administrator under section 6(a), the “regulatory actions” analyzed in the statement should only include those that would provide protection against that risk. EPA could not and should not identify and analyze the costs, benefits and economic consequences of regulatory alternatives that provide inadequate protection and could not lawfully be adopted under section 6(a).

E. The Analysis of Costs and Benefits in the Required EPA Statement of Economic Consequences Does Not Override The Obligation to Select Requirements under Section 6(a) that Provide Sufficient Protection Without Regard To Costs Or Other Non-Risk Factors

Section 6(c)(2)(B) provides that, “in selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable,” the statement published under subparagraph (A) “in accordance with subsection (a).” This provision requires EPA, in deciding what requirements it will impose, to give weight to the analysis of costs and benefits in the its statement of “reasonably ascertainable economic consequences” but only if “practicable” and only as allowed under subsection (a) – i.e. where the restrictions selected by the Agency fully protect against the unreasonable risk, without regard to economic considerations. Thus, the cornerstone statutory mandate to assure that the chemical no longer presents an unreasonable risk cannot be compromised based on a cost-benefit or least-cost analysis.

This interpretation is confirmed in the detailed analysis and additional views of Democratic Senators issued at the time of the LCSA’s enactment:

“The scope of the statement EPA is required to prepare under clauses (i)–(iv) is bounded in two important respects. First, it is to be based on information reasonably available to EPA, and hence does not require new information collection or development. Second, EPA’s consideration of costs and benefits and cost-effectiveness is limited to the requirements of the rule itself and the 1 or more “primary” alternatives it considered, not every possible alternative. The role of the statement required under subparagraph (c)(2)(A) in selecting the restrictions to include in its rule is delineated in subparagraph (c)(2)(B). Under this provision,

EPA must “factor in” the considerations described in the statement “to the extent practicable” and “in accordance with subsection (a).” As revised, subsection (a) deletes the paralyzing “least burdensome” requirement in the existing law and instructs that EPA’s rule must ensure that the chemical substance or mixture “no longer presents” the unreasonable risk identified in the risk evaluation. **Thus, it is clear that the considerations in the statement required under subparagraph (c)(2)(A) do not require EPA to demonstrate benefits outweigh costs, to definitively determine or select the least-cost alternative, or to select an option that is demonstrably cost-effective or is the least burdensome adequately protective option. Rather, it requires only that EPA take into account the specified considerations in deciding among restrictions to impose, which must be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified.** The Frank R. Lautenberg Chemical

Safety for the 21st Century Act clearly rejects the regulatory approach and framework that led to the failed asbestos ban and phase-out rule of 1989 in *Corrosion Proof Fittings v. EPA* 947 F.2d 1201 (5th Cir. 1991).⁸

Thus, it is clear that while considerations of cost, benefits and cost-effectiveness must be taken into account if practicable, they cannot dictate the choice of remedy, which must achieve the level of protection necessary to eliminate the unreasonable risk.

It is also clear that, because EPA's "Statement of Effects" must only be based on "reasonably available information" and EPA is not obligated to undertake new information collection and development, industry has an affirmative responsibility to provide relevant data and analysis in a timely manner and, where it fails to do so, cannot complain that the Statement is incomplete or inadequate.⁹ For example, if industry questions EPA's estimates of the cost of reformulating products with substitute solvents, it must provide alternate estimates with supporting documentation rather than demand that EPA correct its estimates in the absence of concrete data.

F. The Availability of Substitutes For Banned or Restricted Uses is Another Factor EPA Must Consider But This Does Not Change the Agency's Obligation to Select Restrictions Sufficient to Protect Fully Against the Unreasonable Risk

Section 6(c)(2)(C) provides that, when deciding whether to prohibit or substantially restrict a specific use of a chemical or establishing a transition period for these requirements, EPA –

“shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.”

While directing the Agency to consider the availability of substitutes that pose lower risks than the regulated chemical for the banned or restricted use, this requirement does not supersede section 6(a). Thus, regardless of the availability of substitutes, EPA remains obligated to select restrictions that eliminate the unreasonable risk, including banning particular uses of a chemical where necessary to provide sufficient protection.

In addition, EPA has authority under section 6(g) to grant time-limited exemptions from requirements of a section 6(a) rule based on a host of factors, including whether the restricted use is “critical” or “essential” and the comparative risk profiles of the regulated chemical and available alternatives. This provision demonstrates that, rather than weakening the restrictions in its section 6(a) rule, EPA must address any substitution concerns by granting appropriate use exemptions where warranted under the criteria in subsection (g).

⁸ Congressional Record S3516 (June 7, 2016) (emphasis added).

⁹ It's also significant that the LCSA does not mandate a full regulatory impact analysis or refer to Executive Order 12866 on regulatory review. In any event, this EO only mandates a regulatory impact analysis for rules with annualized impacts on the economy of \$100 million or more. The proposed vapor degreasing rule would not meet this threshold.

In this case, as described more fully below, there are many demonstrated TCE alternatives currently available for vapor degreasing, and thus the absence of substitutes should not be a factor in choosing the best remedy under section 6(a) or a reason to delay the rule's effective date under section 6(d). If there are specific operations where adequate substitutes are not available, the appropriate response is to grant use exemptions under section 6(g).¹⁰

II. TCE USE IN VAPOR DEGREASING PRESENTS AN UNREASONABLE RISK

The record amply supports EPA's determination that TCE use in vapor degreasing presents an "unreasonable risk of injury to health or the environment" requiring restriction under TSCA section 6(a).

The original version of TSCA did not include a definition of unreasonable risk. While Congress had an opportunity to add such a definition in the LCSA, it chose not to, stipulating only that a determination of unreasonable risk cannot include cost or other non-risk factors. However, as EPA has elsewhere noted, a number of factors are commonly used to make risk-based judgments, including the nature, irreversibility and severity of the hazard, the size of the exposed population, the levels, frequency and duration of exposure and uncertainties in the evidence of hazard and exposure. In addition to these scientific issues, policy considerations are important in weighing the seriousness of a risk. This would include, for example, cancer risk levels that EPA and other agencies have traditionally deemed unacceptable and Margins of Exposure (MOEs), safety factors and other benchmarks that regulators have developed to determine the acceptability of non-cancer risks (including developmental and reproductive toxicity, neurotoxicity and other serious health effects). Moreover, since potentially exposed or susceptible subpopulations must be protected against unreasonable risk, EPA must directly address the exposure and hazard scenarios that affect these groups and, considering these factors, determine whether the unique risks they experience are unreasonable.

There is no fixed formula for weighing these scientific and policy considerations (or others that may be relevant); each chemical will require a unique set of judgments.

By any standard, TCE use in vapor degreasing presents an unreasonable risk because of –

- 1) The unusual and extensive number of adverse health effects attributed to TCE and the strength of the scientific evidence documenting their occurrence;
- 2) The large size of the worker populations exposed to TCE;
- 3) The largely uncontrolled nature of exposure and high projected exposure levels; and
- 4) The large calculated risks, which significantly exceed established regulatory benchmarks for determining whether risks are unacceptable.

A. TCE Causes Serious Adverse Health Effects, Including Cancer, Harm to Male And Female Reproduction and Damage to Unborn Fetuses and Newborn Infants

Acute poisoning and long-term or chronic adverse health effects from TCE exposure are extremely well-characterized and have been extensively reviewed in previous assessments by EPA and other authoritative bodies. Once in the blood stream, TCE travels through the whole body and can access all

¹⁰ EPA indicates it is considering this approach for certain degreasing operations. See 82 FR at 7451.

the organs, cross the placenta to access the fetal circulation, and pass through the blood brain barrier into the brain (historically it was used as an analgesic and anesthetic).¹¹ For this reason, the adverse health effects are not exposure route-specific: that is, systemic effects are similar, whether exposure is through oral, dermal or inhalation routes.¹² Company doctors warned against exposing workers to TCE almost a century ago. A 1932 letter from Dr. Carey McCord (medical advisor for Chrysler Corp.) published in the Journal of the American Medical Association warned that, "any manufacturer contemplating the use of trichloroethylene may find in it many desirable qualities. Too, in the absence of closed systems of operations [no ventilation], he may find in this solvent the source of disaster for exposed workmen."¹³

1. Acute Poisoning Effects

Even short-term exposures to TCE can lead to headaches, dizziness, loss of consciousness, and, at higher exposure levels, to coma and even death.¹⁴ Short-term inhalation exposures to high realistic levels in people have been reported to cause neurological effects, including blurred vision, impaired hearing, dizziness and loss of balance, muscle weakness and tremors, impaired cognitive function, and altered heartbeat. Systemic effects including liver and kidney damage are also observed. Short-term dermal exposures such as from spills or splashing have been reported to cause skin rashes. These effects in people are consistent with results reported in laboratory animals (reviewed in detail in ATSDR 2014).¹⁵

2. Reproductive Harm

Chronic workplace exposures in men can lead to reduced sex drive, poor sperm quality, and altered reproductive hormone levels. According to EPA:

"The toxicological literature provides support for male and female reproductive effects following TCE exposure. Both the epidemiological and animal studies provide evidence of adverse effects to female reproductive outcomes. However, more extensive evidence exists in support of an association between TCE exposures and male reproductive toxicity. There is evidence that metabolism of TCE in male reproductive tract tissues is associated with adverse effects on sperm measures in both humans and animals. Furthermore, human studies support an association between TCE exposure and alterations in sperm density and quality, as well as changes in sexual drive or function and altered serum endocrine levels (Ref. 1)."¹⁶

TCE's potential for reproductive harm is a serious concern to the public, and well documented.

3. Cancer

After comprehensively reviewing all the data, in 2014 IARC classified TCE as "known" to cause cancer in humans (Group 1), based on evidence of kidney cancers in people, and rodent studies showing that it is

¹¹ Helliwell PJ, Hutton AM. 1950. Trichloroethylene anesthesia. I. Distribution in the foetal and maternal circulation of pregnant sheep and goats. *Anesthesia* 5:4-13. In ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. <https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf>

¹² ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. <https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf>

¹³ <http://jamanetwork.com/journals/jama/article-abstract/282234> (JAMA July 30, 1932)

¹⁴ Id.

¹⁵ Id. ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. <https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf>

¹⁶ 81 FR at 91596

a multisite carcinogen (liver, kidney, lung, testes, and blood) by both the oral and inhalation routes of exposure.¹⁷ As EPA discusses in the proposed rule, TCE also meets its definition of “carcinogenic to humans”, the strongest hazard descriptor in EPA’s 2005 Cancer Guidelines:

“Studies in both humans and animals have shown changes in the proximal tubules of the kidney following exposure to TCE (Ref. 1). The TCE IRIS assessment concluded that TCE is carcinogenic to humans based on convincing evidence of a causal relationship between TCE exposure in humans and kidney cancer (Ref. 3). A recent review of TCE by the International Agency for Research on Cancer (IARC) also supported this conclusion (Ref. 4). The 13th report on carcinogens (RoC) by the National Toxicology Program also concluded that TCE is reasonably anticipated to be a human carcinogen 2015 (Ref. 5). These additional recent peer reviews are consistent with EPA’s classification that TCE is carcinogenic to humans by all routes of exposure based upon strong epidemiological and animal evidence (Refs. 1 and 3).”¹⁸

4. Developmental Harm

Considerable concern has also been raised about TCE’s effects on unborn fetuses and infants, as explained by EPA:

“An evaluation of the overall weight of the evidence of the human and animal developmental toxicity data suggests an association between pre- and/or post-natal TCE exposures and potential adverse developmental outcomes. TCE-induced heart malformations and immunotoxicity in animals have been identified as the most sensitive developmental toxicity endpoints for TCE. Human studies examined the possible association of TCE with various prenatal effects. These adverse effects of developmental TCE exposure may include: Fetal death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions); decreased growth (low birth weight, small for gestational age); congenital malformations, in particular heart defects; and postnatal effects such as growth, survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers. Some epidemiological studies reported an increased incidence of birth defects in TCE-exposed populations from exposure to contaminated water. As for human developmental neurotoxicity, studies collectively suggest that the developing brain is susceptible to TCE toxicity. These studies have reported an association with TCE exposure and central nervous system birth defects and postnatal effects such as delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit disorder.”¹⁹

5. Cardiac Effects

The public is extremely concerned about developmental risks, including fetal cardiac malformations.²⁰ The EPA IRIS assessment of TCE (2011) based its Point of Departure (POD) for developmental toxicity on

¹⁷ IARC 2014. International Agency for Research on Cancer, Monograph 106. Available here: <https://monographs.iarc.fr/ENG/Monographs/vol106/mono106-001.pdf>

¹⁸ 81 FR at 91596.

¹⁹ 81 FR at 91595.

²⁰ Olah, Laura. Citizens for Safe Water Around Badger, Merrimac WI. Comments and valentines presented at the public EPA meeting Feb 14th 2017 by J. Sass, NRDC and submitted to EPA-HQ-OPPT-2017-0002

fetal cardiac abnormalities in rodents.²¹ The study – Johnson et al 2003 - reported a statistically significant increase in severe heart malformations associated with fetal exposure to TCE in the drinking water of the pregnant dams.²² The study findings are supported by similar findings in chick embryos, data supporting a possible mode of action, and some weakly positive epidemiologic data (see discussion in IRIS 2011, Section 4.8.3.3.2):

Cardiac defects:

- In humans;
 - ATSDR (2008b, 2006a, 2014); Yauck et al. (2004)
- In rats;
 - Dawson et al. (1993, 1990); Johnson et al. (2003); Johnson et al. (2005); Johnson et al. (1998b; 1998a) a ; Smith et al. (1989), (1992); Epstein et al. (1992)
- In chickens;
 - Bross et al. (1983); Boyer et al. (2000); Loeber et al. (1988); Drake et al. (2006a; 2006b); Mishima et al. (2006); Rufer et al. (2010; 2008)
- In rats following oral gestational dosing with metabolites of TCE;
 - Johnson et al., 1998b; Johnson et al., 1998a; Epstein et al., 1992; Smith et al., 1992; Smith et al., 1989.

In summary, the findings in the Johnson et al (2003) rodent study are supported by findings in other rodent studies, studies in other species, some epidemiologic data, and a plausible mode of action, making EPA's overall assessment very strong.²³

While the Johnson et al study exposed the test animals to TCE throughout gestation, another highly relevant study conducted a few years prior (Epstein et al 1992), is an important contribution to understanding the cardiac developmental risks from TCE. Epstein et al treated rats with a metabolite of TCE called dichloroacetic acid (DCA) only on specific days of gestation, and reported that treatments on days 9 through 15 were a particularly vulnerable developmental period (equivalent in humans to approximately weeks 3 to 37 of embryonic development)²⁴, and days 12-15 were the most sensitive to

²¹ EPA (U.S. Environmental Protection Agency), Toxicological review of trichloroethylene (CASRN 79-01-6) in support of summary information on the Integrated Risk Information System (IRIS) [EPA Report]. (EPA/635/R-09/011F), 2011, Washington, DC <http://www.epa.gov/iris/supdocs/0199index.html>
https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/0199tr.pdf

²² Johnson PD, Goldberg SJ, Mays MZ, Dawson BV. Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat. *Environ Health Perspect.* 2003 Mar;111(3):289-92. Erratum in: *Environ Health Perspect.* 2014 Apr;122(4):A94.

²³ EPA IRIS (2011) notes that there are also studies that did not report significant cardiac effects, possibly due to small sample size which reduces the statistical power to see an effect.

²⁴ Marcela, S. G., Cristina, R. M. M., Angel, P. G. M., Manuel, A. M., Sofia, D.-C., Patricia, D. L. R.-S., Bladimir, R.-R. and Concepción, S. G. (2012), Chronological and Morphological Study of Heart Development in the Rat. *Anat Rec*, 295: 1267–1290. doi:10.1002/ar.22508. Available at <http://onlinelibrary.wiley.com/doi/10.1002/ar.22508/full>

risk of cardiac malformations.²⁵ Interestingly, the malformations were much more sensitive to the time of treatment, rather than the dose, indicating that windows of susceptibility are particularly relevant for TCE toxicity and that a dose-response may not always be evident. In humans, many of the critical events in cardiac development occur during the first trimester, when many women may not even know they are pregnant, is critical.²⁶ Therefore, evidence from animal bioassays support the need for regulatory action to prevent even transient or short-term TCE exposures to reproductive-aged women.

As the TCE Work Plan points out: “The TCE IRIS assessment underwent several levels of peer review including agency review, science consultation on the draft assessment with other federal agencies and the Executive Office of the President, public comment, external peer review by the EPA’s Science Advisory Board (SAB) in 2002, scientific consultation by the U.S. National Academy of Sciences (NAS) in 2006 (NRC, 2006)⁶, external peer review of the revised draft assessment by the EPA’s Science Advisory Board (SAB) in January 2011 (EPA, 2011c)⁷, followed by final internal agency review and EPA-led science discussion on the final draft.”²⁷ It has been challenged, shaped, updated and improved by the peer review process. OPPT is correct to use it as a primary data source for TCE’s human health toxicity information, rather than developing a new hazard and dose response assessment for the Work Plan.

Although the Human Equivalent Concentration at the 99th percentile (HEC99)²⁸ for heart malformations is small (HEC99= 0.0037 ppm, rat drinking water study by Johnson et al, 2003), it is similar to the HEC99 for kidney toxicity (HEC99= 0.0056 ppm, rat oral gavage study from NTP, 1988) and for immunotoxicity effects (HEC99= 0.033 ppm, mouse drinking water study, Keil et al 2009). Moreover, the HECs are consistent with the IRIS assessment that derived an RfC of 0.0004 ppm based on findings from oral studies using a PBPK model to perform route-to-route extrapolation of results. This is similar to the most sensitive hazard value from inhalation studies in the Work Plan (HEC99 of 0.013 ppm for kidney effects) divided by an MOE of 30,²⁹ adding confidence to Work Plan assessment, and OPPTs use of an oral dose study (Johnson et al 2003).

In 2016, EPA scientists published an updated systematic review of the available scientific literature on TCE-related developmental cardiac defects, reporting on the quality, strengths, and limitations of the available studies (Makris et al 2016).³⁰ Their updated review and assessment confirmed EPA’s IRIS assessment (EPA 2011) that used the Johnson et al drinking water study in rodents, supported by several

²⁵ Epstein DL, Nolen GA, Randall JL, Christ SA, Read EJ, Stober JA, Smith MK. Cardiopathic effects of dichloroacetate in the fetal Long-Evans rat. *Teratology*. 1992 Sep;46(3):225-35. PubMed PMID: 1523580.

²⁶ Dhanantwari P, Lee E, Krishnan A, et al. Human Cardiac Development in the First Trimester: A High Resolution MRI and Episcopic Fluorescence Image Capture Atlas. *Circulation*. 2009;120(4):343-351.

²⁷ EPA 2014 TCE WorkPlan, page 29

²⁸ The HEC99 is the lower-end of the range of hazard values for the “sensitive” human (the 99th percentile) for each target organ/endpoint

²⁹ The MOE approach in this assessment is a ratio of the estimated exposure and the hazard expressed as the HEC99. The TCE WorkPlan assessment applies a factor of 30 to the MOE, composed of 10 for intraspecies variability and uncertainty and a factor of 3 for the pharmacodynamics portion of the interspecies extrapolation factor.

³⁰ Makris SL, Scott CS, Fox J, Knudsen TB, Hotchkiss AK, Arzuaga X, Euling SY, Powers CM, Jinot J, Hogan KA, Abbott BD, Hunter ES 3rd, Narotsky MG. A systematic evaluation of the potential effects of trichloroethylene exposure on cardiac development. *Reprod Toxicol*. 2016 Oct;65:321-358. doi:10.1016/j.reprotox.2016.08.014. Review. PubMed PMID: 27575429.

other studies and mechanistic evidence, to derive exposure limits (reference values).^{31 32} Fetal cardiac effects – including deformities in the septum and heart valves – are very serious and may cause lifelong impairments or death. EPA used this endpoint because it is the most sensitive – and, therefore, will support the most health-protective assessment – and is consistent with its long-standing policy that a single exposure of a chemical at a critical window of fetal development may produce adverse developmental effects (EPA, 1991).³³

B. Tens of Thousands of Workers Breathe or Have Dermal Contact with TCE in Largely Uncontrolled Settings from Vapor Degreasing Products

According to EPA,³⁴ vapor degreasing is “a cleaning process that uses solvent vapor to remove contaminants such as grease, oils, dust and dirt from fabricated parts.” The solvents are boiled so they release a hot vapor which then condenses on the parts, causing dripping or beading which separates the contaminants from the parts. The cleaned parts are suspended on a rack to drain the solvent.

Degreasing operations can occur in batch processes (where each load is added to the machine after the previous load is degreased) or in in-line systems (where the machine is continuously loaded with contaminated parts). EPA has identified five types of batch degreasing operations. The most prevalent are “open-top” degreasers, estimated by EPA to number between 2,600 and 6,000. Batch systems with enclosed or closed-loop operations are considerably less common, numbering around 120 according to EPA. For in-line degreasing machines, conveyorized systems are used to provide a continuous supply of parts and these systems are typically enclosed except for the conveyor inlet and outlet portals. EPA estimates that there are 150 in-line systems currently using TCE.

EPA projects that there are approximately 40,800 to 102,000 persons (workers and occupational bystanders) exposed to TCE from open-top degreasing operations, and an additional 2,040 and 2,550 persons exposed from closed-loop and in-line systems, respectively.³⁵ Of this total exposed population, EPA estimates that around 1,000 are pregnant women susceptible to TCE’s developmental effects. EPA calculates that the greatest exposures are for conveyorized degreasers, followed by open-top systems. Exposures for closed loop systems were projected to be significantly lower.³⁶

Vapor degreasing takes place in a variety of industries, such as metal plating, electronics assembly, metal or composites part fabrication and repair shops. Many of the businesses in these sectors are small operations with limited industrial hygiene sophistication.

³¹ EPA (U.S. Environmental Protection Agency), Toxicological review of trichloroethylene (CASRN 79-01-6) in support of summary information on the Integrated Risk Information System (IRIS) [EPA Report]. (EPA/635/R-09/011F), 2011, Washington, DC <http://www.epa.gov/iris/supdocs/0199index.html>

³² Johnson PD, Goldberg SJ, Mays MZ, Dawson BV. Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat. *Environ Health Perspect.* 2003 Mar;111(3):289-92. Erratum in: *Environ Health Perspect.* 2014 Apr;122(4):A94. PubMed PMID: 12611656

³³ EPA 1991. Guidelines for Developmental Toxicity Risk Assessment. U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC, EPA/600/FR-91/001, 1991.

³⁴ 82 FR 7441.

³⁵ 82 FR 7442.

³⁶ 82 FR 7443.

C. EPA Correctly Identified Significant Health Risks as a Result of TCE Use In Vapor Degreasing and Determined That These Risks are “Unreasonable”

EPA estimated baseline exposures for all batch vapor degreasing machines, regardless of facility size, and for in-line vapor degreasing machines (both conveyORIZED and continuous web). Baseline exposures for in-line machines were not specifically calculated in the TCE risk assessment. For the supplemental analysis, estimating the baseline exposures involved using a near-field/far-field modeling approach to estimate airborne concentrations of TCE and Monte Carlo simulation to establish the range and likelihood of exposures. The nearfield/far-field model estimates airborne concentrations in a near field (a zone close to the source of exposure) and a far field (a zone farther from the source of exposure but within the occupational building). The Near Field/Far Field (NF/FF) mass balance model has been extensively peer-reviewed, is routinely and widely used, and was validated by showing good agreement (within 3-fold) between model output and measured data.^{37 38}

Controls required by the 2007 NESHAP were accounted for in the estimations. EPA used these estimated airborne concentrations to estimate 8-hour time weighted average (TWA) exposures for workers (i.e., in the near field) and occupational bystanders (i.e., in the far field), based on the methodology used in the peer reviewed TCE risk assessment and described in the “Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Vapor Degreasing” (EPA 2016).

The estimated 8-hour TWA exposure levels for open top vapor degreasing systems ranged from 2.74 ppm to 491.36 ppm for workers, with the 50th percentile at 55.16 ppm and the 99th percentile at 190.17 ppm. For occupational bystanders, the exposure levels ranged from 0.33 ppm to 440.61 ppm, with the 50th percentile at 20.45 ppm and the 99th percentile at 144.93 ppm. The estimated 8-hour TWA exposure levels for conveyORIZED degreasers were even higher, ranging from 5.14 ppm to 32,722 ppm for workers, with the 50th percentile and 99th percentile being 180.74 ppm and 1162.6 ppm, respectively. For bystanders, the levels ranged from 0.63 ppm to 29,410 ppm, with the 50th percentile and 99th percentile being 80.93 ppm and 745.11 ppm, respectively. The estimated 8-hour TWA exposure levels for continuous web degreasers were lower overall than for open top vapor degreasing systems or conveyORIZED degreasers. These estimates ranged from 4.18 ppm to 50.61 ppm for workers, with the 50th percentile and 99th percentile being 8.18 ppm and 22.42 ppm, respectively. For bystanders, the levels ranged from 0.52 ppm to 45.49 ppm, with the 50th percentile and 99th percentile being 3.70 ppm and 17.49 ppm, respectively.

EPA assumed that all of the closed-loop systems achieve a 98% reduction in exposure compared to open top vapor degreasing systems which may be an overestimate for airtight systems, and an underestimate for airless vacuum-to-vacuum systems. This assumption leads to exposure estimates of 0.05 ppm to 9.8 ppm for workers.

³⁷ Jayjock, M. A., T. Armstrong, and M. Taylor. 2011. The Daubert Standard as Applied to Exposure Assessment Modeling Using the Two-Zone (NF/FF) Model Estimation of Indoor Air Breathing Zone Concentration as an Example. *Journal of Occupational and Environmental Hygiene*, 8(11), D114-D122. As reported in EPA TCE Workplan 2014.

³⁸ Keil, C. B., C. E. Simmons, and A. T. Renee. 2009. *Mathematical Models for Estimating Occupational Exposure to Chemicals* (2nd ed.) American Industrial Hygiene Association (AIHA).

External expert reviewers, overall, concurred with EPA's approach as scientifically sound and defensible, given the unavoidable gaps in data.³⁹ For example, Dr. Kathleen Gilbert wrote that, "In an ideal world this assessment would be based on measurements of internal TCE levels following different types of human inhalation exposure scenarios. It would also include more definitive epidemiological data of human health responses to these scenarios. However, in many cases this data is not available, and unlikely to become available, at least in the foreseeable future. This means that exposure modeling and data extrapolation is required for risk assessment. This seems appropriate."⁴⁰

SCHF and NRDC agree with EPA that while the data gaps are unfortunate, they are unavoidable at this time, and the models OPPT uses to bridge the data gaps and refine its assessment are sound and scientifically-defensible, have cleared peer review, and represent the best available information at this time.⁴¹

Industry argues without basis that the Work Plan exposure calculations may not be adequate for regulatory purposes or should be considered simply as a screening-level assessment. Such arguments ring hollow given the industry's failure to come forward with more comprehensive monitoring data despite being on notice for many years that EPA and other agencies were concerned about TCE's risks and considering action to protect the public. In light of the clear threats to human health and the lack of exposure information from industry, the model-based estimates of workplace and consumer exposure for degreasers are clearly reliable for TSCA regulatory purposes.

D. The EPA Calculated Margins of Exposure (MOEs) for Non-Cancer Effects are Well Below the Benchmark MOEs that Define Acceptable Risk Levels

EPA used Margins of Exposure (MOEs) to estimate non-cancer risks for acute and chronic exposures. EPA describes the MOE as the health point of departure (an approximation of the no-observed adverse effect level) for a specific endpoint divided by the exposure concentration for the specific scenario of concern. EPA relied on information of TCE's hazards from EPA's IRIS review and estimations of worker and consumer exposure as described above. As used in the TCE assessment, the MOE is a ratio of the estimated exposure to the hazard expressed as the HEC99. In accordance with established EPA practice, the Agency determined an Uncertainty Factor (UF) to capture the possibility that, because of difference in susceptibility between animals and humans and variabilities in human response, adverse effects could occur at exposure levels below the HEC99. For TCE, the UF was 10 for most end-points (and somewhat higher for others). Accordingly, EPA used an MOE of 10 or higher as its "benchmark" – i.e. the exposure level below which non-cancer health effects could be expected to occur.

Inhalation risks were estimated for all acute exposure scenarios and risks were identified for all types of machines, regardless of the type of exposure (typical vs. reasonable worst case scenario). For acute

³⁹ Peer Review Meeting for EPA's Draft TSCA Work Plan Chemical Risk Assessment for Trichloroethylene: Degreaser and Arts/Crafts Uses (CASRN: 79-01-6) 1,1,2-trichloroethene. Information available here: <https://www.scgcorp.com/tcl2013/index.asp>

⁴⁰ OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013. Available at: https://www.epa.gov/sites/production/files/2015-09/documents/tce_consolidated_peer_review_comments_september_5_2013.pdf

⁴¹ EPA's mandate under Section 26(k) of TSCA is to utilize the scientific information "reasonably available" to the Agency at the time the rulemaking is conducted. Industry recalcitrance in providing chemical data is no longer a justification for EPA regulatory inertia under TSCA.

exposures associated with open top vapor degreasing systems, the MOE is 0.00006 for fetal heart malformations, which is 166 thousand times greater than the benchmark MOE of 10. The MOE for fetal heart malformations from acute exposures associated with conveyORIZED systems is 0.00001, while for continuous web systems, the MOE is 0.0005, which is 20 thousand times greater than the benchmark MOE. Even for acute exposures with closed-loop systems, which EPA presumed would reduce TCE emissions as much as 98% from open top vapor degreasing systems, the MOE for fetal heart malformations is 0.003, which is 3 thousand times below the benchmark MOE of 10. **The MOEs for every vapor degreasing scenario are below the benchmark MOE, demonstrating that all acute TCE exposures from vapor degreasing present an unreasonable risk.**

It is likely that EPA's benchmark MOE is an underestimate of risk for several reasons. First, it is unlikely that the 3-fold uncertainty factor for intra-species variability (UFH=3, Table 2-18, page 69) is adequate, because the PBPK model inputs came from only 42 adults, which isn't likely to capture the full range of inter-individual variability in relevant factors such as genetic polymorphisms, metabolic differences, age, gender, and social stressors. Second, as OPPT acknowledged, there was some unavoidable uncertainty in the exposure assessments due to lack of monitoring data. Third, by excluding dermal exposures some exposure was not accounted for. Because of these uncertainties and possible underestimates, SCHF and NRDC concur with peer review comments of Dr. Melnick that the benchmark MOE can be helpful in distinguishing greater or lesser concern, but cannot be presumed to be a bright line that rules out effects and risks at lower exposure levels.⁴²

E. EPA Estimated Chronic Risks Are Above the Risk Levels That EPA and other Authoritative Bodies Have Historically Considered Acceptable

Chronic exposures from TCE use in vapor degreasing also present serious risks. For noncancer effects, the most sensitive of which are developmental, the benchmark MOE is also 10. For chronic exposures associated with open top vapor degreasing systems, conveyORIZED systems, continuous web systems, and closed-loop systems, the MOEs are 0.00008, 0.00001, 0.00007, and 0.004, respectively. These risks range from 125 thousand times more than the benchmark to 2,500 times above the benchmark, making them all unreasonable.

With respect to cancer, the risk posed to workers ranges from 5.16 x10⁻¹ (5 in one hundred) for open top vapor degreasing systems to 1x10⁻² (1 in 1 hundred) for closed-loop systems, exceeding common cancer benchmarks of 10⁻⁶ to 10⁻⁴ (1 in 1 million to 1 in 10 thousand). Therefore, EPA's proposed determination is that chronic TCE exposures due to vapor degreasing also present unreasonable risks of cancer.

SCHF and NRDC support EPA/OPPT's use of the inhalation unit risk (IUR) of 2 x 10⁻² per ppm (4 x 10⁻⁶ per microgram/cubic meter) reported in the TCE IRIS assessment to estimate excess cancer risks for the occupational scenarios.⁴³ The IUR is the estimated upper bound excess lifetime cancer risk resulting

⁴² OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013. Available at: https://www.epa.gov/sites/production/files/2015-09/documents/tce_consolidated_peer_review_comments_september_5_2013.pdf

⁴³ To convert concentrations in air (at 25°C) from ppm to mg/m³: mg/m³ = (ppm) × (molecular weight of the compound)/(24.45). For TCE: 1 ppm = 5.37 mg/m³. To convert concentrations in air from µg/m³ to mg/m³: mg/m³ = (µg/m³) × (1 mg/1,000 µg).

from continuous exposure to an airborne agent at $1 \mu\text{g}/\text{m}^3$. As detailed earlier, the IRIS assessment represents the most up-to-date and scientifically credible document, and we support its use in this case and throughout the Work Plan assessment. The risk estimate is based on human kidney cancer risk, adjusted for potential risk of non-Hodgkin Lymphoma (NHL) and liver cancer reported in the epidemiologic literature and reviewed in IRIS (2011). There is high confidence in the IUR because the cancer risk estimate is based on good quality data, there was consistency in risk estimates across species and in both sexes, and there is strong evidence that TCE is mutagenic (Work Plan, page 21; IARC 2014).

The IUR of 4×10^{-6} per $\mu\text{g}/\text{m}^3$ can be stated in plain language as an excess cancer risk of 4 cases per 1 million people breathing $1 \mu\text{g}/\text{m}^3$ TCE over a lifetime. This is very relevant, and concerning, given that even ambient outdoor air levels have been measured as high as $18 \mu\text{g}/\text{m}^3$ (Work Plan Table 2-2, page 33). Although these are not directly comparable to the risk estimates above, which are over a lifetime of exposure, it demonstrates that the risk thresholds determined by IRIS are within the range at which people may be exposed to TCE in the ambient air, at least for short periods of time.

EPA has estimated that, in order to avoid cancer and non-cancer unreasonable risks, the 8-hour TWA exposure should be approximately 1 ppb. However, EPA's inhalation exposure level estimates for all types of vapor degreasing machines exceed that figure by several orders of magnitude for workers and occupational bystanders for all non-cancer effects (e.g., developmental effects, kidney toxicity, and immunotoxicity) and cancer risks. Therefore, all uses of TCE under all conditions of vapor degreasing pose risks that are unacceptable.

In short, EPA's estimated cancer and non-cancer risks significantly exceed the benchmarks EPA has historically used to define unacceptable cancer risks. In light of the very large populations exposed at unacceptable levels, this is strong evidence of unreasonable risk, which cannot be addressed in any other way except by eliminating the chemical from all vapor degreasing operations.

F. EPA's Risk Estimates Underestimate Risk by Failing to Include Dermal Exposures

The external peer reviewers of EPA's Workplan Risk Assessment agreed that the main route of exposure for TCE is likely inhalation, but noted that dermal exposures may still be relevant:⁴⁴

- "During the July 7 pre-meeting, several of the Panel members raised a concern about the decision to exclude dermal exposure from this assessment. I share this concern and recommend that any revised assessment include this route of exposure in it. To support this recommendation, I examined the directions for use for several of the products listed in the Supplemental Product Information document provided to us. For many of the spray formulations, I discovered something like the following on the label: "Eye/face Protection: For normal conditions, wear safety glasses. Where there is reasonable probability of liquid contact, wear splash-proof goggles. Skin Protection: Use protective gloves such as nitrile or neoprene.

⁴⁴ OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013. 090613_TCE_FINAL_All Reviewers Comments. Available at: <https://www.scgcorp.com/tcl2013/prcomments.asp>

Also, use full protective clothing if there is prolonged or repeated contact of liquid with skin.”⁴⁵
(Dr. Penny Fenner-Crisp, Panel Chair)

- “Users, both in the commercial and consumer population, often don’t follow the label directions, in fact, never even bother to read them. It’s clear to me that dermal exposure will be occurring in the course of use in all of the scenarios being evaluated. Often the object being treated is held in a bare hand. The object may then be wiped dry with a shop cloth, which in turn, with repeated use, gets wet and soaks through to the skin of the holder. Furthermore, there is the question of enforceability of label directions for these products.”⁴⁶ (Dr. Penny Fenner-Crisp, Panel Chair)
- “By not including dermal exposure in the exposure assessment, internal doses are likely to be underestimated. The document recognizes this deficiency (page 71) and notes that TCE is rapidly absorbed in humans following dermal exposure (page 35), but claims that the use of the lower-end HEC99 values provides a counterweight to not considering dermal exposure. That is a poor excuse for excluding this potentially relevant route of exposure. The assessment does not provide data to justify the claim...”⁴⁷ (Dr. Ron Melnick)

In response to reviewer comments, in the final WorkPlan, OPPT provides some modeled and experimental results suggesting that the ratio of dermal to respiratory intake is small (Work Plan Report page 28; Tibaldi et al 2014; Kezic et al 2000). Nonetheless, OPPT acknowledges that its assessment may underestimate total exposures by disregarding the dermal route (TCE Work Plan page 18). This only increases the urgency for EPA to move forward with enforceable regulations to protect workers, consumers, and their families from unsafe TCE exposures.

G. The Risks of TCE to Vulnerable Populations from Vapor Degreasing Are Real and Well-Defined and Require Special Protection under TSCA

In addition to risks to general worker populations, TCE used in vapor degreasing operations poses unique risks to men and women of childbearing age, unborn children and infants. These groups fall within the definition in section 3(12) of TSCA of “potentially exposed or susceptible subpopulations.” Under section 6(a) and 6(c), EPA has an obligation to determine whether the risks experienced by these subpopulations are unreasonable (separate from the level of risk to the general exposed population) and then to protect them from such unreasonable risks (again apart from any restrictions imposed to protect the general population). There is no question that this is the case here. For example, EPA found

⁴⁵ OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013. 090613_TCE_FINAL_All Reviewers Comments. Available at: <https://www.scgcorp.com/tcl2013/prcomments.asp>

⁴⁶ OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013. 090613_TCE_FINAL_All Reviewers Comments. Available at: <https://www.scgcorp.com/tcl2013/prcomments.asp>

⁴⁷ OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013. 090613_TCE_FINAL_All Reviewers Comments. Available at: <https://www.scgcorp.com/tcl2013/prcomments.asp>

that a subpopulation of 1000 pregnant women were exposed to TCE in vapor degreasing operations, placing their unborn fetuses at unique risk of cardiac defects and other malformations.

It is also important to note that OPPT's use of the HEC99 – which SCHF and NRDC strongly support – does not necessarily capture the risks TCE poses to uniquely susceptible or sensitive groups within the population. Although the Work Plan refers to the HEC99 value as the human equivalent exposure concentration for the “sensitive” human, it comes from the IRIS assessment, where it is defined as an exposure for which there is 99% likelihood that a randomly selected individual will have an internal dose less than rodent internal dose at the POD for each critical effect (Work Plan page 22). As peer review expert Dr. Ron Melnick points out, “the HEC99 value does not represent the ‘sensitive’ human because it does not account for pharmacodynamic variability in the human population. Furthermore, the HEC99 is based on only the range of human parameters entered into the PBPK model that provided this value, and may not represent the lower 99th percentile of human pharmacokinetic variability.”⁴⁸ The HEC99 is an appropriate hazard value to use, but additional adjustments to address sensitive individuals are still needed.

Similarly, the POD derived from fetal cardiac effects used by OPPT in the Work Plan Risk Assessment represents the evaluation and detection of a more sensitive endpoint in the target organ. SCHF and NRDC support OPPT's selection of this POD, but points out that it is appropriately conservative, but not overly conservative, since it is an actual representation of a measured sensitive endpoint in a target organ. This point was made by expert peer reviewer Dr. Melnick to EPA.⁴⁹ It is also within an order of magnitude of HEC99 hazard values for kidney toxicity (0.0056 ppm from oral exposure, NTP 1988) and immunotoxicity (0.033 ppm from oral exposure, Keil et al 2009), and not that much smaller than the HEC99 for kidney toxicity from inhalation (0.013 ppm, Woolhiser et al 1996). See Work Plan Table 2-18 (page 69) and summary table below, excerpted from peer review comments of Dr. Melnick:

Target organ	Route of exposure	HEC ₉₉ (ppm)	Reference
Liver	Inhalation	9.1	Kjellstrand et al, 1983
	Oral	11	Woolhiser et al, 2006
Kidney	Inhalation	0.013	Woolhiser et al, 2006
	Oral	0.0056	NTP, 1988
Neurotoxicity	Inhalation	4.8	Arito et al, 1994
	Oral	7.1	Isaacson et al, 1990
Immunotoxicity	Inhalation	11	Woolhiser et al, 2006
	Oral	0.033	Keil et al, 2009
		1.7	Sanders et al, 1982
Reproductive toxicity	Inhalation	0.5	Chia et al, 1996
	Oral	9.3	DuTeaux et al, 2004
Developmental toxicity	Inhalation	6.2	Healy et al, 1982
	Oral	0.0037	Johnson et al, 2003
		3	Fredriksson et al, 1993

⁴⁸ OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013. 090613_TCE_FINAL_All Reviewers Comments. Available at: <https://www.scgcorp.com/tcl2013/prcomments.asp>

⁴⁹ OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013. 090613_TCE_FINAL_All Reviewers Comments. Available at: <https://www.scgcorp.com/tcl2013/prcomments.asp>

In short, while generally OPPT conducted a realistic and scientifically-defensible estimate of the health hazards from TCE exposure, high-end risks to sensitive subgroups within the populations were not fully captured, potentially leading to underestimation of the risk, a shortcoming that OPPT will need to address in future risk evaluations.

Overall, evidence from both laboratory studies and epidemiology demonstrate that TCE is a known human carcinogen, and causes toxicity in humans to multiple organs and systems including developmental damage. EPA has used an accepted and defensible approach to estimate exposure and risk, and its assessment shows that a large population of workers is exposed to multiple adverse effects at levels that are unsafe under established regulatory benchmarks. In summary, these risks are plainly unreasonable and regulatory action to protect workers is justified and long overdue.

III. EPA'S ANALYSIS DEMONSTRATES THAT A BAN ON TCE USE IN VAPOR DEGREASING IS THE ONLY RESTRICTION UNDER SECTION 6(a) THAT WILL ADEQUATELY PROTECT AGAINST THE UNREASONABLE RISK

After determining that TCE use in vapor degreasing presents an unreasonable risk of injury, EPA's next task was to examine the list of authorized restrictions in section 6(a) and select requirements that would assure that the chemical "no longer presents such risk." The result of this analysis was a conclusion that a ban on this use is the only remedy that would be effective in eliminating the unreasonable risk and, therefore, the only approach that would satisfy TSCA. We support this conclusion, which we believe is fully explained and justified in the preamble to the proposal and the administrative record.

A. EPA Correctly Limited Its Analysis to Options That Could Provide Sufficient Protection to Eliminate the Unreasonable Risk and Would be Effective and Reliable in Achieving These Risk Reductions

EPA correctly framed its analysis of risk management options by examining a wide range of regulatory options under section 6(a) and then evaluating whether they "could reduce risks (non-cancer and cancer) to levels below those of concern, based on EPA's technical analysis of exposure scenarios." This evaluation was necessary in order that EPA's rule "would address the identified unreasonable risks so that the chemical no longer presents such risks."⁵⁰ By screening out options that could not eliminate the unreasonable risk, EPA was then able to focus on a smaller set of options that could potentially achieve the benchmark MOE (or "safe" level of exposure) for the most sensitive non-cancer endpoint, thereby reducing cancer risk to acceptable levels as well.

For each option that could meet this standard of protection, EPA then examined whether it would in practice be effective in achieving the risk reduction goal. As EPA explained this step:

"After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered **how reliably the regulatory options would actually reach these benchmarks**. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In evaluating whether a regulatory option would ensure that the

⁵⁰ 82 FR 7440.

chemical substance no longer presents the identified unreasonable risk, **the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks**, as well as whether the option's protectiveness was impacted by environmental justice or children's health concerns."⁵¹

Obviously, the reliability and practicability of a remedy are factors that bear heavily on whether it will in fact reduce the risk to a sufficient extent and are therefore essential criteria in meeting EPA's responsibilities under section 6(a). Here, these factors pointed inexorably to the conclusion that only bans on TCE use in vapor degreasing – and not other remedies such as labeling, product reformulation, engineering controls or respirators – would provide adequate protection and could pass scrutiny under the law.

B. EPA Correctly Rejected Warnings and Labeling as an Adequate Remedy Because They Would Not be Effective In Motivating Workers and Consumers to Take Effective Safeguards Against the Risk

EPA rejected label warnings and instructions under TSCA section 6(a)(3) on the ground that they are not uniformly read, comprehended or followed and thus provide limited protection, particularly to consumers. This was not a mere opinion on EPA's part but resulted from an examination of nearly fifty studies.⁵² Based on this review, EPA's conclusions as described in its initial TCE rulemaking were as follows:

"The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies."⁵³

In the degreasing proposal, EPA further concluded that comprehension of warnings would be unusually challenging because of the complexity of the information conveyed:

"EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user would need to read, understand, and act upon is extremely complex. It would be challenging to most users to follow or convey the complex product label instructions required to explain how to reduce

⁵¹ 82 FR 7440 (emphasis added).

⁵² OPPT summarized these studies in a paper entitled *The Effectiveness of Labeling on Hazardous Chemicals and Other Products* (March 2016)(Ref. 33 in rulemaking docket).

⁵³ 81 FR at 91601.

exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. **It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.**⁵⁴

These conclusions are particularly compelling in light of the nature of the TCE-exposed population relevant to this rulemaking. Many of the degreasing operations subject to the proposal are small shops that lack effective worker training and hazard communication programs. Their employees may be part-time and/or short duration workers who are unlikely to study product warnings and labeling (and may not even understand English). And occupational bystanders – a group at serious risk from these TCE uses – may not even come into contact with product labels because they are not using the products directly.

C. The Agency Properly Determined that Reducing TCE Concentrations in Products, Engineering Controls and/or Equipment Substitution Would not Achieve the Risk Reduction Targets

EPA also evaluated whether continued TCE use for vapor degreasing might be made safe by reducing the concentration of TCE in the degreasing formulations, with concentrations varying from 5 to 95 percent in the product, by requiring local exhaust ventilation near the vapor degreaser with an assumed 90 percent reduction in exposure, and/or by using closed-loop systems for open-top degreasing equipment. To examine these options, it recalculated projected TCE exposure levels to reflect the reductions in exposure they would achieve. Even with these reductions, it found, exposure remained too high – by orders of magnitude – “to avoid cancer and non-cancer unreasonable risks.”⁵⁵

D. While Concluding that Respirators Could Potentially Reduce the Risk, EPA Found that This Option Had Significant Drawbacks and was Not Adequately Protective When Compared To Eliminating TCE Use Entirely

In contrast, EPA determined that, in conjunction with a closed-loop degreasing system or other measures like reducing TCE levels in the solvent solution, respirators with an ATF of 10,000 could reduce worker exposure levels to 0.4 ppb, below the 1 ppb level that EPA deemed protective of non-cancer and cancer risks.⁵⁶ It then compared these requirements to prohibiting TCE in vapor degreasing– an option that would fully protect against the risks – using a variety of metrics, including protectiveness, feasibility and cost.

First, EPA concluded that the combination of respirators with product reformulation and equipment substitution was “unlikely to be practical for users because the exposure reductions needed would only be achieved by a reduction in the concentration of TCE in the degreasing solution to 5% [at which] the effectiveness of the solution would be greatly reduced.”⁵⁷

⁵⁴ **82 FR 7441.** (emphasis added)

⁵⁵ 82 FR at 7444.

⁵⁶ 82 FR 7444.

⁵⁷ Id.

Second, EPA pointed out that “there are many documented limitations to successful implementation of respirators with an APF of 10,000” (the pressure level required for adequate reduction in TCE exposure levels.) EPA summarized these well-known problems as follows:⁵⁸

“Not all workers can 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. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, ‘improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).’”

EPA based these conclusions on expert analyses by OSHA, which has extensive experience with respirators under its workplace standards.

We strongly concur that the impediments to an effective respirator program limit the ability of respirators to provide consistent, reliable protection against exposure in practice. It is for this very reason that, under the well-established “hierarchy of controls” applied by OSHA and the industrial hygiene community, respirators are the least preferred workplace protection strategy, to be implemented only if more effective measures like chemical substitution, engineering controls or work practices are not feasible. In this case, substitution of other solvents for TCE in vapor degreasing **is** a feasible remedy and, based on long-standing OSHA policies, should be presumed to be more protective than respirators or other personal protective equipment for these applications.

Another downside to a respirator requirement – further limiting how much protection it would provide in practice -- is the difficulty of achieving compliance by the small establishments where much TCE vapor degreasing use and exposure occur. OSHA has promulgated a comprehensive respiratory protection standard (29 CFR 1910.134) containing numerous elements, *e.g.*, for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; and respirator use; respirator cleaning, maintenance, and repair. These requirements would be beyond the resources or expertise of, say, a small machine shop or metal plater, which would likely lack any previous experience with respirator programs. The difficulty of compliance would be magnified by the nature of the workforce in these shops, which is likely to have high turnover and many part-time employees with little or no industrial hygiene sophistication. Training these workers to use respirators conscientiously would be a huge challenge. And given the number and nature of the businesses involved, OSHA has limited resources to enforce these standards, and may soon be facing additional

⁵⁸ 882 FR 7445

budget reductions. Finally, even if they were effective, respirators would not necessarily provide protection to occupational bystanders, leaving them at unacceptable risk.

EPA also examined the merits of combining a requirement for closed loop vapor degreasers with an air exposure limit of 1 ppb as an eight-hour Time Weighted Average (TWA). Depending on the effectiveness of the closed-loop systems, respirators might not be necessary to meet this limit although extensive employee monitoring might be required. EPA did not propose this option although it did request comment on it.⁵⁹ We agree with EPA that its effectiveness is somewhat uncertain and the costs it imposes would likely be greater than simple substitution of TCE with another solvent. After applying all these considerations, EPA opted for banning the TCE vapor degreasing use over less protective, reliable and implementable options, explaining that “non-cancer and cancer risks from this use of TCE would be eliminated” under a ban. EPA elaborated that:

“The proposed approach would ensure that employees are no longer at risk from TCE exposure associated with vapor degreasing. Prohibiting the manufacturing (including import), processing and distribution in commerce of TCE for use in vapor degreasing would minimize the availability of TCE for vapor degreasing. The downstream notification of these restrictions ensures that processors, distributors, and other purchasers are aware of the manufacturing (including import), processing, distribution in commerce and use restrictions for TCE in vapor degreasing, and helps to ensure that the rule is effectively implemented by discouraging off-label use of TCE manufactured for other uses. Downstream notification is important because EPA is not proposing to prohibit manufacturing, processing and all uses of TCE, just those activities associated with vapor degreasing. This integrated supply chain approach is necessary to address the identified unreasonable risks presented by the use of TCE in vapor degreasing.”⁶⁰

In sum, EPA selected the only remedies that would assure that these TCE-containing products no longer present an unreasonable and thus chose the only path that would meet its obligations under TSCA section 6(a). We strongly support this approach.

IV. EPA’S DETERMINATION THAT BENEFITS EXCEED COSTS STRONGLY SUPPORTS THE PROPOSED RULE

As required by section 6(c)(2)(A), EPA’s proposed rule is accompanied by a statement comparing its costs and benefits. As explained in Part I above, EPA has no authority to compromise the effectiveness of the remedy it selects under section 6(a) based on cost-benefit tradeoffs. Nonetheless, this comparison is a relevant consideration in choosing among options of sufficient protectiveness and also provides an important overall perspective on the chosen remedy’s contribution to societal well-being.

Strikingly, EPA concluded that banning TCE use in vapor degreasing will produce benefits significantly in excess of the costs (even without including certain important benefits) and would have a more favorable ratio of benefits and costs than other options considered.

EPA’s evaluation of benefits was based on the avoidance of cancer (kidney and liver tumors and non-Hodgkin’s lymphoma) because these benefits are monetizable. It concluded that, by preventing or

⁵⁹ 82 FR 7445.

⁶⁰ 82 FR 7444.

delaying these cancers and the attendant harms to length and quality of life, medical costs and loss of income and personal well-being, the proposed rule would achieve annualized 20-year monetized savings of between \$65-447 million (3% discount rate) and \$32-227 million (7% discount rate).

Because they could not be monetized,⁶¹ EPA did not assign a dollar value to avoidance of the non-cancer effects of TCE exposure. However, according to EPA, the benefits of preventing these harms to health would be substantial:

“EPA believes that the balance of costs and benefits cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects as well as cancer. As discussed previously, the multitude of potential adverse effects associated with TCE exposure can profoundly impact an individual's quality of life. Some of the adverse effects associated with TCE exposure can be immediately experienced and can affect a person from childhood throughout a lifetime (*e.g.*, cardiac malformations, developmental neurotoxicity, and developmental immunotoxicity). Others (*e.g.*, adult immunotoxicity, kidney and liver failure or cancers) can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature.”

EPA stressed that, “[w]hile the risk of non-cancer health effects associated with TCE exposure cannot be quantitatively estimated, the qualitative discussion . . . highlights how some of these non-cancer effects occurring much earlier in life from TCE exposure may be as severe as cancer's mortality and morbidity and thus just as life-altering.” It added that “[c]onsidering only monetized benefits would significantly underestimate the impacts of TCE-induced non-cancer adverse outcomes” which the proposed use ban would prevent.⁶²

On the cost side, EPA found that the annual costs of reformulating degreasing products are likely to be around \$30-45 million (annualized over 20 years at 3%) and \$32-46 million (annualized over 20 years at 7%). EPA further concluded that downstream notification and recordkeeping costs would be 3,200-4,400 annualized over 20 years.

EPA also examined the relative costs and benefits of the principal regulatory alternative potentially capable of protecting against the unreasonable risk – requiring certain closed systems coupled with air-

⁶¹ EPA explained that:

“First, dose response information and concentration response functions in humans are not available, which would allow EPA to estimate the number of population-level non-cancer cases that would be avoided by reducing exposures to levels corresponding with MOE benchmarks. Second, even it were possible to calculate the number of cases avoided, EPA may not be able to monetize the benefits of these avoided cases due to limitations in data needed to apply established economic methodologies. However, being unable to quantitatively assess individual risk and population-level non-cancer cases avoided from TCE exposure does not negate the impact of these effects. Similarly, the inability to monetize an adverse effect does not reflect the severity of the effect, the lifetime nature of the impact, or the magnitude of the benefit in preventing the adverse impact from TCE exposure, such as a cardiac malformation, on a person. In considering the benefits of preventing TCE exposure, EPA considered the type of effect, the severity of the effect, the duration of the effect, and costs and other monetary impacts of the health endpoint.”⁸² FR 7452

⁶² 82 FR 7453.

supplied respirators. It concluded that this alternative would be less protective and produce smaller benefits and would have costs roughly comparable to those of the preferred option. *Thus, the option selected by EPA would both achieve the largest benefits in relation to the costs and represent the most cost-effective approach.*

V. EPA'S ANALYSIS OF SUBSTITUTES DEMONSTRATES THAT A WIDE RANGE OF EFFECTIVE, LOW HAZARD SUBSTITUTES IS AVAILABLE

As required by section 6(c)(2)(C), EPA considered to the extent practicable the availability, costs, technical and economic feasibility and risks of chemicals that could be substituted for TCE in vapor degreasing operations. This analysis is primarily informational: under TSCA section 6(a), EPA is obligated to impose restrictions that would protect against the unreasonable risk, irrespective of potential substitutes for the targeted chemical, although it may take them into account in granting use exemptions from its rule under section 6(g). Nonetheless, the EPA analysis demonstrates that a wide range of effective, economical and safer substitutes is available.

EPA "identified a wide variety of technically and economically feasible alternatives for vapor degreasing with TCE."⁶³ While acknowledging that some substitutes such as methylene chloride or N Propyl bromide (nPB) "also present risks to workers", EPA pointed out that "there are numerous other solvents available." As it explained, "[t]hese include designer solvents such as hydrofluorocarbon (HFC) and hydrofluoroether (HFE) solvent blends and hydrofluoroolefin (HFO), as well as other alternative solvents and cleaning systems, such as terpene-based cleaners, volatile methyl siloxanes, soy-based cleaners, and water-based cleaners." AS EPA noted,

"[A]queous cleaning systems present less risk to workers. Water-based cleaners have been used for many years in applications where users originally used TCE or other chlorinated solvents in vapor degreasing. In these systems, water-based cleaners are used to clean grease or oil from parts, the parts are rinsed, sometimes with deionized water if a spot free part is required for the next process, and dried. The cleaner concentrate, typically made up of boric acid or gluconic acid and other constituents, is generally diluted to between about 5% and 20% in a heated wash bath, depending on the cleaning task and the agitation in the equipment. The rinse is generally heated as well. Often driers composed of air knives that drive the water from the part are used.

Depending on the circumstances, several different types of equipment capable of using water-based cleaners can replace vapor degreasing machines that use TCE. Ultrasonic cleaning systems have transducers for generating the ultrasonic action in a bath. There are some immersion systems where the parts are placed on a platform and moved up and down in the cleaning agent. In certain circumstances parts can be sprayed at pressures of about 60 psi and greater in spray cabinets. Conveyorized spray systems, where the parts go through high pressure spray at between about 80 and 120 psi, are also used in some cases. These systems often have wash, rinse and dry sections."

In comments supporting EPA's proposed rule, 3M touted the benefits of its HFE Engineered Fluids as a TCE replacement in degreasing, describing these products as providing "properties demanded in precision cleaning applications" while possessing low flammability and low toxicity. According to 3M,

⁶³ 82 FR 7449.

these fluids “are well positioned to ease the transition away from TCE with the least human health and environmental impact and minimize the future use of chlorinated toxics” such as perchloroethylene and methylene chloride.⁶⁴

The Toxic Use Reduction Institute (TURI) lab has aggregated safer TCE alternatives for degreasing in an extensive online database at www.cleansolutions.org that can be consulted. The TURI website states that there are proven alternatives for metal degreasing (including alcohols, acetone, ketone, and acetates) and aqueous and semi-aqueous processes including ultrasonic processing. The TURI lab also tests products for efficacy.

Noting that some businesses have expressed concern about the lack of TCE substitutes in specific degreasing operations even though industry has confirmed that the “use of TCE in vapor degreasing is declining very rapidly in certain sectors,” EPA’s proposal solicits comment on the use of TSCA section 6(g) to grant time-limited use exemptions from its ban.⁶⁵

We agree that this mechanism is the proper vehicle for accommodating difficulties in substitution since the availability of substitutes is not a permissible factor in determining whether a chemical presents an unreasonable risk or selecting a remedy to eliminate that risk under section 6(a). However, the criteria for granting use exemptions under LCSA are stringent. Under section 6(g)(1)(A), for example, EPA must find that –

“The specific condition of use is a critical or essential use for which no economically or technically feasible safer alternative is available, taking into account hazard and exposure.”

The burden of demonstrating that this standard is satisfied should fall on the requesting company and EPA should require that it submit all necessary documentation, including evidence that the use proposed for exemption is critical or essential and that possible alternatives are either technically or economically infeasible or less safe. Since the exemption must be time-limited, EPA should also require a plan and schedule to identify and evaluate acceptable substitutes, as it has under similar exemption provisions under other laws.

Section 6(g)(4) requires use exemptions to include “conditions . . .to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.” In the case of TCE, the conditions EPA imposes should consist of enforceable requirements to reduce worker exposure during degreasing operations through a combination of engineering controls and respirators sufficient to attain the highest level of protection practicable and cost-effective.

EPA has an important role to play in encouraging industry to move to substitutes that are truly “reduced-risk.” For example, N Propyl bromide (nPB) is an unacceptable option due to its severe health effects (it is neurotoxic and a reproductive toxicant) despite its ease as a drop-in substitute for TCE in vapor degreasing. California’s Proposition 65 lists nPB as a reproductive toxicant and EPA has both developed a Workplan risk assessment on nPB and included it in the initial list of 10 chemicals selected for risk evaluations. Steps to prevent nPB’s increased use as a TCE substitute (perhaps through a TSCA

⁶⁴ Kurt T. Werner, Comments of 3M on Proposed TCE Vapor Degreasing Rule, March 1, 2017.

⁶⁵ 82 FR 7451

Significant New Use Rule) are critical to maximize the public health benefits of a TCE ban for vapor degreasing.

VI. THERE IS NO BASIS FOR REFERRING RISKS RELATED TO TCE USE IN VAPOR DEGREASING TO OSHA UNDER SECTION 9(a) OF TSCA

Section 9(a) of TSCA creates a mechanism by which EPA may refer a chemical presenting an unreasonable risk to another agency for action under its governing authority in lieu of rulemaking under section 6(a) of TSCA. A section 9(a) referral to another federal agency is permissible only where the unreasonable risk “may be prevented or reduced to a sufficient extent” by regulatory action by that agency. Through LCSA, Congress limited the referral authority by providing in section 9(a)(3)-(4) that, if the other agency does not respond to the referral by the date set by EPA or thereafter fails to initiate regulatory action within 90 days of that response, EPA “shall initiate or complete appropriate action under section 6.”⁶⁶

Determining whether a section 9(a) referral is warranted entails a comparison of the authorities that EPA and the other agency can bring to bear in addressing an unreasonable risk. If TSCA provides for a level of protection that would eliminate the unreasonable risk but the other agency could not afford equivalent protection, then action by that agency could not prevent or reduce the risk “to a sufficient extent.” As a result, regulation under TSCA would be the required path and the Administrator would have no basis for making a section 9(a) referral. With the enhanced protectiveness and stronger risk management authority provided by the LCSA, the burden to justify foregoing regulation under TSCA and relying on another law under section 9(a) is now higher than before. As the Democratic Senators emphasized in their joint statement upon TSCA’s enactment, “the interagency referral process . . . established under section 9 of existing TSCA must now be regarded in a new light since TSCA can no longer be construed as a “gap filler” statutory authority of last resort. The changes in section 9 are consistent with this recognition and do not conflict with the fundamental expectation that, where EPA concludes that a chemical presents an unreasonable risk, the Agency should act in a timely manner to ensure that the chemical substance no longer presents such risk.”⁶⁷

Since workers comprise the population exposed to TCE vapor degreasing, EPA considered whether to refer the unreasonable risks presented by these products to the Occupational Safety and Health Administration (OSHA) under section 9(a). However, EPA properly decided against this course after comparing its authority to eliminate these risks to that of OSHA, concluding that “there is no other federal law that provides authority to prevent or sufficiently reduce these cross-cutting exposures.”⁶⁸

⁶⁶ Congress was obviously concerned that the agency receiving the referral could agree to address the risk but then drag its feet in actually taking action. This in fact occurred for the one formal 9(a) referral that occurred under the old law – for 1,3 butadiene (50 FR 41393 (Oct, 10, 1985)). OSHA did not finally promulgate a workplace standard for this chemical until 10 years later.

⁶⁷ Congressional Record – Senate S3517 (June 7, 2016).

⁶⁸ 82 FR 7454. EPA’s analysis of section 9(a) addresses the range of consumer and occupational exposures targeted by its two TCE proposals in tandem. It correctly points out that that any 9(a) referral would need to be made to both OSHA and the Consumer Product Safety Commission (CPSC), resulting in action to address a common set of risks by two separate agencies with differing authorities as opposed to the comprehensive approach that could be undertaken under TSCA. While this is a strong argument against a section 9(a) referral, an equally strong case exists that a referral to OSHA alone of the worker protection issues raised by the vapor degreasing rule would

To support this conclusion, EPA pointed out that TSCA requires EPA to evaluate and then protect against unreasonable risks without regard to cost or other non-risk factors, whereas OSHA is limited to addressing “significant risks of harm” (a term interpreted by the courts to impose a high bar) and is constrained in the restrictions it imposes by considerations of economic feasibility. Thus, risks that EPA found to be “unreasonable” under TSCA might not be deemed “significant” by OSHA and, in contrast to EPA, OSHA could not ban particular chemical uses or require notifications to downstream users. EPA also stressed that certain categories of workers are outside OSHA’s jurisdiction, resulting in a narrower scope of regulation than EPA can require under TSCA. Although not mentioned by EPA, it’s also noteworthy that OSHA has limited authority over small businesses, where much of the use of TCE targeted by EPA occurs, further limiting its ability to provide effective protection to exposed workers.

The current OSHA time-weighted average 8-hour Permissible Exposure Limit (PEL) for TCE is 100 parts per million (ppm), significantly higher than the current health effects data on TCE would warrant. It was adopted in 1971 and has never been updated. OSHA has no plans to revise the TCE PEL and thus would be unlikely to address the risks described in a section 9(a) referral, even if such a referral were otherwise justified. And the former OSHA Administrator, David Michaels, has recognized the superiority of TSCA authorities in eliminating these risks, informing his EPA counterpart that, “[g]iven certain limitations imposed on OSHA’s authority under the OSH Act, this agency believes that TSCA provides . . . a means of eliminating or reducing the risks associated with these chemical uses in a more coordinated fashion across both consumer and occupational settings.”⁶⁹

As noted above, one of the revisions to Section 9(a) of TSCA enacted in LCSA would expressly require (as a condition of deferral) that EPA specify the time period required for the other agency to take action to eliminate the unreasonable risk, and if that agency did not take action within that period, EPA would be required to promulgate a rule under Section 6 (or file an imminent hazard action under section 7). Since OSHA has made clear that it does not intend to take action on TCE and plans to defer to EPA’s greater authority, a referral would be a useless action that only delays EPA’s rulemaking and would lack any basis in law or in fact.

In sum, EPA soundly concluded that it could not justify a section 9(a) referral to OSHA and should not revisit that conclusion in its final rule.⁷⁰

VII. THE “GOOD SCIENCE” CONSIDERATIONS OF SECTION 26(h) ARE NOT APPLICABLE TO THE TCE RULEMAKING AND IN ANY CASE EPA HAS PROPERLY USED THEM IN ITS TCE RISK ASSESSMENT

Section 26(h) of amended TSCA sets out general “principles” for using science in decision-making under the new law. These principles are not absolute requirements; EPA must “consider” them “as applicable” in individual science assessments. The science principles are straightforward, self-executing and

likewise be unwarranted because of OSHA’s limited authority and scope of regulation as compared to those of EPA under TSCA.

⁶⁹ Letter dated March 31, 2016 from David Michaels to Assistant Administrator James J. Jones (reference 65 in EPA docket).

⁷⁰ EPA also considered but correctly rejected a referral to other EPA offices implementing other environmental laws. 82 FR 7455.

generally consistent with current and past agency practice and therefore do not require significant changes in how EPA conducts risk assessments.

Since the TCE risk assessment was developed under the old law, the provisions of section 26(h) are not “applicable” requirements that the assessment must meet under section 26(l)(4). In any case, as EPA notes,⁷¹ all of the section 26(h) considerations are addressed in the TCE risk evaluation, rule preamble and other supporting materials for EPA’s proposal. For example:

- EPA has explained how the TCE risk assessment uses scientific information, technical procedures, measures, procedures methodologies, protocols and models “in a manner consistent with the best available science.”
- EPA has demonstrated that the scientific approaches used to develop data on TCE’s risks are standardized and well-established test methods that are “reasonable for and consistent with” use of the data for regulatory risk assessments and that the data themselves are “relevant” for making judgments about chemical risks and the need for risk management based on those risks.
- The “degree of clarity and completeness” of the science used in the TCE risk assessment is “documented” in that assessment and backup materials.
- The risk assessment and backup materials fully “evaluate and characterize . . . the variability and uncertainty” in the assessment and its findings.
- The assessment itself underwent independent peer review and, as described above, the science relating to TCE’s risks to human health has been extensively reviewed over many years by the independent EPA Science Advisory Board, the National Academy of Sciences and International Agency for Research on Cancer.

VIII. EPA’S THREE-PHASE IMPLEMENTATION FRAMEWORK IS APPROPRIATE BUT EPA SHOULD ADOPT A FASTER SCHEDULE FOR TCE ELIMINATION IN DEGREASING OPERATIONS

EPA’s proposed ban on TCE use in vapor degreasing includes three components: (1) a prohibition on TCE manufacture/importation, processing and distribution in commerce for this use; (2) a direct prohibition on commercial use of TCE in vapor degreasing; and (3) a requirement for manufacturers, processors and distributors (other than retailers) to provide notification of these prohibitions throughout the supply chain and maintain limited records.

SCHF and NRDC support this three-pronged approach. The upstream prohibitions on TCE-containing products manufactured for vapor degreasing uses will eliminate these products from the stream of commerce and limit their availability to commercial and consumer users. The prohibition on commercial use will apply enforceable requirements to commercial end-users and prevent TCE exposure at the site of application. Downstream notification in writing of these prohibitions will make all the levels in the supply chain aware of applicable requirements, prevent off-label use of TCE-containing products for the

⁷¹ 82 FR 7455.

prohibited uses and strengthen compliance and enforcement. These benefits more than offset the relatively modest costs of notification and record-keeping.

Under the proposed rule, the prohibition of upstream manufacture, processing and distribution in commerce would go into effect 18 months after the date of publication of the final rule, and the downstream use prohibition would take effect 6 months thereafter. Downstream notification and recordkeeping requirements would take effect within 45 days of publication.⁷²

TSCA section 6(d)(1) specifies that the effective date of a section 6(a) rule “shall be as soon as practicable.” In this case, the immediacy of the risk and large exposed population heavily favor expedited compliance with the EPA use prohibitions. While we understand that some time is required to convert TCE degreasing operations to non-TCE processes, it appears from the evidence cited in EPA’s preamble that a 12-month phase-out period for upstream activities and a 12-month period for downstream use would be feasible. We encourage EPA to adopt this shortened implementation schedule in its final rule.

We agree with EPA, however, that incentives should be provided to encourage companies to convert to less toxic degreasing systems that avoid the substitution of highly toxic agents including nPB and methylene chloride for TCE. In the preamble,⁷³ EPA notes that one option might be a longer phase-out period for companies that commit to shift to aqueous cleaning systems or less toxic solvents and asks for comment on this approach. The difficulty we perceive is that the amount of additional time needed for such conversions may vary from one firm to another and a uniform extension of the implementation date for these conversions might allow too much time in some cases and too little in others, unnecessarily prolonging exposure to TCE in some situations. To address this concern, EPA might provide in its rule a fairly limited extension of the rule compliance date (6 months or so) for conversions to non-toxic degreasing systems but add a provision to the rule recognizing the availability of the section 6(g) exemption process to grant additional time on an individualized basis with a particularized showing of why such time is justified and what steps the applicant will take to complete the conversion as soon as possible.

CONCLUSION

The use of TCE in vapor degreasing presents a significant and widespread risk of multiple serious health effects to tens of thousands of exposed workers, including pregnant women who are at increased risk of developmental effects. EPA has used sound and reliable methods to calculate likely levels of exposure to TCE from vapor degreasing and the resulting levels of risk. These projected risks are well in excess of established benchmarks and thresholds for regulatory action employed by EPA and other agencies to protect against cancer and non-cancer effects. EPA has correctly determined that a ban on TCE use in vapor degreasing is the only remedy that will be effective in eliminating the unreasonable risk it poses and that the benefits of a ban would greatly exceed its costs.

SCHF and its partners strongly believe that EPA’s proposed rule is essential to protect public health and implement LCSEA’s TSCA reform goals. We urge EPA to finalize the rule as proposed by the one-year deadline in the law.

⁷² See proposed sections 751.305-313.

⁷³ 82 FR 7456.

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On behalf of:

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
Asbestos Disease Awareness Organization
Bayou St John Conservation Alliance
Breast Cancer Action
Breast Cancer Prevention Partners
Center for Environmental Health
Citizens for a Clean Pompton Lakes
Clean and Healthy New York
Clean Production Action
Clean Water Action
Clean Water for North Carolina
Earthjustice
Ecology Center
Environmental Health Strategy Center
Healthy Legacy
Ithaca-SHIP.org

League of Conservation Voters
Learning Disabilities Association
Maryland PIRG
Midwest Environmental Justice Organization
MountainTrue
NC Conservation Network
Oregon Environmental Council
Physicians for Social Responsibility
POWER Action Group
Safer States
SCA Associates
Science and Environmental Health Network
Toxics Free Future
U.S. Public Interest Research Group (PIRG)
Utility Workers Union of America
VPIRG
WE ACT for Environmental Justice