UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Proposed Restrictions on Certain Trichloroethylene Uses under Section 6 of the Amended Toxic Substances Control Act

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Docket ID EPA-HQ-OPPT-2016-0163

Safer Chemicals Healthy Families (SCHF) submits these comments on the Environmental Protection Agency's (EPA's) proposed rule to restrict certain uses of trichloroethylene (TCE) 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 and effective legislation possible to reduce the risks of toxic chemicals in use today.

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 will engage constructively with EPA and other stakeholders 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 comments:

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
American Sustainable Business Council
Asbestos Disease Awareness Organization
BlueGreen Alliance
Breast Cancer Action
Breast Cancer Prevention Partners *(formerly Breast Cancer Fund)*
Clean and Healthy New York
Clean Production Action
Clean Water Action

[1] 81 Federal Register 91592 December 16, 2016).

Conservation Minnesota
Earthjustice
Ecology Center
Environmental Health Strategy Center
Health Care Without Harm
Healthy Legacy
League of Conservation Voters
Learning Disabilities Association of America
Maryland Public Interest Research Group
Minnesota Center for Environmental Advocacy
National Medical Association
Natural Resources Defense Council
Physicians for Social Responsibility
Safer States
Science and Environmental Health Network
Stupid Cancer
Toxic-Free Future
U.S. Public Interest Research Group (PIRG)
Vermont Public Interest Research Group
WE ACT for Environmental Justice
Women for a Healthy Environment

SUMMARY OF KEY POINTS

This proposed rule – coupled with two companion EPA proposals published shortly thereafter – 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.

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

The case for immediate action on the two TCE uses to be banned under EPA's proposal – aerosol degreasing and spot removal in dry cleaning operations – 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 uses targeted by the EPA proposal are largely uncontrolled. As a result of these uses, tens of thousands of workers and consumers – 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 standards for risk management. Banning TCE use in aerosol degreasing and dry cleaning spot removal is the only way to provide meaningful protection against these risks because lesser remedies will be 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.

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 over-ride the obligation to provide sufficient protection against unreasonable risks, without regard to costs or other non-risk factors.

- 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 AEROSOL DEGREASING AND DRY CLEANING SPOT REMOVAL 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, bystanders and consumers breathe and/or have dermal contact with TCE in largely uncontrolled commercial or residential settings from aerosol degreasing and spot removal products.
- 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^{-4}) 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 the two TCE 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 the two uses 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 and consumers 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 and to consumer users of aerosol degreasing products.
- EPA also evaluated whether continued TCE use might be made safe by reducing the concentration of TCE in the degreasing and spot removal 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."
- For both aerosol degreasing products and spot removal applications, EPA determined that, either alone or in conjunction with other measures, respirators could reduce exposures to levels that are protective of 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 aerosol degreasing and spot removal 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 and consumers.

- **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 $170,000-$183,000 annualized over 15 years. This is dramatically less than the benefits of the rule ($4.4 million to $25 million per year) 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 concluded that it would be less protective and produce smaller benefits but result in much greater costs (between $8200 and $9100 annualized per facility).

- **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 aerosol degreasing and dry clean spot removal 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 AEROSOL DEGREASING AND SPOT REMOVAL TO OSHA AND CPSC 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 a large portion of the population exposed to TCE aerosol degreasing and spot removal 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 "TSCA is the only regulatory authority able to prevent or reduce risk from these uses of TCE to a sufficient extent across the range of uses and exposures of concern." The Agency similarly decided against making a referral to the Consumer Product

Safety Commission based on limitations on the Commission's authority to address unreasonable risks of chemicals.

- **EPA HAS APPLIED THE "GOOD SCIENCE" CONSIDERATIONS OF TSCA SECTION 26(h)**

Section 26(h) of amended TSCA sets out general "principles" for using science in decision-making under the new law. These principles are straightforward, flexible and generally consistent with current and past agency practice. Moreover, since the TCE risk assessment was developed under the old law, it is doubtful that section 26(h) even applies. Nonetheless, EPA's transparent and fully documented risk assessment, based on peer-reviewed data, methods and findings, easily meets section 26(h)'s "good science" benchmarks.

- **EPA HAS DESIGNED ITS USE PROHIBITIONS TO ASSURE COMPLIANCE THROUGHOUT THE SUPPLY CHAIN**

EPA proposes to impose its prohibitions on TCE use in aerosol degreasing and spot removing 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 expedited implementation schedule under which the requirements of its rule will take effect within 6-9 months of its publication date. SCHF strongly supports this approach. The immediacy of the risk and large exposed population heavily favor immediate compliance with the proposed use prohibitions and there is no reason for any delay.

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 consistent with 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."[3]

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. [4]

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 nonrisk 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."

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 LCSA legislative history is clear that Congress wanted to eliminate any such "balancing test."[5]

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).[6] This requirement would be "applicable' to

[3] Congressional Record – Senate 3519 (June 7, 2016).
[4] For example, because EPA is proceeding directly to rulemaking based on an existing risk assessment, the prioritization provisions of section 6(b)(1)-(2) and the risk evaluation provisions of section 6(b)(4) are inapplicable.
[5] Congressional Record – Senate 3516 (June 7, 2016).
[6] 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."

the TCE rulemaking under section 26(l)(4). Thus, SCHF expects EPA to promulgate a final TCE rule by December 16, 2017, 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. 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,
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> 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).[7]

In this case, as described more fully below, the cost of taking the proposed action to prohibit the two TCE uses is very small, when compared to the benefits or otherwise.

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

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 restricted 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. Rather than weakening the restrictions in its section 6(a) rule, EPA's consideration of available substitutes provides a basis for including such exemptions in the rule where warranted under the criteria in subsection (g).

In this case, as described more fully below, there are many demonstrated TCE alternatives currently available, and thus the absence of substitutes should not be a factor in choosing the best remedy under section 6(a), a reason to delay the rule's effective date under section 6(d), or a basis for granting use exemptions under section 6(g).

II. TCE USE IN AEROSOL DEGREASING AND DRY CLEANING SPOT REMOVAL PRESENTS AN UNREASONABLE RISK

The record amply supports EPA's determination that the TCE uses to be banned under EPA's proposal present 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 choose 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 aerosol degreasing and dry cleaning spot removal 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 and consumer populations exposed to TCE as a result of the two uses;

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 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).[8] 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.[9] 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

[8] 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

[9] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf

of operations [no ventilation], he may find in this solvent the source of disaster for exposed workmen."[10]

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.[11] 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). [12]

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)."[13]

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 a multisite carcinogen (liver, kidney, lung, testes, and blood) by both the oral and inhalation routes of exposure.[14] 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:

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[10] http://jamanetwork.com/journals/jama/article-abstract/282234 (JAMA July 30, 1932)
[11] Id.
[12] Id. ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[13] 81 FR at 91596
[14] IARC 2014. International Agency for Research on Cancer, Monograph 106. Available here: https://monographs.iarc.fr/ENG/Monographs/vol106/mono106-001.pdf

"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)."[15]

4. <u>Developmental Harm</u>

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." [16]

5. <u>Cardiac Effects</u>

The public is extremely concerned about developmental risks, including fetal cardiac malformations.[17] The EPA IRIS assessment of TCE (2011) based its Point of Departure (POD) for

[15] 81 FR at 91596.
[16] 81 FR at 91595.
[17] 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

developmental toxicity on fetal cardiac abnormalities in rodents.[18] 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.[19] 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.[20]

As the TCE Work Plan points out, [21] the TCE IRIS assessment has successfully cleared several layers of extensive public scrutiny and peer review including agency review, science

[18] 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

[19] 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.

[20] 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.

[21] "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

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), external peer review of the revised draft assessment by the EPA's Science Advisory Board (SAB) in January 2011, and final internal agency review and EPA-led science discussion on the final draft. 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) [22] 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,[23] 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).[24] 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 other studies and mechanistic evidence, to derive exposure limits (reference values).[25] [26] Fetal cardiac effects – including deformities in the

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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." EPA 2014 TCE WorkPlan, page 29

[22] The HEC99 is the lower-end of the range of hazard values for the "sensitive" human (the 99th percentile) for each target organ/endpoint

[23] 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.

[24] 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.

[25] 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

[26] 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

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).[27]

B. *Tens of Thousands of Workers, Bystanders and Consumers Breathe or Have Dermal Contact with TCE in Largely Uncontrolled Commercial or Residential Settings from Aerosol Degreasing and Spot Removal Products*

1. Aerosol Degreasing

According to EPA,[28] degreasing is a process that uses aerosol spray products, typically applied from a pressurized can, to remove residual contaminants from parts. Aerosol degreasers are primarily used for niche industrial or manufacturing uses and some commercial service uses, such as degreasing of metals, degreasing of electrical motors, and electronic cleaners. EPA estimates that about 2,200 commercial facilities use TCE aerosol spray degreasers. Consumer use of TCE in aerosol degreasers is similar to commercial use but occurs in consumer settings. The aerosol products used in consumer settings are the same as those used in commercial settings.

EPA estimates that 10,800 workers and occupational bystanders are exposed to TCE during commercial aerosol degreasing and 22,000 consumers and bystanders are exposed to TCE during consumer applications. Of the exposed workers, EPA estimates that 900 are pregnant women. By their nature, aerosol degreasing exposures are likely to be uncontrolled although ventilation may be used at times to disperse vapors. Occupational use of degreasing products may often be repetitive and continuous whereas consumer exposure is more intermittent. Both dermal and inhalation routes of exposure typically occur in aerosol degreasing operations and use of gloves and other protective equipment is episodic and uneven.

2. Spot Cleaning in Dry Cleaning Facilities

As EPA describes,[29] TCE is used for spot cleaning in dry cleaning facilities to remove oily-type stains, including fats, waxes, grease, cosmetics, and paints. Stained fabrics are typically "pre-spotted" with spot treatment products, which are often solvent-based such as those containing TCE, prior to being placed in dry cleaning machines. TCE is applied by a squirt bottle directly onto the stain on the garment. Squirt bottles are hand filled from larger volume containers of the spotting agent. After application, the TCE-based spotting agent is patted with a brush to break up the stain without harming fabric and suction vacuumed from the garment, which is

[27] EPA 1991. Guidelines for Developmental Toxicity Risk Assessment. U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC, EPA/600/FR-91/001, 1991.
[28] 81 FR at 91601.
[29] 81 FR at 91607.

then placed in the dry cleaning machine. Concentrations of TCE in commercial spotting agents vary from 10% to 100%.

EPA estimates that there are approximately 61,000 dry cleaning facilities in the United States, with an estimated 210,000 workers. Thirteen (13) percent of dry cleaning workers are Asian (as compared to 5 percent of the national population) and 30 percent are Hispanic (as compared to 16 percent of the national population).

Approximately 32,000 to 52,000 of dry cleaning facilities are estimated to be using TCE in spot cleaning, with an estimated 105,000 to 168,000 workers and occupational bystanders. Of these, EPA estimates that 5400 are pregnant women. Again, exposures in these facilities can be by inhalation or skin contact, can be repetitive and continuous, and are generally uncontrolled, with limited use of protective equipment to reduce exposure.

C. EPA Has Estimated That TCE Exposure Levels are Significant as a Result of These Uses Based on Valid and Peer Reviewed Models That are Adequate and Reliable for TSCA Risk Evaluation Purposes

In order to derive reliable estimates for TCE emissions in the workplace, including both commercial degreasing and dry cleaning facilities, EPA/OPPT used data from the National Emissions Inventory (NEI), the Toxics Release Inventory (TRI) and a study on the use of spotting chemicals prepared for the California EPA and EPA Region 9 (CalEPA/EPA, 2007).[30] SCHF agrees with OPPT that these are robust and credible sources of reported data, relied upon by risk assessors, regulators and researchers in the US and around the world.

To estimate workplace exposures, these emission estimates were incorporated into a Near Field/Far Field (NF/FF) mass balance model, which 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.[31] EPA also strengthened the accuracy and reliability of the model with monitoring data from the Occupational Safety and Health Administration (OSHA) (Coble, 2013) and relatively recent site-specific data from the National Institute for Occupational Safety and Health (NIOSH).[32] Proving the accuracy of its model, EPA reports that exposure estimates with and without engineering controls such as local exhaust ventilation (LEV) were of the same order of magnitude as measured values:

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[30] CalEPA/EPA 2007. Spotting Chemicals: Alternatives to Perchloroethylene and Trichloroethylene in the Textile Cleaning Industry. Report prepared for CalEPA/U.S.EPA by K. Wolf and M. Morris from the Institute for Research and Technical Assistance. http://www.irta.us/reports/DTSC%20Spotting%20Chemical%20for%20Web.pdf

[31] 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.

[32] NIOSH 1997. Control of Spotting Chemical Hazards in Commercial Drycleaning. Publication Number 97-158. Centers for Disease Control and Prevention, Atlanta, GA. http://www.cdc.gov/niosh/docs/hazardcontrol/hc20.html

- For commercial degreasing facilities, EPA's exposure estimate ranged from 0.04 to 197 parts per million (ppm) and measured data from OSHA ranged from 0.06 to 380 ppm;
- For dry cleaning facilities, EPA's site-specific exposure estimate ranged from 0.8 to 2.1 ppm; measured data reported by NIOSH ranged from 2.37 to 3.11 ppm.

Consumer exposures from solvent degreasing and spray-applied coatings were calculated using the Exposure and Fate Assessment Screening Tool Version 2 (E-FAST2)/Consumer Exposure Module (CEM). The modeling was more heavily relied upon for consumer scenarios because there are no emissions and monitoring data (Work Plan page 20). The high-end inhalation exposure estimates for the consumer scenarios were as follows:

- 0.4 ppm for users of TCE-containing clear protective coating sprays
- 0.1 ppm for bystanders of TCE-containing clear protective coating sprays
- 2 ppm for users of TCE-containing solvent degreasers
- 0.8 ppm for bystanders of TCE-containing solvent degreasers

Note that exposures for residential consumers are similar to occupational exposures for workers in dry cleaning facilities – about 2 ppm, putting many of these individuals at excess risk for both cancer and non-cancer health impacts. Workers in commercial degreasing facilities had exposures that were one hundred times higher, about 200 ppm, putting them at even greater risk.

External expert reviewers, overall, concurred with EPA's approach as scientifically sound and defensible, given the unavoidable gaps in data.[33] 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."[34]

SCHF concurs – 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

[33] 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-trichloethene. Information available here: https://www.scgcorp.com/tcl2013/index.asp

[34] 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

at this time.[35] Industry arguments that the Work Plan exposure calculations may not be adequate for regulatory purposes or should be considered simply as a screening-level assessment 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 an MOE approach to estimate non-cancer risks, relying 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.

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 concurs 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 higher exposure levels.[36]

[35] 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.

[36] 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

Even though EPA's approach was insufficiently conservative, it is striking that the worker and bystander MOEs for multiple end-points -- developmental effects, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity and liver toxicity -- were well below the benchmark for aerosol degreasing operations, with the benchmark in some cases 3000 times greater than actual exposures: [37]

Table 2-34. Chronic Non-Cancer Risk Estimates for Commercial Use of Degreaser Product at Small Shops

Health Effect Domain and Study	Lowest HEC (ppm) of each health effects domain	WORKER NON-CANCER MOEs [1]				BYSTANDER NON-CANCER MOEs [1]				Total UF or Benchmark MOE
		With LEV--Low-end exposure estimate	No LEV--Low-end exposure estimate	With LEV--Upper-end exposure estimate	No LEV--Upper-end exposure estimate	With LEV--Low-end exposure estimate	No LEV--Low-end exposure estimate	With LEV--Upper-end exposure estimate	No LEV--Upper-end exposure estimate	
DEVELOPMENTAL TOXICITY (Johnson et al., 2003)	HEC50= 0.012	**0.17**	**0.017**	**0.0025**	**0.0003**	**1.3**	**0.13**	**0.0030**	**0.0003**	10
	HEC95= 0.0051	**0.072**	**0.0072**	**0.0011**	**0.0001**	**0.54**	**0.05**	**0.0013**	**0.0001**	
	HEC99= 0.0037	**0.052**	**0.0052**	**0.0008**	**0.0001**	**0.40**	**0.04**	**0.0009**	**0.0001**	
KIDNEY (NTP, 1998)	HEC50= 0.042	**0.59**	**0.059**	**0.0088**	**0.0009**	**4.4**	**0.4**	**0.01**	**0.001**	10
	HEC95= 0.0085	**0.11**	**0.012**	**0.0018**	**0.0002**	**0.9**	**0.09**	**0.0021**	**0.0002**	
	HEC99= 0.0056	**0.079**	**0.0079**	**0.0012**	**0.0001**	**0.6**	**0.06**	**0.0014**	**0.0001**	
IMMUNOTOXICITY Keil et al., 2009 (Decrease in thymus weight and thymus cellularity)	HEC50= 0.092	**1.3**	**0.1**	**0.019**	**0.0020**	**9.7**	**0.97**	**0.023**	**0.0023**	100
	HEC95= 0.045	**0.6**	**0.06**	**0.0095**	**0.0010**	**4.7**	**0.47**	**0.011**	**0.0011**	
	HEC99= 0.033	**0.5**	**0.05**	**0.0069**	**0.0007**	**3.5**	**0.35**	**0.0082**	**0.0008**	
IMMUNOTOXICITY Keil et al., 2009 (Autoimmunity)	HEC50= 0.092	**1.3**	**0.13**	**0.019**	**0.0020**	**9.7**	**0.97**	**0.022**	**0.0023**	30
	HEC95= 0.045	**0.6**	**0.063**	**0.0095**	**0.0010**	**4.7**	**0.47**	**0.011**	**0.0011**	
	HEC99= 0.033	**0.5**	**0.046**	**0.0069**	**0.0007**	**3.5**	**0.35**	**0.0082**	**0.0008**	
REPRODUCTIVE TOXICITY (Chia et al. 1996)	HEC50= 1.4	**19.7**	**2.0**	**0.3**	**0.03**	147	**15**	**0.35**	**0.034**	30
	HEC95= 0.7	**9.8**	**1.0**	**0.15**	**0.015**	74	**7**	**0.17**	**0.017**	
	HEC99= 0.5	**7.0**	**0.7**	**0.11**	**0.011**	53	**5**	**0.12**	**0.012**	
NEUROTOXICITY (Arito et al., 1994)	HEC50= 13	**183**	**18**	**2.7**	**0.28**	1369	**137**	**3.2**	**0.32**	300
	HEC95= 6.4	**90**	**9**	**1.3**	**0.14**	674	**67**	**1.6**	**0.16**	
	HEC99= 4.8	**67**	**7**	**1.0**	**0.10**	505	**51**	**1.2**	**0.12**	
LIVER (Kjellstrand et al. 1983)	HEC50= 25	351	35	**5.3**	**0.53**	2632	263	**6**	**0.61**	10
	HEC95= 12	168	17	**2.5**	**0.26**	1263	126	**3**	**0.29**	
	HEC99= 9.1	128	13	**1.9**	**0.19**	958	96	**2**	**0.22**	

Notes: (1) MOEs below benchmark MOE indicating risk are denoted in bold text. They indicate potential health risks. (2) Exposure estimates with/without LEV are found in Table 2-10.

Results were similar for bystanders and workers in dry cleaners exposed to TCE spot removal formulations:[38]

[37] EPA. 2014. TSCA Work Plan Chemical Risk Assessment. Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses. CASRN: 79-01-6. EPA/740/R1/4002. Office of Chemical Safety and Pollution Prevention, Washington, DC. *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment-0*, at 112.

[38] Id. at 113.

Table 2-35. Chronic Non-Cancer Risk Estimates for Commercial Use of Spotting Agent at Dry Cleaning Facilities

Health Effect Domain and Study	Lowest HEC (ppm) of each health effects domain	WORKER NON-CANCER MOEs [1]				BYSTANDER NON-CANCER MOEs [1]				Total UF or Benchmark MOE
		With LEV--Low-end exposure estimate	No LEV--Low-end exposure estimate	With LEV--Upper-end exposure estimate	No LEV--Upper-end exposure estimate	With LEV--Low-end exposure estimate	No LEV--Low-end exposure estimate	With LEV--Upper-end exposure estimate	No LEV--Upper-end exposure estimate	
DEVELOPMENTAL TOXICITY (Johnson et al., 2003)	HEC50= 0.012	**6.3**	**0.0253**	**0.63**	**0.0027**	72	**0.0253**	**7.2**	**0.0028**	10
	HEC95= 0.0051	**2.7**	**0.0107**	**0.27**	**0.0011**	31	**0.0107**	**3.1**	**0.0012**	
	HEC99= 0.0037	**1.9**	**0.0078**	**0.19**	**0.0008**	22	**0.0078**	**2.2**	**0.0009**	
KIDNEY (NTP, 1998)	HEC50= 0.042	22	**0.088**	**2.2**	**0.0093**	253	**0.0884**	25	**0.0098**	10
	HEC95= 0.0085	**4.5**	**0.018**	**0.45**	**0.0019**	51	**0.0179**	**5.1**	**0.0020**	
	HEC99= 0.0056	**2.9**	**0.012**	**0.29**	**0.0012**	34	**0.0118**	**3.4**	**0.0013**	
IMMUNOTOXICITY Keil et al., 2009 (Decrease in thymus weight and thymus cellularity)	HEC50= 0.092	**48**	**0.194**	**4.8**	**0.020**	554	**0.194**	**55**	**0.022**	100
	HEC95= 0.045	**24**	**0.095**	**2.4**	**0.010**	271	**0.095**	**27**	**0.011**	
	HEC99= 0.033	**17**	**0.069**	**1.7**	**0.007**	199	**0.069**	**20**	**0.008**	
IMMUNOTOXICITY Keil et al., 2009 (Autoimmunity)	HEC50= 0.092	48	**0.194**	**4.8**	**0.020**	554	**0.194**	55	**0.022**	30
	HEC95= 0.045	**24**	**0.095**	**2.4**	**0.010**	271	**0.095**	**27**	**0.011**	
	HEC99= 0.033	**17**	**0.069**	**1.7**	**0.007**	199	**0.069**	**20**	**0.008**	
REPRODUCTIVE TOXICITY (Chia et al. 1996)	HEC50= 1.4	737	**2.9**	74	**0.31**	8423	**2.9**	842	**0.33**	30
	HEC95= 0.7	369	**1.5**	37	**0.16**	4212	**1.5**	421	**0.16**	
	HEC99= 0.5	263	**1.1**	**26**	**0.11**	3008	**1.1**	301	**0.12**	
NEUROTOXICITY (Arito et al., 1994)	HEC50= 13	6844	**27**	684	**2.9**	78214	**27**	7821	**3.0**	300
	HEC95= 6.4	3369	**13**	337	**1.4**	38505	**13**	3851	**1.5**	
	HEC99= 4.8	2527	**10**	**253**	**1.1**	28879	**10**	2888	**1.1**	
LIVER (Kjellstrand et al. 1983)	HEC50= 25	13161	53	1316	**5.5**	150412	53	15041	**5.8**	10
	HEC95= 12	6317	25	632	**2.7**	72198	25	7220	**2.8**	
	HEC99= 9.1	4791	19	479	**2.0**	54750	19	5475	**2.1**	

Notes: (1) MOEs below benchmark MOE indicating risk are denoted in bold text. They indicate potential health risks. (2) Exposure estimates with/without LEV are found in Table 2-13.

Thus, EPA correctly determined that for both aerosol degreasing and spot removal uses, non-cancer risks were well above acceptable levels for a broad range of exposure scenarios and health end-points.

E. EPA Estimated Cancer Risks are in a Range (10^{-2} - 10^{-4}) Well Above the Risk Levels That EPA and other Authoritative Bodies Have Historically Considered Acceptable

SCHF supports 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.[39] The IUR is the estimated upper bound excess lifetime cancer risk resulting from continuous exposure to an airborne agent at 1 µg/m³. 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).

[39] To convert concentrations in air (at 25°C) from ppm to mg/m^3: mg/m^3 = (ppm) × (molecular weight of the compound)/(24.45). For TCE: 1 ppm = 5.37 mg/m^3. To convert concentrations in air from µg/m^3 to mg/m^3: mg/m^3 = (µg/m^3) x (1 mg/1,000 µg).

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 $\mu g/m^3$ can be stated in plain language as an excess cancer risk of 4 cases per 1 million people breathing 1 $\mu g/m^3$ TCE over a lifetime. This is very relevant, and concerning, given that even ambient outdoor air levels have been measured as high as 18 $\mu g/m^3$ (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's cancer risk estimates for TCE haven't changed much over decades, other than to become stronger, more confident, and greater. This suggests that EPA has had the science right for a long time, and that protective regulations are long overdue.

	1985/7	**2001**	**2009**	**2011**
CANCER	Probably (B2)	Highly likely	Cancer by all routes of exposure	Cancer by all routes of exposure/ mutagenic
Oral unit risk estimate for cancer	0.011 mg/kg-day – Excess cancer risk of 1 per 100,000 people at 1 µg /kg-day	0.02 – 0.4 per mg/kg-day. Excess cancer risk of 2-40 per 100,000 people at 1 µg /kg-day	0.05 per mg/kg-day. Excess cancer risk of 5 per 100,000 people at 1 µg /kg-day	0.05 per mg/kg/day
Inhalation cancer risk estimates	0.009 ppm ($1.7x10^{-6}$ µg /m^3). Excess cancer risk of 1.7 per 1 million at 1 $\mu g/m^3$		0.02 per ppm (4×10^{-6} per $\mu g/m^3$) – Excess cancer risk of 4 per 1 million people breathing 1 $\mu g/m^3$ TCE over a lifetime	0.02 per ppm (4×10^{-6} per $\mu g/m^3$)

Cancer risk at RfC/RfD	Not available	Not available	$2x10^{-5}$	

Over the years, EPA regulatory programs have typically used a target cancer level of between $1x10^{4}$ and $1x10^{-6}$ for determining the acceptability of the cancer risk in a population. Restated, these risk levels correspond to:

- the probability of 1 chance in 1 million of an individual developing cancer;
- the probability of 1 chance in 100,000 of an individual developing cancer, which is equiv alent to 10 cancer cases in 1 million; and
- the probability of 1 chance in 10,000 of an individual developing cancer, which is equival ent to 100 cancer cases in 1 million.

In the Workplan Risk Assessment, all of the degreaser scenarios exceeded the three target cancer levels (some by a significant margin), with the exception of one of the bystander scenarios. Likewise, all of the worst case exposures for the spot cleaner scenarios (both user and bystander scenarios) and one of the typical exposure scenarios with no LEV exceeded the three target levels. The remaining spot cleaner scenarios exceeded the target level of $1x10^{-4}$.

In short, EPA's estimated cancer risks (like the 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.

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:[40]

- "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

[40] 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

gloves such as nitrile or neoprene. Also, use full protective clothing if there is prolonged or repeated contact of liquid with skin."[41] (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."[42] (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…"[43] (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 the Targeted Uses Are Real and Well-Defined and Require Special Protection under TSCA*

In addition to risks to general worker and consumer populations, TCE used in aerosol degreasing and dry cleaning spot removal 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

[41] 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

[42] 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

[43] 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

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 that a subpopulation of 900 pregnant women were exposed to TCE in aerosol degreasing operations and another 5400 pregnant women were exposed from spot removal, placing their unborn fetuses at unique risk of cardiac defects and other malformations. EPA also found that Asian and Hispanic workers – two environmental justice groups that are disproportionately exposed to chemicals – are heavily represented in the employee populations for aerosol and degreasing operations.[44]

It is also important to note that OPPTs use of the HEC99 – which SCHF strongly supports – 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." [45] 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 represents the evaluation and detection of a more sensitive endpoint in the target organ. SCHF supports OPPTs 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. [46] 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:

[44] 81 FR at 91616.

[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

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 1.7	Keil et al, 2009 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 3	Johnson et al, 2003 Fredriksson et al, 1993

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 and consumers 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 and consumers is justified and long overdue.

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

After determining that the two TCE 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." The result of this analysis was a conclusion that a ban on the two uses 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) so that TCE no longer presents unreasonable risks, based on EPA's technical analysis of exposure scenarios." This screen enabled EPA 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**. In determining whether a regulatory option would impose requirements to the extent necessary so that TCE no longer presents the identified unreasonable risks, **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."[47]

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 the two TCE uses – and not other remedies such as labeling, product reformulation, ventilation 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. EPA cited several studies to support this position:

> "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

[47] 81 FR 91600 (emphasis added).

> 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."[48]

EPA further concluded that comprehension of warnings for TCE aerosol degreasing and spot removal uses would be unusually challenging because of the complexity of the information conveyed:

> "The Agency further determined 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. . . . [I]t would be challenging to most users to follow the complex product label instructions required to explain how to reduce 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, and window periods during pregnancy when the developing fetus is susceptible to adverse effects from acute exposures, as well as effects to bystanders**. It is unlikely that label language changes will for this use result in widespread, consistent, and successful adoption of risk reduction measures by users.**[49]

These conclusions are particularly compelling in light of the nature of the TCE-exposed population. The dry cleaners and small degreasing shops that use TCE-containing products generally lack effective worker training and hazard communication programs and 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). Consumers who do not typically work around hazardous chemicals and lack professional training are likewise poorly equipped to study product labels and apply recommended handling practices. And occupational or consumer 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 and/or Requiring Better Exhaust Ventilation would not Achieve the Risk Reduction Targets

EPA also evaluated whether continued TCE use for aerosol 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, and/or by requiring local exhaust ventilation at TCE-using facilities, reducing TCE exposures by 90 percent. To examine these options, it recalculated projected TCE exposure levels to reflect the reductions in exposure they would achieve. Even

[48] 81 FR at 91601.
[49] **Id**. (emphasis added)

with these reductions, it found, exposure 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."[50]

EPA conducted a similar analysis for TCE spot removal use in dry cleaning operations – again concluding that "alternate regulatory options such as reducing the concentration of TCE in spot cleaner for dry cleaning facilities and using local exhaust ventilation to improve ventilation near worker activity could not achieve the target MOE benchmarks for non-cancer endpoints . . . and standard cancer risk benchmarks."[51]

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

For both aerosol degreasing products and spot removal applications, EPA determined that, either alone or in conjunction with other measures, "respirators could reduce exposures to levels that are protective of non-cancer and cancer risks."[52] It then compared a respirator requirement to prohibiting TCE in aerosol degreasing and spot removal products – an option that would fully protect against the risks – using a variety of metrics, including protectiveness, feasibility and cost.

Respirators did not fare well in this comparison. As EPA pointed out, "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:[53]

> "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

[50] 81 FR at 91604.
[51] 81 FR at 91609.
[52] 81 FR 91605
[53] 81 FR 91605

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).'"

We strongly concur that these 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 aerosol degreasing and spot removal **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 TCE exposure occurs. 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 dry cleaner, 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 budget reductions. Finally, even if they were effective, respirators would not provide protection to bystanders (either other employees or consumers who frequent dry cleaners), leaving them at unacceptable risk.

EPA also examined the merits of combining a respirator program (using lower power respirators) with a requirement for improved ventilation. But it found that the costs of this option would be greater than the costs of a respirator requirement alone and that in either event the costs would be considered prohibitive by affected facilities. EPA also noted that there would still be uneven compliance with a less stringent respirator requirement and therefore workers would not be adequately protected.

A final important consideration that influenced EPA's thinking for degreasing products is that neither ventilation controls nor respirators could be implemented for consumer users of these products and, thus, risks to consumers could not be meaningfully reduced. In theory, one solution might be to prohibit aerosol-degreasing products for consumer use while allowing continued commercial use. However, as EPA pointed out, many consumers now use commercial degreasing products, which are widely available for purchase, and this practice

would likely continue so long as commercial degreasing products are in the stream of commerce.[54]

After applying all these considerations, EPA opted for banning the two TCE uses over less protective, reliable and implementable options, explaining that "non-cancer and cancer risks would be completely eliminated" under a ban because:

> "The proposed approach would ensure that workers and consumers are no longer at risk from TCE exposure associated with this use. Prohibiting the manufacturing, processing and distribution in commerce of TCE for use in aerosol degreasing would minimize the availability of TCE for aerosol degreasing. The prohibition of the use of TCE in commercial aerosol degreasing would eliminate commercial demand for TCE aerosol degreasing products and significantly reduce the potential for consumer use of commercial products. These complementary provisions would protect both workers and consumers; workers would not be exposed to TCE and the risk to consumers would be minimized because commercial aerosol degreasing products containing TCE would not be available, so consumers would not be able to divert commercial-use products from the supply chain."[55]

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).

IV. EPA'S DETERMINATION THAT BENEFITS GREATLY 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 a ban of the two targeted TCE uses will produce benefits far in excess of the costs (even without including certain benefits) and would have a more favorable ratio of benefits and costs than other options considered.

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[54] EPA explains that "it has determined that consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy. Coupled with the fact that many products identified as commercial or professional are readily obtainable in a variety of venues (*e.g.,* the Internet, general retailers, and specialty stores, such as automotive stores), EPA does not find that this option would protect consumers. In addition, this option alone would not address the risks to workers from commercial aerosol degreasing." 81 FR at 91605

[55] 81 FR at 91604. These conclusions apply to aerosol degreasing but EPA's conclusions for spot removal products are very similar, except for consumer uses, which are not a consideration for these products. See 82 FR at 91609-10.

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 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 15-year monetized savings of between $700,000 to $2.7 million (aerosol degreasing) and $3.7-$22.3 million (spot removal in dry cleaners). The benefits range across the two use categories would thus be $4.4 million to $25 million per year.

Because they could not be monetized,[56] 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 bans would prevent.[57]

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[56] 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."81 FR at 91612

[57] 81 FR at 91617.

On the cost side, EPA found that users who replace TCE with substitute solvents would experience negligible costs because the costs of these substitutes are roughly the same as current products. It concluded that total costs of reformulating aerosolized degreasing products are likely to be around $416,000 in the first year and between $32,000 and $41,000 annualized over 15 years. For dry cleaners using TCE-containing spot removers, EPA estimated that comparable costs would be $286,000 in the first year and $22-28,000 annualized over 15 years. For each product category, EPA concluded that downstream notification and recordkeeping costs would be $51,000 in the first year and $3,900-5,000 annualized over 15 years.

Overall, EPA found that the total costs of the proposed rule would be between $170,000-183,000 annualized over 15 years. This is dramatically less than the benefits of the rule ($4.4 million to $25 million per year) even excluding non-monetizable benefits of avoided non-cancer health effects.

EPA also examined the relative costs and benefits of the principal regulatory alternative potentially capable of protecting against the unreasonable risk – requiring air-supplied respirators, with or without ventilation equipment. It concluded that this alternative would be less protective and produce smaller benefits (although it could not quantify the difference) and that the costs would be much greater (between $8200 and $9100 annualized per facility to implement a respirator program).[58] *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 aerosol degreasing and dry clean spot removal 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.

For degreasing products, EPA concluded that "[t]here are currently TCE alternatives available on the market for all of the existing uses of aerosol degreasing that are similar in efficacy and cost [and] [a]ll substitutes are expected to be less hazardous than TCE."[59] EPA added that:

> "Many substitutes are expected to be significantly less hazardous than TCE, based on currently available information. These include formulations that may be categorized as

[58] Based on EPA's estimate of 63,000 affected facilities, this would mean annual aggregate costs of as high as $573 million, an economic burden that EPA understandably found would be cost-prohibitive.
[59] 81 FR at 91602

acetone-, citrus terpene-, hydrocarbon-, and water-based degreasers. Several formulations are made with chemicals that are expected to have lower relative exposure potential, compared to TCE, based on currently available information. These include citrus terpenes and water-based degreasers."

For spot removal products used in dry cleaners, EPA similarly concluded that "[t]here are currently a wide variety of comparably effective substitutes on the market and in use in dry cleaning operations that are similarly priced to TCE [and] [i]n general, substitutes are less toxic than TCE."[60] As EPA notes,[61] according to the Drycleaning and Laundry Institute, a trade association representing more than 4,000 dry cleaning operations in the United States, not all dry cleaning facilities use TCE, and many other alternatives are available and equally effective.

The expert peer review report on the Workplan assessment provides considerable information about Paint, Oil and Grease (POG) spotting agents that do not contain TCE or PERC. In particular, spot remover product testing information from the Institute for Research and Technical Assistance (IRTA), a technical nonprofit organization, was included in the report. The IRTA data was generated for a project sponsored by California Environmental Protection Agency's Department of Toxic Substances Control (DTSC) and U.S. EPA Region 9, to identify low-VOC safer alternatives for a range of different textile cleaning processes.[62] IRTA also conducted a cost analysis to compare the cost of using TCE spotting agents with the cost of using the alternatives; the results indicated that the cost of using the alternatives is lower than the cost of using TCE. The following were found to be cost-effective, low-VOC, low-toxicity alternatives: Cold Plus is a water-based commercial spotting agent; Mirachem NP 2520 is a water-based cleaner developed for cleaning in the screen printing industry; Soy Gold 1000 and Soy Gold 2500 are methyl esters used for cleaning ink in the screen and lithographic printing industries and are used in other cleaning applications.

Since the IRTA report – already 10 years old – even more successful work has been done to identify alternatives to TCE and PERC. The Toxic Use Reduction Institute (TURI) lab has aggregated safer TCE alternatives for degreasing in an extensive online database at www.cleanersolutions.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.

The availability of adequate substitutes is demonstrated by experience under TCE bans in several states and the EU. As EPA notes, TCE use is limited in aerosol degreasing products

[60] 81 FR at 91607
[61] 81 FR at 91611
[62] CalEPA/EPA (California Environmental Protection Agency/U.S. Environmental Protection Agency). 2007. Spotting Chemicals: Alternatives to Perchloroethylene and Trichloroethylene in the Textile Cleaning Industry. Report prepared for CalEPA/U.S.EPA by K. Wolf and M. Morris from the Institute for Research and Technical Assistance. http://www.irta.us/reports/DTSC%20Spotting%20Chemical%20for%20Web.pdf

intended for consumers due to existing VOC regulations in California and in a number of other states. According to the Agency,[63] "[t]he range of the State-mandated prohibitions demonstrate that other chemicals can be substituted for TCE for a wide range of uses because other chemicals or mixtures of chemicals can impart properties similar to those of TCE." Further, the fact that 10 states and the District of Columbia have specifically prohibited the use of TCE in general purpose degreasers yet these products continue to be sold in those jurisdictions demonstrates that TCE is not critical to the degreasing use and there are efficacious substitutes. TCE is also prohibited in the European Union in aerosol degreasers. TCE substitutes are used for aerosol degreasing, confirming that "TCE is not a critical chemical for aerosol degreasing and that substituting alternate chemicals would not be overly difficult."

A similar picture exists for dry cleaning spot removal uses of TCE. As EPA describes, TCE use is prohibited in California for use in aerosol and non-aerosol consumer spot removers. TCE is also prohibited in the European Union for spot cleaning use in dry cleaning facilities. Thus, the Agency concluded that "prohibitions in California and the European Union indicate that the transition can be made to substitutes, demonstrating that switching to alternatives would not be overly difficult for users."[64]

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 Significant New Use Rule) are critical to maximize the public health benefits of a TCE ban for these two uses.

VI. THERE IS NO BASIS FOR REFERRING RISKS RELATED TO TCE USE IN AEROSOL DEGREASING AND SPOT REMOVAL TO OSHA AND CPSC 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

[63] 81 FR at 91606.
[64] 81 FR at 91611.

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."[65]

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 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."[66]

Since workers comprise a large portion of the population exposed to TCE aerosol degreasing and spot removal 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 "TSCA is the only regulatory authority able to prevent or reduce risk from these uses of TCE to a sufficient extent across the range of uses and exposures of concern."[67]

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 nonrisk 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 OSHA lacks authority to protect consumers who use TCE-containing products and that certain categories of workers are outside its 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

[65] 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.

[66] Congressional Record – Senate S3517 (June 7, 2016).

[67] 81 FR at 91619,

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 highly 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."[68]

EPA also considered and decided against making a referral under section 9(a) to the Consumer Product Safety Commission (CPSC). A major factor in this decision was the limitations on CPSC's authority, as compared to EPA's, to address unreasonable risks of chemicals. Although the term "unreasonable risk" appears in both laws, the Consumer Product Safety Act (CPSA) defines the term to require an explicit balancing of costs and benefits while, as amended by the LCSA,[69] TSCA provides that costs and other nonrisk factors are irrelevant to the determination of unreasonable risk. In addition, CPSC's jurisdiction does not extend to commercial products and thus, in contrast to EPA, it could not ban or otherwise regulate these products to keep them out of the hands of consumers. CPSC has informed EPA that it has no plans to regulate TCE-containing products and its Executive Director has advised that "[b]ecause TSCA reaches both occupational and consumer uses, we recognize that EPA could address risks associated with TCE more appropriately than CPSC."[70]

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 OSHA and/or CPSC to take action to eliminate the unreasonable risk, and if OSHA/CPSC did not take action, EPA would be required to take action under Section 6 (or file an imminent hazard action under section 7). Since both agencies have made clear that they do not intend to take action on TCE and plan 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.

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

[69] A consumer product safety rule under the CPSA must include a finding that "the benefits expected from the rule bear a reasonable relationship to its costs." 15 U.S.C. 2058(f)(3)(E).

[70] Letter dated April 19, 2016, from Patricia Adkins, CPSC Executive Director, to Assistant Administrator James J. Jones (reference 64 in EPA docket),

In sum, EPA soundly concluded that it could not justify a section 9(a) referral to OSHA or CPSC and should not revisit that conclusion in its final rule.[71]

VII. EPA HAS APPLIED THE "GOOD SCIENCE" CONSIDERATIONS OF SECTION 26(h)

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." The principles are also straightforward, self-executing and generally consistent with current and past agency practice and therefore do not require significant changes in how EPA conducts risk assessments. Moreover, since the TCE risk assessment was developed under the old law, it is doubtful that section 26(h) even applies.

In any case, as EPA notes,[72] 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 HAS PROPERLY IMPOSED USE PROHIBITIONS ON UPSTREAM MANUFACTURERS AND PROCESSORS AND ON DOWNSTREAM USERS, ALONG WITH A DOWNSTREAM NOTIFICATION REQUIREMENT

EPA's proposed bans on TCE use in aerosol degreasing and spot removal in dry cleaners include three components: (1) a prohibition on TCE manufacture/importation, processing and distribution in commerce for these two uses; (2) a direct prohibition on commercial use of TCE

[71] EPA also considered but correctly rejected a referral to other EPA offices implementing other environmental laws. 81 FR 91619.
[72] 81 FR at 91619-20.

in aerosol degreasing and spot removal operations; 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 supports this three-pronged approach. The upstream prohibitions on TCE-containing products manufactured for aerosol degreasing and spot removal 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. Together, the upstream and downstream prohibitions will go far to eliminate the availability of commercial aerosol degreasing products to consumer applicators. 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 prohibited uses and strengthen compliance and enforcement. These benefits more than offset the relatively modest costs of notification and record-keeping.[73]

Under the proposed rule, the prohibition of upstream manufacture, processing and distribution in commerce would go into effect 180 calendar days after the date of publication of the final rule, while the downstream use prohibition would take effect 270 days after final rule publication. Downstream notification and recordkeeping requirements would take effect within 45 days of publication.[74]

We strongly support this expedited implementation schedule. 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 immediate compliance with the use prohibitions and there is no reason for any delay.

CONCLUSION

The use of TCE is aerosol degreasing and dry cleaner spot removal operations presents a significant and widespread risk of multiple serious health effects to tens of thousands of exposed workers and consumers, including pregnant women and other vulnerable groups and environmental justice communities. EPA has used sound and reliable methods to calculate likely levels of exposure to TCE from these uses 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 these TCE uses is the only remedy that will be effective in eliminating the unreasonable risks they pose and that the benefits of a ban would greatly exceed its costs.

[73] 81 FR at 91620,
[74] See proposed sections 751.305-313.

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

Respectfully submitted

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On behalf of:

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
American Sustainable Business Council
Asbestos Disease Awareness Organization
BlueGreen Alliance
Breast Cancer Action
Breast Cancer Prevention Partners *(formerly Breast Cancer Fund)*
Clean and Healthy New York
Clean Production Action
Clean Water Action
Conservation Minnesota
Earthjustice
Ecology Center
Environmental Health Strategy Center
Health Care Without Harm
Healthy Legacy
League of Conservation Voters
Learning Disabilities Association of America
Maryland Public Interest Research Group
Minnesota Center for Environmental Advocacy
National Medical Association
Natural Resources Defense Council
Physicians for Social Responsibility
Safer States
Science and Environmental Health Network
Stupid Cancer
Toxic-Free Future
U.S. Public Interest Research Group (PIRG)
Vermont Public Interest Research Group
WE ACT for Environmental Justice
Women for a Healthy Environment