UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families and Natural Resources Defense Council
On Proposed Restrictions on Methylene Chloride and N-Methylpyrrolidone Use in Paint Removal under Section 6 of the Amended Toxic Substances Control Act

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Safer Chemicals Healthy Families (SCHF) and Natural Resources Defense Council (NRDC) submit these comments on the Environmental Protection Agency's (EPA's) proposed rule to restrict use of methylene chloride (MC) and n-methylpyrrolidone (NMP) in paint and coating removal under section 6 of the newly enacted Frank H. Lautenberg Chemical Safety for the 21st Century Act (LCSA).[1]

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

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

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

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

[1] 82 Federal Register 7464 (January 19, 2017).

Alaska Community Action on Toxics
Alliance for a Healthy Tomorrow
Asbestos Disease Awareness Organization
Breast Cancer Prevention Partners
Clean and Healthy New York
Clean Water Action- Connecticut
Earthjustice
Ecology Center
Environmental Health Strategy Center
Healthy Legacy
League of Conservation Voters
Learning Disabilities Association
Maryland PIRG
Oregon Environmental Council
Science and Environmental Health Network
U.S. Public Interest Research Group (PIRG)
VPIRG
WE ACT for Environmental Justice

SUMMARY OF KEY POINTS

This proposed rule – coupled with two companion EPA proposals on trichloroethylene (TCE) – 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 risk assessments on MC and NMP were 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 these assessments. 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 MC and NMP is imperative to demonstrate immediate and tangible progress in meeting the law's risk reduction goals.

The case for immediate action to restrict MC and NMP use in paint and coating removal is compelling. MC poses a serious risk of asphyxiation and has caused 49 reported deaths; it also is known to cause several types of cancers as well as liver, kidney and reproductive toxicity. A broad set of studies across multiple species show that NMP causes developmental toxicity (fetal death or decreased infant birth rates and reduced body weights) and other health effects. Paint and coating removal operations using MC and NMP are largely uncontrolled and result in high exposure. EPA estimates that 62,000 workers and 2 million consumers – including many women of childbearing age at risk of developmental effects -- are exposed to MC and NMP during paint and coating removal. EPA's analysis shows that these exposures present risks of cancer and non-cancer effects significantly above levels that EPA and other risk managers have traditionally considered unacceptable.

If the new TSCA law cannot be used to address such compelling and significant 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

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

presenting unreasonable risks within one year of proposal. This deadline applies to the MC and NMP rulemaking under the terms of TSCA section 26(l)(4). We urge EPA to finalize the MC and NMP rule in accordance with these comments within this timetable.[3]

Addressing MC and NMP in a single integrated rulemaking is plainly the best strategy to protect public health. These solvents are interchangeable for many applications. If EPA restricted one but not the other, many paint and coating users would simply shift to the unregulated solvent, replacing one set of health risks with another. Indeed, as EPA's proposal notes, NMP-based paint removers have gained sales at the expense of MC as a result of misleading marketing describing NMP as "green" or "bio-degradable" and implying that it is safer than MC. A rule highlighting the serious health impacts of both chemicals and subjecting them to a common set of restrictions on a parallel timeline would prevent marketplace deception and confusion, discourage unsafe substitutes and steer users to safer solvents.

We strongly believe that the only effective remedy for the health risks posed by MC and NMP is to ban their use for paint and coating removal. EPA's analysis demonstrates that only a ban will provide meaningful protection against these risks because the other remedies (labeling, respirators, product reformulation etc.) examined by the Agency will not achieve sufficient risk reduction under the law.

EPA is proposing a ban on the majority of paint and coating uses for MC but has deferred action on furniture refinishing. We support EPA's general approach but urge the Agency to extend its proposed ban to furniture refinishing uses, which the Agency has found present unreasonable risks and account for a sizable portion of worker and consumer exposure to MC during paint and coating removal.

EPA has proposed for comment two options for restricting NMP -- a ban on paint and coating removal use and a less protective alternative consisting of product reformulation, labeling and personal protective equipment (PPE). Compared to a ban, this less stringent option will provide smaller health benefits, cost more and create compliance and enforcement challenges. Because it will not eliminate NMP's unreasonable risks, it will also provide insufficient protection under LCSA. Equally important, by banning one solvent but allowing continued use of the other, EPA will send confusing messages to the marketplace about their comparative risks and undermine the case for moving to non-toxic solvent systems. Accordingly, EPA should reject the second option identified in its proposal and instead ban NMP for paint and coating removal.

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

We will show below in these comments that:

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

Together with its TCE rulemakings, EPA's MC and NMP proposal represents the first application of the new section 6 requirements since LCSA was enacted. Thus, the framework EPA establishes in these rulemakings will set an important precedent for future regulation of chemicals determined to present unreasonable risks of injury to health or the environment. We are pleased that the three proposals correctly interpret the language and intent of LCSA by recognizing 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.

- **MC USE IN PAINT AND COATING REMOVAL PRESENTS AN UNREASONABLE RISK**

The record amply supports EPA's determination that use of MC in paint and coating removal presents an "unreasonable risk of injury to health or the environment" requiring restriction under TSCA section 6(a):

- MC's adverse health effects are well documented and have been confirmed in multiple peer-reviewed studies.
- MC is known to cause asphyxiation from acute exposure and is responsible for 49 reported deaths (and probably many more that are unreported or attributed to other causes). Acute exposure can also cause neurological effects such as incapacitation, loss of consciousness, health failure and coma.
- MC is likely to be carcinogenic in humans with a mutagenic cause of action. Cancers attributed to MC include brain and liver cancer, non-Hodgkin lymphoma multiple myeloma and liver and lung tumors. MC also causes several non-cancer chronic effects, notably liver damage.
- According to EPA, roughly 32,000 workers and 1.3 million consumers breathe MC each year in largely uncontrolled settings during paint and coating removal.

- EPA has determined that MC's exposure levels within this large population are significant based on monitoring data and valid and peer-reviewed models for exposure estimation that are adequate and reliable for TSCA risk evaluations.
- The EPA-calculated Margins of Exposure (MOEs) for MC'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 MC 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 MC-exposed population is within a range (10^{-3} - 10^{-4}) that EPA and other authoritative bodies have historically deemed unacceptable and to warrant regulation.

➢ **A BAN ON MC USE IN PAINT AND COATING REMOVAL IS THE ONLY RESTRICTION UNDER SECTION 6(a) THAT WILL ADEQUATELY PROTECT AGAINST THE UNREASONABLE RISK**

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

- EPA correctly focused on options that could provide exposed workers with sufficient protection against MC-related non-cancer and cancer risks and further screened these options to determine whether they would in fact be effective and reliable in eliminating these risks.
- Applying these criteria, EPA rejected label warnings and instructions under TSCA section 6(a)(3) on the ground that they are not uniformly read, comprehended or followed and thus provide limited protection, particularly in small businesses with high employee turnover.
- EPA also evaluated whether continued MC use might be made safe by reducing the concentration of MC in formulations and/or by requiring local exhaust ventilation at MC-using facilities. However, it found that, after taking these measures, MC exposures remained too high – by orders of magnitude – "to achieve the target MOE benchmarks for non-cancer end-points for acute and chronic exposures and standard cancer risk benchmarks for chronic exposures."
- EPA also determined that, in conjunction with other measures, respirators could reduce MC 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 MC in paint and coating 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 MC-exposed workers.

- After applying all these considerations, EPA opted for banning manufacture, processing and distribution in commerce of MC for commercial and consumer use in paint and coating removal (other than furniture refinishing) and prohibiting commercial use of MC for these applications. It rejected less protective, reliable and implementable options, explaining that "non-cancer and cancer risks from this use of MC would be eliminated" under the proposed ban.

➢ **BECAUSE EPA HAS DETERMINED THAT MC USE FOR FURNITURE REFINISHING PRESENTS AN UNREASONABLE RISK, IT IS REQUIRED UNDER TSCA TO RESTRICT THESE USES**

- Although EPA concluded that the risks to workers during furniture refinishing are unreasonable, it did not propose any restrictions to address these risks in the belief that adequate MC substitutes in this use are unavailable.
- Even stipulating that EPA is correct, this consideration would not justify failure to take action to reduce the unreasonable risk presented by MC use in furniture refinishing under LCSA. A determination of unreasonable risk obligates EPA to propose and finalize a rule restricting the chemical under section 6(a). And under section 6(a), the rule must assure that the chemical no longer presents an unreasonable risk, a standard that does not allow for considering costs, substitutes or other economic factors in setting the level of protection.
- However, using section 6(d) of TSCA, EPA could set a firm target date for eliminating MC from furniture refinishing but allow a transition period of 5 years, providing breathing space to industry while at the same time setting in motion incentives and drivers for developing adequate substitutes. This approach – and not an open-ended delay in imposing any restrictions – is the correct course under LCSA.

➢ **NMP USE IN PAINT AND COATING REMOVAL ALSO PRESENTS AN UNREASONABLE RISK**

EPA also evaluated the risks presented by NMP use in paint and coating removal and likewise determined that these risks were "unreasonable" under TSCA and therefore required restriction under section 6. Again, the proposed rule and record provide strong evidence to support this determination:

- A broad set of relevant studies in multiple species demonstrate that acute and chronic maternal NMP exposure is associated with dose-dependent adverse developmental effects, including increased fetal and postnatal mortality, fetal body weight reductions and other effects on the mother and fetus. NMP has also exhibited reproductive effects and a variety of acute and chronic toxicity concerns.
- According to EPA, roughly 30,300 workers at 4300 commercial establishments and 732,000 million consumers -- including numerous women of childbearing age -- have inhalation and dermal exposure to NMP each year in largely uncontrolled settings during paint and coating removal.
- EPA has determined that NMP's exposure levels within this large population are significant based on monitoring data, literature estimates and valid and peer-reviewed models for exposure estimation that are adequate and reliable for TSCA risk evaluations.

- The EPA-calculated Margins of Exposure (MOEs) for NMP's developmental effects are well below the benchmark MOEs that the Agency has historically used to determine acceptable risk for these endpoints, confirming that NMP exposures are widely occurring at levels that are unsafe and unacceptable.
- Several groups at greater risk of NMP health effects – women of childbearing age, unborn fetuses and infants, and workers from Hispanic communities who make up a disproportionate portion of the paint removal workforce – fall within LCSA's definition of "potentially exposed or susceptible subpopulations" that require specific protection from unreasonable risks under the law.

➢ **EPA SHOULD IMPOSE A BAN ON NMP USE IN PAINT AND COATING REMOVAL AND REJECT THE ALTERNATIVE OF A REFORMULATION, LABELING AND PPE APPROACH**

- EPA's proposal seeks comment on two alternatives for mitigating NMP's unreasonable risks in paint and coating removal. *Option 1* is a "supply chain" approach that would effectively ban manufacture, processing, distribution and use of NMP for nearly all commercial and consumer paint and coating removal. *Option 2* would combine worker protection measures, product reformulation and labeling to achieve reductions in exposure but would allow continued use of NMP in in paint and coating subject to these restrictions.
- EPA has concluded that *Option 1* would "ensure that workers and consumers from the general population (as well as workers and consumers who are women of childbearing age) are no longer exposed to unreasonable risks from NMP exposure during paint and coating removal."
- In combination with a ban on MC use in paint and coating removal, *Option 1* would also send a clear and consistent message to the marketplace to move away from toxic solvents for this application and substitute non-toxic alternatives.
- The ability of *Option 2* to protect against unreasonable risks is contradicted by EPA's own strongly stated reservations about the effectiveness of two critical elements of this Option -- labeling and warnings (particularly for consumers) and respirators. EPA has consistently cited reliability and effectiveness of implementation as a key factor in whether a remedy will be fully protective yet Option 2 clearly fails to pass muster on this score under the Agency's own analysis.
- Not surprisingly in view of its greater complexity, EPA found that *Option 2* would impose implementation costs significantly in excess of those of *Option 1*. At the same time, because of the difficulty of implementation and enforcement and its limited effectiveness in reducing exposure, *Option 2*'s health benefits would be significantly lower than *Option 1*'s. Thus, when compared on a cost-benefit or cost-effectiveness basis, *Option 2* is inferior to *Option 1*, in addition to failing to provide full protection against the unreasonable risk as required by TSCA.
- For these reasons, the only correct course under the law would be a ban on NMP use in paint and coating removal, similar to the ban EPA is proposing for MC.

➢ **EPA'S ANALYSIS OF SUBSTITUTES AND INDEPENDENT ASSESSMENTS DEMONSTRATE THAT A WIDE RANGE OF EFFECTIVE, LOW HAZARD MC and NMP 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 MC and NMP in paint and coating removal. The EPA analysis and independent assessment demonstrate that a wide range of effective, economical and safer substitutes is available. This finding is not a prerequisite for a ban on MC and NMP use for paint and coating removals but it provides confidence that industry can transition away from these chemicals without undue disruption or hardship.

- **EPA NEEDS TO PROVIDE A STRONGER JUSTIFICATION FOR SECTION 6(g) EXEMPTIONS FOR MILITARY APPLICATIONS OF MC AND INCLUDE ADDITIONAL CONDITIONS TO ASSURE WORKER PROTECTION AND A RAPID TRANSITION TO SUBSTITUTE CHEMICALS**

  - Based on national security needs, EPA is proposing to grant exemptions under TSCA section 6(g) for the use of MC and NMP in paint and coating removal from mission-critical corrosion-sensitive components of military aviation and vessels.
  - While this exemption may be warranted, EPA's rationale and supporting documentation are extremely general and lack supporting data or other concrete information that would better identify the mission-critical components impacted and the basis for concluding that substitute chemicals fail to deliver the performance necessary to support the mission readiness of aircraft and vessels.
  - The proposed national security exemptions also lack conditions to maximize protection of public health and safety during exempt uses, as required by the statute. This is a glaring omission given the significant risks that these chemicals pose to workers in paint and coating removal applications. At a minimum, DOD and its contractors should be required to implement effective worker protection programs that provide meaningful warnings and labeling and require respirators and other protections against exposure at unsafe levels.
  - Another necessary "condition" to assure health protection that is lacking in EPA's proposal is an enforceable commitment by DOD to aggressively pursue R&D efforts and related testing to validate the acceptability of MC and NMP substitutes for the mission-critical uses covered by the proposed exemptions.

- **THERE IS NO BASIS FOR REFERRING RISKS RELATED TO MC AND NMP USE IN PAINT AND COATING 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 both workers and consumers are exposed to MC and NMP in paint and coating removal, EPA considered whether to refer the unreasonable risks presented by these uses to the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC) under section 9(a).
  - However, EPA properly decided against this course after comparing its authority to eliminate these risks to that of OSHA and CPSC, concluding that "with the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce" risks from these chemicals across the full spectrum of exposures.

- This was the correct conclusion since neither agency could readily justify a ban on paint and coating removal uses under the laws it applies, marshal the resources to regulate these uses any time soon, or implement a coordinated approach that would effectively address the interrelated risks of these chemicals to workers and consumers.

➢ **WHILE THE "GOOD SCIENCE" CONSIDERATIONS OF TSCA SECTION 26(h) ARE NOT APPLICABLE TO MC AND NMP RISK ASSESSMENTS, THE TWO ASSESSMENTS ARE IN COMPLIANCE WITH THESE CONSIDERATIONS**

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

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

EPA's MC and NMP proposal, together with its two TCE proposals, 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 three rulemakings is based is compelled by the wording and intent of LCSA and provides a strong foundation for future rules targeting unsafe chemicals.

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

These rules must be "consistent with the scope of the completed risk assessment and consistent with other applicable requirements of section 6." Thus, the MC/NMP proposal must conform to the requirements of section 6 except where they are inapplicable. [5]

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

[5] For example, because EPA is proceeding directly to rulemaking based on an existing risk assessment, the prioritization provisions of section 6(b)(1)-(2) are inapplicable. Similarly, since the risk assessment was completed before the new law took effect, the science "considerations' in section 26(h) and (i) would be inapplicable. To incorporate these considerations in the risk assessment would require reopening and revising it. Congress obviously did not intend this because it described carryover risk assessments as "completed" in section 26(l)(4).

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

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."[6]

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

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

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

Section 6(a) provides that, upon determining that a chemical presents an unreasonable risk, EPA must examine the list of permitted remedies and select the requirements it considers best to address the risk. In making this selection, EPA must restrict the chemical "to the extent necessary so that the chemical no longer presents such risk." This directive replaces a discredited requirement under the old law to impose the "least burdensome" restrictions. In addition, because Congress eliminated any risk-cost tradeoff in the definition of unreasonable risk, the adequacy of a remedy depends strictly on its effectiveness in eliminating the risk. EPA has no ability to compromise this level of protection based on economic

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Moreover, the "applicable" requirements EPA must comply with under this provision are those in section 6, not other portions of the law.

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

[7] Such extensions cannot exceed 2 years. Where the subject chemical is on EPA's Workplan List, as is the case for MC and NMP, 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."

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,

> EPA must ''factor in'' the considerations described in the statement ''to the extent practicable'' and ''in accordance with subsection (a).'' As revised, subsection (a) deletes the paralyzing ''least burdensome'' requirement in the existing law and instructs that EPA's rule must ensure that the chemical substance or mixture ''no longer presents''' the unreasonable risk identified in the risk evaluation. **Thus, it is clear that the considerations in the statement required under subparagraph (c)(2)(A) do not require EPA to demonstrate benefits outweigh costs, to definitively determine or select the least-cost alternative, or to select an option that is demonstrably cost-effective or is the least burdensome adequately protective option. Rather, it requires only that EPA take into account the specified considerations in deciding among restrictions to impose, which must be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified.** The Frank R. Lautenberg Chemical Safety for the 21st Century Act clearly rejects the regulatory approach and framework that led to the failed asbestos ban and phase-out rule of 1989 in Corrosion Proof Fittings v. EPA 947 F.2d 1201 (5th Cir. 1991).[8]

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

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

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

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

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

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

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

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 MC and NMP alternatives currently available for paint and coating removal. Water-based adhesives and cleaners can be substituted for many products that contain methylene chloride on NMP. Soy-based strippers, mechanical methods, and benzyl alcohol are safer substitutes for methylene chloride and NMP based strippers. Thus the absence of substitutes should not be a factor in choosing the best remedy under section 6(a) or a reason to delay the rule's effective date under section 6(d) (except for furniture refinishing uses as described below). If there are specific operations where adequate substitutes are not available, the appropriate response is to grant use exemptions under section 6(g).

II. MC USE IN PAINT AND COATING REMOVAL PRESENTS AN UNREASONABLE RISK

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

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

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

By any standard, MC use in paint and coating removal presents an unreasonable risk because of –

1) The serious, multiple adverse health effects attributed to MC and the strength of the scientific evidence documenting their occurrence;

2) The large size of the worker and consumer populations exposed to MC;

3) The largely uncontrolled nature of exposure and high projected exposure levels; and

4) The large calculated risks for these exposures, which significantly exceed established regulatory benchmarks for determining whether non-cancer and cancer risks are unacceptable.

A. MC Causes Serious Adverse Health Effects, Including Death and Severe Incapacitation from Acute Exposure, Multiple Types of Cancer, and Non-Cancer Chronic Effects

EPA's 2011 IRIS Assessment of MC, which underwent a comprehensive public comment and peer review process, provides a definitive analysis of the health effects linked to MC exposure.[10] In summary, acute inhalation exposure to MC can cause coughing, wheezing and/or shortness of breath. It can also lead to headache, mental confusion, nausea, vomiting, dizziness, fatigue and, at higher levels, asphyxiation leading to suffocation, loss of consciousness, coma and in some cases death. Non-fatal nervous system effects can be lasting and possibly permanent, causing impairment of normal functions and incapacitation. Skin exposure can lead to redness and irritation may occur if skin comes in contact with liquid MC and, if MC remains on the skin for an extended period of time, it may lead to skin burns. Contact with eyes can cause severe irritation and possibly chemical burns to the eyes. MC is classified by EPA as a probable human carcinogen based on evidence from animal studies of liver and lung cancer, and the Work Plan identifies it as likely to be carcinogenic in humans by a mutagenic mode of action (Section 3.3.1.2.1; EPA IRIS 2011).[11] Cancers attributed to MC include brain and liver cancer, non-

[10] SCHF is supportive of EPA's use of the IRIS Assessment (EPA 2011). The MC IRIS assessment followed the principles set forth by the various risk assessment guidelines issued by the National Research Council (NRC) and EPA. Primary, peer-reviewed literature identified through September 2011 was systematically reviewed and included where that literature was determined to be critical to the assessment. The IRIS chemical assessments are considered authoritative and are relied upon by governments and individuals around the world. The program was created in 1985 to foster consistency across EPA programs as well as other agencies at all levels of government. IRIS assessments are reasonably comprehensive and include health information on nervous system effects, organ toxicity, and developmental/reproductive effects. IRIS is the only federal program to provide toxicity values for both cancer and non-cancer effects. IRIS assessments themselves are not regulatory decisions or full risk assessments; they inform decisions under the Clean Air Act, Safe Drinking Water Act, Superfund, and TSCA. In addition to the tremendous scientific value of IRIS assessments, they are transparent in both process and outcome and are therefore considered a credible and reliable source of health hazard information by the public, regulators, researchers, and others (NAS 2014. Review of EPA's Integrated Risk Information System (IRIS) Process. GAO 2017. http://www.gao.gov/assets/690/682765.pdf). If it were not for pressure from the regulated industry, IRIS could complete chemical assessments at a more timely pace. See Sass J and Rosenberg D. 2011. *The Delay Game: How the Chemical Industry Ducks Regulation of the Most Toxic Substances.*
https://www.nrdc.org/sites/default/files/IrisDelayReport.pdf

[11] EPA 2011. Following U.S. EPA (2005a) Guidelines for Carcinogen Risk Assessment, MC is "likely to be carcinogenic in humans," based predominantly on evidence of carcinogenicity at two sites in 2-year bioassays in male and female B6C3F1 mice (liver and lung tumors) with inhalation exposure (NTP, 1986) and at one site in male B6C3F1 mice (liver tumors) with drinking water exposure (Serota et al., 1986b Hazleton Laboratories, 1983).
https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=70

Hodgkin lymphoma multiple myeloma and liver and lung tumors. Chronic exposure to MC also causes liver toxicity.

SCHF AND NRDC support EPA's inclusion of cancer, chronic and acute risks for occupational and consumer exposures in the final MC risk assessment (Sections 3.3.1.3 and 3.4.2.2, Table 3-11). Even with these improvements, EPA notes that there remain many serious data gaps in the overall hazard database (see uncertainty discussion in section 3.5.3), including a lack of data about developmental neurotoxicity, longer term exposures and resulting neurotoxicity and immunotoxicity.[12]

The severe nervous system effects from acute MC exposure have raised serious concerns. Based on data from OSHA, CPSC, state records, and publicly reported information, EPA has identified 49 fatalities since 1976 resulting from consumer or commercial worker exposure to MC during paint and coating removal.[13] Moreover, as EPA underscores, this is likely an underestimate of the deaths that have occurred:

> "In 2012, the Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (MMWR) published results of an investigation into deaths among bathtub refinishers using methylene chloride. The authors of the investigation and the MMWR editors emphasized that the reported number of deaths due to methylene chloride is an underestimate and subject to at least three limitations: A lack of reporting to the OSHA incident database by self-employed individuals, no equivalent database to track consumer incidents and fatalities, and the likelihood that deaths due to methylene chloride exposures are misattributed to heart disease, since the pathology is similar (Ref. 33). . . . For example, in several cases, workers were seen in hospital emergency rooms with symptoms of solvent exposure, were not properly diagnosed, and were sent back to the same work that ultimately killed them (Ref. 32)."[14]

As EPA describes in the preamble to its proposal, these deaths have involved both consumers and experienced workers. The circumstances have invariably been tragic and unexpected.[15] For example, CDC reported that, "In February 2012, a worker using a product containing methylene chloride to refinish a bathtub was found dead, slumped over a bathtub in an unventilated bathroom. In September 2011, a worker using a product containing methylene chloride to strip the glaze from a bathtub collapsed in the bathtub and later died."[16]

B. *Over 30,000 Workers and 1.3 Million Consumers Are Exposed to MC in Largely Uncontrolled Settings during Paint and Coating Removal*

MC's use in paint and coating removal products is long-standing. As described by EPA,[17] paint and coating removal (or "paint stripping") involves removing paint, varnish, lacquer, graffiti or other coatings

[12] While the IRIS MC assessment includes a 3x database uncertainty factor for the chronic noncancer RfC it was not included in the benchmark margin of exposures evaluated for chronic duration scenarios for workers. EPA notes that the MOE approach is endpoint specific, applied for a specific duration and not intended to be protective for other endpoints that have limited data. EPA response to comments for MC Work Plan Risk Assessment, p. 21
[13] 82 FR 7482.
[14] Id.
[15] 82 FR 7482-3.
[16] https://blogs.cdc.gov/niosh-science-blog/2013/02/04/bathtub-refinishing/
[17] 82 FR 7475

from surfaces, including the interior or exterior of buildings, vehicles, structures, boats, aircraft or other objects. These surfaces (or "substrates") can be wood, metals, plastics, concrete and fiberglass. Paint and coating removal occurs in a wide variety of commercial activities, such as building renovations and repairs, bathtub refinishing, automotive refinishing, furniture refinishing, art restoration and conservation, aircraft repair, marine craft repair, and graffiti removal. Use procedures vary across applications but typically MC is brushed onto the substrate and scraped off after curing for 20 or 30 minutes. Depending on the nature of the operation, MC can be applied by a hand-held brush, sprayed on the surface, or applied by pouring, rolling or wiping. Immersion methods such as tank dipping are also used. Larger operations may be automated; others are manual.

Consumer use of paint and coating removal products for a myriad of home improvement and other projects inside and outside residences is widespread. These products are in many cases identical to the products marketed for commercial use and are readily available at big box stores, local hardware stores and specialty paint retailers as well as through the Internet.[18] Products intended for one type of application are often used for others because of the interchangeability of function.

Unfortunately, residential uses of MC products involve many of the same exposure scenarios that characterize contractors and other workers using these products. Homes all over the country are being renovated, sometimes by homeowners with or without the help of small contractors. If they want to strip paint from the woodwork, they can readily buy paint stripper in the local hardware store which contains MC. The label says 'use only in a well-ventilated area', but this is hard to achieve for door molding, wainscoting, and other woodwork that cannot be removed. Recommendations to set up fans to ventilate work on beams of 12 foot ceilings, or to throw open windows on cold winter days, has limited practical effectiveness.[19]

EPA has identified 59 different paint and removal products, formulated by 10 firms, which contain MC. The Agency estimates that 32,600 workers are exposed annually to MC during paint and coating removal; slightly less than half of these workers (roughly 15,000) are engaged in furniture refinishing while other removal operations account for the remainder. According to the Agency, 4900 furniture refinishing facilities use MC-containing removers while 8600 facilities use these removers for other purposes. EPA projects that 1.3 million consumers are exposed to MC annually during paint and coating removal.[20]

C. EPA Has Determined That MC Exposure Levels are Significant as a Result of Paint and Coating Removal Based on Monitoring Data, Literature Estimates and Valid and Peer Reviewed Exposure Models That are Adequate and Reliable for TSCA Risk Evaluation Purposes

To evaluate MC exposure levels for paint and coating removal operations, EPA modeled numerous acute and chronic exposure scenarios for a wide range of uses.[21] For acute risks, EPA assessed four different

[18] Id.

[19] Markowitz, S. 2017. Docket ID: EPA-HQ-OPPT-2016-0736-0061

[20] 82 FR 7475-6.

[21] 82 FR 7477.

occupational scenarios under current use conditions plus scenarios reflecting various risk reduction options. The current use scenarios assumed parameters similar to typical use conditions within the affected industries, including such variables as whether work was conducted indoors or outdoors and the percent of MC in the formulation used. For chronic exposures, EPA modeled not only these variations but also differences in the number of working days with MC exposure each year and exposed working years. Overall, 16 occupational scenarios for chronic exposure were modeled. This comprehensive and methodical approach can hardly be considered only a "screening assessment", as many in industry have charged.

EPA based its workplace exposure assessment on air monitoring data from peer-reviewed literature sources that directly measured air concentrations of MC resulting from paint stripping activities.[22] These data provided a robust basis for analysis and showed significant MC concentrations, often well above the MC OSHA standard:

> "Many air concentrations reported and used in the risk assessment exceeded the current OSHA PEL of 25 ppm; in some industries where paint and coating removal was conducted by immersion in tanks or vats of methylene chloride, air concentrations were measured at above 7,000 milligrams per cubic meter, or 2,016 ppm. Even in industries with lower expected exposures, air concentrations frequently were reported in excess of 250 milligrams per cubic meter, or 72 ppm, such as during graffiti removal and automotive refinishing (Ref. 2)."[23]

Even these "dramatically high air concentrations" (in EPA's words) may not fully capture the extent of exposure. Measured or modeled workplace exposure levels may fail to capture many of the routine events that magnify both exposures and risks. As Dr. Steven Markowitz, occupational medicine physician for over 30 years and a Professor at the City University of New York, emphasized in his comments to EPA during its public meeting (Feb 14, 2017), workers often work with more than one chemical product, and even perform multiple task at a time, particularly when under time pressures, and sometimes with inadequate tools and insufficient ventilation. [24] In addition, even when a worker is focused on a single task and/or working with a single chemical product, s/he is likely to be in close proximity to other workers performing the same tasks, adding to the single chemical exposure level, or different tasks creating a mixture of toxic chemical exposures. Workers don't begin each new day with new clean clothing or shoes in a new clean work site, so yesterday's solvent vapors add to the next day's exposures. This is relevant for solvents like MC that don't wash out of leather, which is a common material for work boots and work gloves.[25] Dr. Markowitz notes in his comments to EPA that, "My experience in touring manufacturing facilities and interviewing workers provides another window on this problem. Leaks, spills, and equipment malfunction are commonplace in chemical plants. Onsite maintenance tasks occur away from the shop and therefore, by their nature, take place under uncontrolled or less controlled circumstances." [26]

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[22] See comments submitted to this docket by Dr. Adam Finkel regarding how these data are likely to underestimate true risk across the industry and between worker populations, leaving many more workers at risk of unsafe exposures to methylene chloride.

[23] 82 FR 7477.

[24] Markowitz, S. 2017. Docket ID: EPA-HQ-OPPT-2016-0736-0061

[25] NJ Health 2017. Fact Sheet on methylene chloride. http://nj.gov/health/eoh/rtkweb/documents/fs/1255.pdf

[26] NJ Health 2017. Fact Sheet on methylene chloride. http://nj.gov/health/eoh/rtkweb/documents/fs/1255.pdf

For its consumer exposure assessment, EPA developed seven exposure scenarios reflecting such factors as the type of homeowner project, the method of applying the paint and coating remover, the indoor or outdoor location where the project occurred, the house volume and air exchange rate and the duration of exposure. Since EPA lacked representative air monitoring data for consumer exposures, it used the peer-reviewed Multi-Chamber Concentration Exposure Model (MCCEM), for which EPA provides publicly available information. [27] Use of this approach was possible because the Agency had access to chamber test emission data such as input emission rates and decay rates to fit this higher tier model.[28]

EPA's exposure assessment had additional strengths that enhanced its credibility. Both occupational and consumer exposure scenarios included central-tendency and upper-end input parameters and assumptions, to capture the range of average and presumably upper-end exposure levels. [29] The PBPK modeling used to derive acute and chronic hazard values for cancer and non-cancer effects used in the assessment was publicly reviewed as part of the IRIS assessment.

In summary, EPA has employed sophisticated measuring and modeling approaches to incorporate real-world emissions data as well as modeled exposure estimates using high-tiered peer-reviewed publicly available models to estimate exposures under several realistic scenarios.

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 on MC's hazards from EPA's IRIS review and estimations of worker and consumer exposure as described above. As used in the MC 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 MC, 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.

Chronic Exposure Risks. A few examples of EPA's MOE comparisons for chronic exposures demonstrate that for a large majority of exposure scenarios, most workers using MC-based paint strippers were at unacceptable risks for adverse liver effects. Risk concerns for liver effects were reported for most workers handling MC-based paint strippers, with or without respiratory protection. Among all of the occupational scenarios, the greatest risk concern was for workers engaging in long-term use of the product (i.e., 250 days/year for 40 years) with no respiratory protection.

For **Professional Contractors**, ALL chronic exposure scenarios are unsafe (see Table 3-27 below), with some exceeding the benchmark level by 400-times (see Scenario 1):

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[27] Multi- Chamber Concentration and Exposure Model (MCCEM) version 1.2. https://www.epa.gov/tsca-screening-tools/multi-chamber-concentration-and-exposure-model-mccem-version-12

[28] Note: Emissions data were not available for MC so EPA used E-FAST2/CEM models in the MC consumer exposure model, as these models do not require emission data)

[29] See comments submitted to this docket by Dr. Adam Finkel regarding how these data are likely to underestimate true risk across the industry and between worker populations, leaving many more workers at risk of unsafe exposures to methylene chloride.

Table 3 27. Occupational Non Cancer Risks for Professional Contractors Following Chronic Exposure to DCM (Scenarios 1, 3, 15 and 16)

	Professional Contractors	ADC (mg/m^3) ** ADCs for scenarios 2 to 16 have been adjusted with the multiplier			Chronic MOE (24hr HEC_{99} = 17.2 mg/m^3) Total UF or Benchmark MOE=10		
		High	Midpoint	Low	High	Midpoint	Low
Highest Exposure	Scenario 1 [No respirator, high ends of ranges for exposure frequency (EF) and working years (WY)]	680	347	14	**0.025**	**0.050**	**1**
	Scenario 3 (Respirator APF 25, high ends of ranges for EF and WY)	27	14	1	**1**	**1**	31
	Scenario 15 (Respirator APF 25, midpoints of ranges for EF and WY)	7	3	0.1	**3**	**5**	123
Lowest Exposure	Scenario 16 (Respirator APF 50, midpoints of ranges for EF and WY)	3	2	0.1	**5**	10	246

Note: MOEs below benchmark MOE indicating risk are denoted in bold text.

For **Furniture Refinishers**, most chronic exposure scenarios are unsafe (see Table 3-29 below), with some exceeding the benchmark level by 333-times:

Note: MOEs below benchmark MOE indicating risk are denoted in bold text.

Table 3 29. Occupational Non Cancer Risks for Furniture Refinishing Following Chronic Exposure to DCM (Scenarios 1, 3, 15 and 16)

	Furniture Refinishing	ADC (mg/m^3) ** ADCs for scenarios 2 to 16 have been adjusted with the multiplier				Chronic MOE (24hr HEC_{99} = 17.2 mg/m^3) Total UF or Benchmark MOE=10			
		Mean	High	Midpoint	Low	Mean	High	Midpoint	Low
Highest Exposure	Scenario 1 [No respirator, high ends of ranges for exposure frequency (EF) and working years (WY)]	114	513	257	0.9	**0.2**	**0.03**	**0.1**	19
	Scenario 3 (Respirator APF 25, high ends of ranges for EF and WY)	5	21	10	0.04	**4**	**0.8**	**2**	478
	Scenario 15 (Respirator APF 25, midpoints of ranges for EF and WY)	1	5	3	0.01	15	**3**	**7**	1911
Lowest Exposure	Scenario 16 (Respirator APF 50, midpoints of ranges for EF and WY)	0.6	3	1	0.005	30	**7**	13	3822

For **Aircraft Strippers**, most chronic exposure scenarios are unsafe (see Table 3-31 below), with some exceeding the benchmark level by 500-times:

Note: MOEs below benchmark MOE indicating risk are denoted in bold text.

Table 3 31. Occupational Non Cancer Risks for Aircraft Stripping Following Chronic Exposure to DCM (Scenarios 1, 3, 15 and 16)

	Aircraft Paint Stripping	ADC (mg/m^3) ** ADCs for scenarios 2 to 16 have been adjusted with the multiplier			Chronic MOE (24hr HEC_{99} = 17.2 mg/m^3) Total UF or Benchmark MOE=10		
		High	Midpoint	Low	High	Midpoint	Low
Highest Exposure ↑	Scenario 1 [No respirator, high ends of ranges for exposure frequency (EF) and working years (WY)]	868	444	20	**0.02**	**0.04**	**0.9**
	Scenario 3 (Respirator APF 25, high ends of ranges for EF and WY)	35	18	1	**0.5**	**1**	22
	Scenario 15 (Respirator APF 25, midpoints of ranges for EF and WY)	9	4	0.2	**2**	**4**	86
↓ Lowest Exposure	Scenario 16 (Respirator APF 50, midpoints of ranges for EF and WY)	4	2	0.1	**4**	**8**	172

For **Immersion Stripping of Wood**, all medium and high exposure chronic scenarios are unsafe (see Table 3-33 below), with some exceeding the benchmark by 1000-times:

Note: MOEs below benchmark MOE indicating risk are denoted in bold text.

Table 3 33. Occupational Non Cancer Risks for Non Specific Workplace Settings (Immersion Stripping of Wood) Following Chronic Exposure to DCM (Scenarios 1, 3, 15 and 16)

	Non-Specific Workplace Settings - Immersion Stripping of Wood	ADC (mg/m^3) ** ADCs for scenarios 2 to 16 have been adjusted with the multiplier			Chronic MOE (24hr HEC_{99} = 17.2 mg/m^3) Total UF or Benchmark MOE=10		
		High	Midpoint	Low	High	Midpoint	Low
Highest Exposure ↑	Scenario 1 [No respirator, high ends of ranges for exposure frequency (EF) and working years (WY)]	1,598	803	8	**0.01**	**0.02**	**2**
	Scenario 3 (Respirator APF 25, high ends of ranges for EF and WY)	64	32	0.3	**0.3**	**0.5**	54
	Scenario 15 (Respirator APF 25, midpoints of ranges for EF and WY)	16	8	0.08	**1**	**2**	215
Lowest Exposure ↓	Scenario 16 (Respirator APF 50, midpoints of ranges for EF and WY)	8	4	0.04	**2**	**4**	430

EPA notes that non-cancer risks were not observed for workers that reduce their exposure to DCM-based strippers by taking **all** of the following precautions: (1) wearing adequate respiratory protection (i.e., APF 50 respirator), (2) limiting exposure to central tendency exposure conditions (i.e., 125 days/year for 20 years) and (3) working in facilities with low-end MC air concentrations. It is unlikely that all of the conditions are present today in the great majority of workplaces. Indeed, even with requirements to implement these measures, they are unlikely to provide reliable and sufficient protection for reasons detailed in EPA's proposed rule, elsewhere in these comments, and in comments submitted to this docket by Dr. Adam Finkel and others.

Acute Exposure Risks. EPA similarly concluded that MOEs for acute exposure risks for central nervous system effects were below the benchmark MOE for nearly all the occupational exposure scenarios, irrespective of the absence or presence of respirators and in both the central-tendency and worst-case assumed air concentrations. As the Agency elaborated:[30]

> "EPA found acute risks for incapacitating central nervous system effects for workers who had no respiratory protection in most industries, or with respirators with APFs of 10 or 25 in the industries with highest likely exposures, such as professional contractors, aircraft refinishers, and workers using immersion methods for paint and coating removal in several industries. MOEs for acute risks ranged from an average of 0.11 (automotive refinishing) to 0.037 (graffiti removal), with a lowest end of 0.0063 (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels

[30] 82 FR 7478.

between 100 times to greater than 1,000 times more than those that are of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects (Ref. 2)."

Consumer Acute Risks. EPA also found that MOEs for acute risks from consumer exposures to MC were below the MOE benchmark. As it described its findings:[31]

> "For consumers, EPA identified risks of concern for all scenarios, with some consumer scenarios demonstrating risks within the first hour of product use when paint and coating removal was conducted indoors (such as in a workshop or bathroom), regardless of whether the product formulation was brush or spray. Risks for incapacitating nervous system effects were found in some indoor scenarios (such as in a bathroom) within four hours of product use. MOEs for consumer acute risks from exposures of one hour or less ranged from 1.6 to 0.2; this equates to estimated exposures that are between six and 50 times greater than those that are expected to produce no risks of concern (Ref. 2)."

Even residential bystanders had unacceptable risks:

> "For residential bystanders, EPA identified risks of concern for all scenarios, even assuming that any bystander in the house was not in the room where the paint and coating removal occurred. Depending on the parameters of the scenario, MOEs for acute risks ranged from 2.9 to 0.5, or between three and 20 times greater than those that are expected to produce no risks of concern (Ref. 2)."

Based on these findings, EPA determined that acute and chronic occupational and consumer exposure to MC during paint and coating removal presents an unreasonable risk of injury.

E. EPA Estimated Cancer Risks are in a Range (10^{-3} - 10^{-4}) Above the Risk Levels That EPA and other Authoritative Bodies Have Historically Considered Acceptable

As emphasized and detailed in comments to this docket by Dr. Adam Finkel, following the 1980 Supreme Court benzene decision,[32] OSHA has defined defines "insignificant risk" as falling between 10-3 and 10-9 (that is, 1 in 1000 to 1 in 1 billion excess risk over a working lifetime), but has predominantly used the least protective end of this range (10-3 to 10-5), whereas EPA tends to set exposure limits in the more health-protective range of about 10-4 to 10-6 (1 in 10,000 to 1 in 1 million), by custom and by explicit statutory instruction. [33] Unfortunately, EPA's estimated risks for paint and coating removal exposure for MC significantly exceed the benchmarks EPA has historically used to define unacceptable risks for cancer end-points**.**

In EPA's assessment, occupational exposure scenarios assumed that the exposure frequency (i.e., the number of days per year workers or bystanders are exposed to MC) was either 125 or 250 days per year for an occupational exposure duration of 20 or 40 years over a 70-yr lifespan. This is likely an underestimate, since many skilled blue-collar workers tend to work with the same or similar skill set

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[31] Id.

[32] *Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607 (1980),

[33] See comments submitted to this docket by Dr. Adam Finkel regarding how these data are likely to underestimate true risk across the industry and between worker populations, leaving many more workers at risk of unsafe exposures to methylene chloride.

over a working lifetime, so that even if they change jobs they don't change the job description dramatically, and therefore are likely to continue using similar high-risk products doing similar tasks over many decades. In other words, an industrial welder or machinist may change job sites every few months and employers every few years, but she is likely to perform similar tasks with similar chemical exposures in all cases.

EPA's assessment determined that workers showed excess cancer risks for all of the industries evaluated when working with MC-based paint strippers for 250 days/year for 40 years with no respiratory protection (Scenario 1). For many occupations, even with respirators (Scenario 2), the high-end ranges for exposure frequency and working years resulted in excess risks.[34] More specifically:

- Occupational Cancer Risks For Professional Contractors (Table 3-18)
    - Scenario 1, (no respirator, high ends of ranges for exposure frequency [EF] and working years [WY]) resulted in a high end calculated excess cancer risk of **3,900 per 1 million** (3.9E-03)
    - Scenario 3, respirator APF 25, high ends of ranges for EF and WY resulted in a high end calculated excess cancer risk of **160 per 1 million** (1.6E-04)
- Occupational Cancer Risks for Furniture Refinishing (Table 3-20)
    - Scenario 1 resulted in a calculated high end excess cancer risk of **2,900 per 1 million** (2.9E-03)
- Occupational Cancer Risks for Aircraft Stripping (Table 3-21)
    - Scenario 1 resulted in a calculated high end excess cancer risk of **5,000 per 1 million** (5.0E-03)
    - Scenario 3 resulted in a calculated high end excess cancer risk of **200 per 1 million** (2.0E-04)
- Occupational Cancer Risks for Graffiti Removal (Table 3-22)
    - Scenario 1 resulted in a calculated high end excess cancer risk of **1,600 per 1 million** (1.6E-03) and an average excess cancer risk of **340 per 1 million** (3.4E-04)
- Occupational Cancer Risks for Non-Specific Workplace Settings Immersion Stripping of Wood
    - Scenario 1 resulted in a calculated high end excess cancer risk of **9,000 per 1 million** (9.1E-03) and an average excess cancer risk of **4,600 per 1 million** (4.6E-03)
    - Scenario 3 resulted in a calculated high end excess cancer risk of **370 per 1 million** (3.7E-04) and an average excess cancer risk of **180 per 1 million** (1.8E-04)
- Occupational Cancer Risks for Non-Specific Workplace Settings; Immersion Stripping of Wood and Metal (Table 3-24)
    - Scenario 1 resulted in a calculated high end excess cancer risk of **1,300 per 1 million** (1.3E-03) and an average excess cancer risk of **1,100 per 1 million** (1.1E-03)

These risks fall within the range that EPA has historically deemed unacceptable and, therefore, the Agency concluded that MC poses an unreasonable risk of cancer.

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

Only inhalation exposure was considered in EPA's risk assessment, and no information was provided regarding dermal exposure or potential absorption. EPA acknowledges that its assessment likely underestimates risks by failing to include dermal exposures (Sections 1.3.2 and 3.5.1), noting that there

[34] The Excess Cancer Risk is calculated using an Inhalation Unit Risk factor of $1x10^{-5}$ per mg/m3

is no PBPK model for use with MC that includes a dermal component, and very little information to inform this route of exposure. While the data gaps are unfortunate, and are apparently unavoidable at this time, EPA's assessment of inhalation risks is sound and scientifically defensible, has been peer reviewed, and represents the best available science. In light of the clear threats to human health and the lack of information on dermal exposure, the MC Work Plan Risk Assessment may underestimate risks, but is robust enough for TSCA regulatory purposes.

G. *The Risks to Vulnerable Populations from MC Use in Paint and Coating Removal Are Real and Well-Defined and Require Special Protection under TSCA*

TSCA requires that EPA must protect "potentially exposed or susceptible subpopulations" from unreasonable risks. Several such subpopulations are at increased risk from exposure to MC from paint and coating removal products.

For example, the use of MC in these products generates hazardous waste and toxic releases of MC into the air, which can contribute to elevated exposures and ill health in communities. This exposure pathway may have disproportionate impacts on women, children, older adults, environmental justice communities and fenceline communities.

Easily inhaled, MC converts to carbon monoxide once inside the body—making it especially dangerous for people with heart or lung disease who are more vulnerable to being oxygen deprived. [35] [36] Thus, individuals with pre-existing heart or lung conditions should be considered a population of special concern under TSCA, due to their unique sensitivity to methylene chloride poisoning. By the same means, MC is also especially dangerous for pregnant women since it will rob the fetus of oxygen. MC can also directly reach the developing fetus through the placenta, and can contaminate the breast milk of nursing mothers. [37] [38]

Another impacted vulnerable subpopulation is children who are bystanders to the residential use of paint and coating removal products. While these children may often be excluded from the immediate area of paint stripper projects, they may remain in the house during this activity and frequent the site of paint remover use in the following hours. Accordingly, as EPA has found, children in homes where family members or professionals are conducting paint and coating removal "face acute risks of central nervous system impacts", which are likely magnified because of their underdeveloped nervous systems.[39]

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[35] https://www.atsdr.cdc.gov/mmg/mmg.asp?id=230&tid=42

[36] NIOSH's original recommendation concerning exposure to methylene chloride was based, in part, on findings of impaired delivery of oxygen to tissues (Ott et al 1983). At that time, NIOSH described methylene chloride-exposed workers who experienced chest pains, heart palpitations, and rapid pulse. The report of excess mortality from ischemic heart disease in one methylene chloride-exposed cohort consistent with earlier findings reported by NIOSH. Citation: Ott MG, Skory LK, Holder BB, Bronson JM, Williams PR. Health evaluation of employees occupationally exposed to methylene chloride--mortality. Scand J Work Environ Health 1983;9(Suppl 1):8-16. Available at: https://www.cdc.gov/niosh/docs/86-114/

[37] https://www.atsdr.cdc.gov/mmg/mmg.asp?id=230&tid=42

[38] In women occupationally exposed to an average methylene chloride concentration of 86 mg/cu m, the compound was found in the placenta, fetus, and breast milk (0.07 mg/L milk average). [WHO; Environmental Health Criteria 32: Methylene chloride p. 37 (1984)] . Available at https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+66

[39] 82 FR 7476.

Finally, EPA has noted that "Hispanic and foreign-born workers, who may have limited English proficiency, are disproportionately represented in construction trades" where MC is used for paint and coating removal and thus are "disproportionately at risk" to MC's adverse effects.[40]

Overall, evidence from both laboratory studies and human incident reports demonstrates that MC poses serious acute risks of death and incapacitation, is a likely human carcinogen at multiple sites, and causes chronic toxicity to the liver. 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. As a result, EPA has correctly determined that MC use for paint and coating removal presents an unreasonable risk requiring risk management under TSCA section 6(a). We strongly support this conclusion.

III. EPA'S ANALYSIS DEMONSTRATES THAT A BAN ON MC USE IN PAINT AND COATING REMOVAL IS THE ONLY RESTRICTION UNDER SECTION 6(a) THAT WILL ADEQUATELY PROTECT AGAINST THE UNREASONABLE RISK

After determining that MC use in paint and coating removal presents an unreasonable risk of injury, EPA's next task was to examine the list of authorized restrictions in section 6(a) and select requirements that would assure that the chemical "no longer presents such risk." The result of this analysis was a conclusion that a ban on the majority of MC paint and coating removal 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. However, we believe that EPA should have also banned MC use in furniture refinishing, as discussed in Part IV below.

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 strategies by examining a wide range of regulatory options under section 6(a) and then evaluating whether they could reduce risks (non-cancer and cancer) to levels below those of concern, based on EPA's technical analysis of exposure scenarios. This evaluation was necessary in order that EPA's rule "would address the identified unreasonable risks so that the chemical no longer presents such risks.[41] By screening out options that could not eliminate the unreasonable risk, EPA was then able to focus on a smaller set of options that could potentially achieve the benchmark MOE (or "safe" level of exposure) for the most sensitive non-cancer endpoint, thereby reducing cancer risk to acceptable levels as well.

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

[40] 82 FR 7485.
[41] 82 FR 7472.

> "After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered **how reliably the regulatory options would actually reach these benchmarks**. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In evaluating whether a regulatory option would ensure that the chemical substance no longer presents the identified unreasonable risk . . . **the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks**, as well as whether the option's protectiveness was impacted by environmental justice, children's health, and potentially exposed or susceptible subpopulations relevant to the Agency's risk evaluation."[42]

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 unavoidably to the conclusion that only a ban on MC use in paint and coating removal – and not other remedies such as labeling, product reformulation, engineering controls or respirators – would provide adequate protection and could pass scrutiny under the law.

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

EPA rejected label warnings and instructions under TSCA section 6(a)(3) on the ground that they are not uniformly read, comprehended or followed and thus provide limited protection, particularly to consumers. This was not a mere opinion on EPA's part but resulted from an examination of nearly fifty studies.[43] Based on this review, EPA's conclusions were as follows:

> "Another option EPA evaluated would require warning labels and instructions on paint and coating removal products containing methylene chloride, pursuant to TSCA section 6(a)(3) (Ref. 28). However, EPA reasoned that warning labels and instructions alone could not significantly mitigate the unreasonable risks presented by methylene chloride in paint and coating removal. EPA based its reasoning on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies (Ref. 28). Additionally, workers being exposed may

[42] 82 FR 7472-3 (emphasis added).

[43] OPPT summarized these studies in a paper entitled *The Effectiveness of Labeling on Hazardous Chemicals and Other Products* (March 2016)(Ref. 28 in rulemaking docket).

not be in a position to influence their employer's decisions about the type of paint removal method, or ensure that their employer provides appropriate PPE and an adequate respiratory protection program.

These conclusions are based on the weight-of-evidence analysis that EPA conducted of the available literature on the efficacy of labeling and warnings. This analysis indicates that a label's effectiveness at changing user behavior to comply with instructions and warnings depends on the attributes of the label and the user, and how those interact during multiple human information processing stages, including attention, comprehension, judgement, and action (Ref. 28)." [44]

For MC used in paint removal products, EPA concluded that compliance with label warnings and instructions would be unusually challenging because of the complexity of the information conveyed:

"Presenting information about methylene chloride on a product label would not adequately address the unreasonable risk presented by this use of this chemical because the nature of the information the user would need to read, understand, and act upon is extremely complex. When the precaution or information is simple or uncomplicated (*e.g.,* do not mix this cleaner with bleach or do not mix this cleaner with ammonia), it is more likely the user will successfully understand and follow the direction. In contrast, it 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 methylene chloride. 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 effects to bystanders. Currently, though some paint removers containing methylene chloride are labeled with information about its fatal effects if used without "adequate ventilation" (Ref. 28) and this information appears on the product safety data sheet, deaths continue to occur. It is unlikely that label language changes for this use of methylene chloride will result in widespread, consistent, and successful adoption of risk reduction measures by users."[45]

It is doubtful that enhanced labeling and use instructions – an approach proposed by industry -- would overcome these problems in light of the nature of the MC-exposed population relevant to this rulemaking. Many paint removal operations subject to the proposal are small shops that lack effective worker training and hazard communication programs.[46] 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).[47] And occupational bystanders – a group at serious risk from these MC uses – may not even come into contact with product labels because they are not using the products directly. For the

[44] 82 FR at 7473-4. .

[45] 82 FR 7474. (emphasis added)

[46] EPA requests comment on the merits of requiring a training and certification program for commercial paint and coating removers, an option recommended by small business representatives participating in the Small Business Advocacy Review (SBAR) panel convened by the Agency. The Agency did not favor this option because "the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products [are] a significant limitation for this approach." Id. We agree with this conclusion.

[47] According to EPA, foreign born workers are more than twice as prevalent in the construction trades as in the population at large and likely have limited English proficiency. Id.

large population of consumers engaged in paint removal, the challenges are even greater. Professional oversight of use conditions will be lacking and experience and sophistication in handling toxic chemicals will be extremely limited. And current labeling is not only incomplete in many cases but actually creates a false sense of security by describing MC-containing products as "easy to use" and suitable for a wide variety of applications.

C. The Agency Properly Determined that Reducing MC Concentrations in Products and/or Improving Ventilation Would not Achieve the Risk Reduction Targets

EPA also evaluated whether continued MC use for paint and coating removal might be made safe by reducing the concentration of MC in formulations and/or by requiring local exhaust ventilation. To examine these options, it recalculated projected TCE exposure levels to reflect the reductions in exposure they would achieve. Even with these reductions, it found that, absent concurrent use of respirators, the options "could not achieve the target MOE benchmarks . . . for non-cancer endpoints for acute and chronic exposures and common cancer risk benchmarks for chronic exposure." [48]

D. While Concluding that Respirators Could Potentially Reduce the Risk for Commercial Uses, EPA Found that This Option Had Significant Drawbacks and was Not Adequately Protective

EPA also considered whether the unreasonable risk presented by commercial pain and coating removal could be adequately addressed through a respiratory protection program. This program would include air monitoring, medical monitoring, dermal and eye protection and respiratory protection through use of a supplied-air respirator with an APF of 1000 or 10,000. Alternatively, users could meet a performance-based air exposure limit of 1 part per million (ppm) through measures of their choosing, which might include engineering controls or improved ventilation, alone or in combination with an air-supplied respirator at a lower APF.[49] EPA concluded that either set of measures "would, in all scenarios evaluated, control the exposure of methylene chloride to levels that allow for meeting the benchmarks for non-cancer and cancer risks."[50]

Nonetheless, EPA decided against this set of options because, while theoretically protective, they would not in fact achieve sufficient risk reduction in light of considerations of reliability, feasibility and cost.

First, EPA pointed out that "there are many limitations to successful implementation of respirators with an APF of 1000 or 10,000" (the pressure level required for adequate reduction in MC exposure levels.) EPA summarized these well-known problems as follows:[51]

> "[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. Individuals with facial hair, like beards or sideburns that interfere with the face-to-respirator seal, cannot wear tight fitting

[48] 82 FR at 7479.
[49] All respirators used would need to be supplied air since MC can clog or damage filters or cartridges for air-purifying respirators.
[50] 82 FR 7481.
[51] 882 FR 7445

respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'"

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

We strongly concur that the impediments to an effective respirator program limit the ability of respirators to provide consistent, reliable protection against exposure in practice. It is for this very reason that, under the well-established "hierarchy of controls" applied by OSHA and the industrial hygiene community, respirators are the least preferred workplace protection strategy, to be implemented only if more effective measures like chemical substitution, engineering controls or work practices are not feasible. In this case, substitution of other solvents for MC in paint and coating removal **is** a feasible remedy for many uses and, based on long-standing OSHA policies, should be presumed to be more protective than respirators or other personal protective equipment for these applications. Indeed, OSHA guidance for MC warns that, "*where engineering controls and work practices do not reduce MC exposures to an acceptable level, workers must wear supplied-air respirators. Respirators are the least preferred method for controlling employee exposure….CAUTION: Filter cartridge respirators cannot be used because MC can pass through available cartridges leaving respirator wearers unprotected*."[52]

Another downside to a respirator requirement – further limiting how much protection it would provide in practice -- is the difficulty of achieving compliance by the small establishments where much MC use for paint and coating removal 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 automotive refinishing shop or a home renovation contractor, who 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 necessarily provide protection to occupational bystanders, leaving them at unacceptable risk.

EPA also concluded that the costs of compliant respirator programs for commercial paint and coating removal operations would be substantial, totaling between $13.775 million and $26.706 million annualized. These costs would exceed the outlays required to replace MC with other solvents and thus

[52] OSHA. https://www.osha.gov/SLTC/methylenechloride/factsheets/mcfsno7.html

EPA "anticipates that companies would choose to switch to substitute chemicals instead of adopting a program for PPE."[53]

Finally, EPA emphasized that a respirator program could only apply to commercial MC use and would not address risks to consumer users of paint and coating removal products. It noted that "EPA does not have the authority to require that consumers change use practices and wear PPE" and that the impracticality and expense of using air-supplied respirators in the home setting would make any such requirement ineffective.[54] Standing alone, it concluded, a ban on consumer paint and coating removal products would not be sufficient to address consumer risks "because they foreseeably would continue to buy and use paint and coating removal products containing [MC] intended for commercial users."[55] Given the extensive evidence of the availability to consumers of commercial products at large retail chains and over the Internet, this expectation is well-founded and provides another reason why respirator programs that allow continued sale of MC-containing products to the public would not be effective in eliminating the unreasonable risk.

E. *EPA Correctly Decided that a Ban on MC Use in Paint and Coating Removal was Necessary to Meet its Obligations under TSCA Section 6(a)*

After applying all these considerations, EPA opted for banning manufacture, processing and distribution in commerce of MC for commercial and consumer use in paint and coating removal (other than furniture refinishing) and prohibiting commercial use of MC for these applications. It rejected less protective, reliable and implementable options, explaining that "non-cancer and cancer risks from this use of MC would be eliminated" under the proposed ban. EPA elaborated that:

> "The proposed approach would reduce the risks to workers, consumers, and bystanders from methylene chloride in paint and coating removal for the uses proposed for regulation so that those risks are no longer unreasonable. Prohibiting the manufacturing, processing and distribution in commerce of methylene chloride for paint and coating removal for the uses proposed for regulation would minimize the overall availability of methylene chloride for paint and coating removal for these uses. Importantly, this proposed regulation is protective of consumer users. EPA cannot regulate consumer use under TSCA section 6(a)(5). The prohibition of the commercial use of methylene chloride for paint and coating removal in the uses proposed for regulation would reduce commercial demand for methylene chloride paint and coating removal products, reduce the likelihood that other types of products formulated with methylene chloride would be used for paint and coating removal, and significantly reduce the potential for consumer use of commercial paint and coating removal products containing methylene chloride."[56]

Although EPA lacked statutory authority to prohibit consumer use of MC directly, it concluded that the comprehensive approach it was proposing would minimize consumer risks more effectively than narrower restrictions targeted at either commercial or consumer uses alone because the volume of MC-

[53] 82 FR 7487
[54] 82 FR 7482
[55] 82 FR7482.
[56] 82 FR 7480.

containing products in commerce and hence available to consumers would be greatly reduced.[57] To further limit off-label consumer use of MC, EPA's proposal includes a downstream notification requirement to make retailers and distributors aware of the MC use prohibitions. It also would require any remaining MC-containing paint and coating removal products to be distributed in volumes no smaller than 55-gallon containers, discouraging diversion of these products into consumer channels. We believe these comprehensive and complementary requirements are essential to address unreasonable risks to consumers and workers and should be included in EPA's final rule.

IV. BECAUSE EPA HAS DETERMINED THAT MC USE FOR FURNITURE REFINISHING PRESENTS AN UNREASONABLE RISK, IT IS REQUIRED UNDER TSCA TO RESTRICT THESE USES BUT CAN PROVIDE ADDITIONAL TIME FOR COMPLIANCE TO ALLOW DEVELOPMENT OF SUBSTITUTES

Despite concluding that MC use in furniture refinishing presents an unreasonable risk, EPA did not propose to regulate this use because of concerns about the availability of substitutes. We disagree with this decision. TSCA leaves EPA no choice but to restrict a chemical once it determines that the chemical presents an unreasonable risk; the limited availability of substitutes does not relieve the Agency from this basic responsibility. For furniture refinishing, we believe that the correct course is to ban MC but set an extended schedule for implementation under section 6(d), providing additional time to develop MC replacements but signaling to the industry that MC must be eliminated by a date certain. Thereafter, if substitution concerns persist, EPA can provide selective relief using the exemption authority in section 6(g).

A. EPA's Analysis Found Significant Risks Due to MC Exposure in Furniture Refinishing

According to EPA, commercial furniture refinishing is comprised of several activities, including repair, reupholstering, repainting and depainting or removing paints and coatings. Furniture stripping using a solvent-based remover is a common feature of these activities. EPA has explained that "to carry out furniture stripping, or to remove paint, lacquer, varnish, or other coatings from wood or metal furniture (or similar items such as doors, radiators, and cabinets), chemical paint and coating removal products may be applied to the furniture by either dipping the furniture in an open tank containing the chemicals, brushing or spraying the product onto the furniture surface, or manually applying the chemical product with a brush, rag, or aerosol spray."[58]

Most commercial furniture refinishing firms primarily use chemical methods for furniture stripping. EPA estimates that there are 15,000 workers at 4900 commercial refinishing operations where MC-based paint and coating removal products are applied.[59]

EPA's risk assessment demonstrated significantly elevated risks among furniture refinishing workers for acute effects, chronic effects and cancer. Among the Agency's findings were the following:[60]

[57] (d.
[58] 82 FR 7492.
[59] 82 FR at 7493.
[60] 82 FR at 7494.

- "MOEs for acute risks in commercial furniture refinishing ranged from a central tendency of 0.08 to 0.035, with a high end of 0.0063 (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels between 125 times to greater than 1,500 times more than those that are expected to produce no risks of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects."
- "Workers and occupational bystanders in this industry were estimated to be at risk of non-cancer liver toxicity as a result of chronic exposure to methylene chloride during paint and coating removal under typical exposure scenarios. When workers' exposures were estimated at facilities repeatedly reporting moderate or high methylene chloride air concentration levels, EPA estimated that there were risks of concern for these workers, even for scenarios evaluated with workers wearing respiratory protection with APF 50. Among all of the occupational scenarios, the greatest risk of concern is for workers engaging in long-term use of the product (*i.e.,* 250 days/year for 40 years) with no respiratory protection. For those workers, MOEs for chronic exposures were 0.025, or reflective of risks 400 times greater than the benchmark. Even for workers assumed to have lower exposure, MOEs did not reach 10. In most workplaces engaged in commercial furniture refinishing, MOEs for chronic exposure ranged from a central tendency of 0.60 to 0.3."
- "In the methylene chloride risk assessment, when exposure for workers and occupational bystanders was estimated in facilities conducting commercial furniture refinishing, EPA identified excess cancer risks if these workers and bystanders were exposed to paint and coating removal with methylene chloride for 250 days per year for 40 years with no respiratory protection. Cancer risks ranged from 2 in 10,000 to 8 in 10,000, with a maximum of 5 in 1,000 (workplaces using immersion methods)."

EPA also underscored that "since 1980, at least seven workers have died while using methylene chloride for commercial furniture refinishing." These deaths are likely not the only ones caused by MC exposure in this industry since "many deaths due to methylene chloride have not been recorded due to a lack of reporting to the OSHA incident database by self-employed individuals and the likelihood that deaths due to methylene chloride exposures are misattributed to heart disease, since the pathology is similar."[61]

EPA also cited evidence that exposures are uncontrolled and worker safeguards minimal in many furniture refinishing operations. For example, Colorado researchers examining small refinishing shops found that in several shops respiratory protection was non-existent or inadequate and that workers experienced acute nervous system effects such as dizziness or nausea. The study concluded that current safety practices in small shops "may be inadequate" and "serious or fatal overexposure can occur."[62]

Although EPA did not propose restrictions to address these serious risks, it did analyze a number of options. A striking conclusion of this analysis was that engineering controls would be "prescriptive and expensive", that furniture refinishing facilities have not generally installed ventilation systems to reduce MC exposure and that ventilation alone would likely not lower MC exposures to 25 ppm (the OSHA workplace standard), let alone to the much lower levels necessary to meet the EPA risk benchmarks.

[61] 82 FR at 7495.
[62] Id.

EPA also examined the effectiveness of requiring respirators and found that supplied-air models with an APF of 10,000 would meet the benchmarks but cautioned that this requirement might not be effective due to "the limitations to successful implementation of supplied-air respirators in the workplace." By contrast, EPA indicated that, under a ban on commercial use of MC for paint and coating removal in commercial furniture refinishing operations, "not only non-cancer risks, but also cancer risks would be eliminated."[63]

B. EPA's Decision Not to Regulate Furniture Refinishing Because of Substitution Concerns was not Justified under TSCA

EPA explicitly found that MC use in these operations posed an unreasonable risk but declined to propose restrictions to eliminate the unreasonable risk because there "may not be any substitute chemicals or alternative practices" that would effectively substitute for MC in this industry sector.[64] Even stipulating that EPA is correct, this consideration would not justify failure to reduce the unreasonable risk presented by MC use in furniture refinishing under LCSA.

As noted above, 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). And under section 6(a), the rule must assure that the chemical no longer presents an unreasonable risk, a standard that does not allow for considering costs or other economic factors in setting the level of protection. Availability of substitutes is an area that EPA must consider under section 6(c)(2)(C) "to the extent practicable" when restricting chemical uses but its conclusions on this score cannot modify or override the Agency's obligation to select restrictions sufficient to eliminate the unreasonable risk. In short, EPA's finding that the furniture refinishing uses of MC present an unreasonable risk compels it to restrict these uses under section 6 and, in so doing, to impose requirements that assure that the unreasonable risk no longer exists.

C. EPA Can Delay the Compliance Date for Furniture Refinishing under Section 6(d) to Provide Time to Develop Adequate Substitutes

Although EPA should have proceeded to regulate MC use in furniture refinishing, there are other mechanisms in the law for taking into account substitution concerns and allowing time to transition away from the restricted chemical where acceptable substitutes do not yet exist. Section 6(d)(1) requires compliance with a rule "as soon as practicable" but allows EPA to set an effective date that is up to five years from the date of promulgation. Where a longer time is needed to address unusually serious use substitution issues, section 6(g) allows EPA to grant time-limited exceptions for specific conditions of use based on a particularized showing of need under the statutory criteria.

EPA could use these mechanisms to provide the industry with significant lead-time to develop MC replacements in furniture refinishing without undue disruption and hardship. By setting a firm target date for eliminating MC but delaying immediate compliance, EPA would provide some breathing space to industry while at the same time setting in motion incentives and drivers for innovation in furniture stripping techniques that meet industry's needs while avoiding use of MC. Thereafter, if there are particular conditions of use where substitutes are not available, section 6(g) exemptions can be granted where warranted under the criteria in the law. We strongly believe that, absent a firm target date for

[63] Id.
[64] 82 FR at 7496.

MC replacement, industry will not make a meaningful investment in alternatives and worker health protections will be needlessly delayed, resulting in avoidable deaths and serious disease.

V. NMP USE IN PAINT AND COATING REMOVAL PRESENTS AN UNREASONABLE RISK

EPA has also conducted a comprehensive risk assessment for NMP use in paint and coating removal. The basic exposure and processing conditions that characterize MC use in this sector also apply to NMP: a large number of workers and consumers are exposed to NMP in largely uncontrolled operations. NMP's hazards are different from those of MC but also of significant concern. NMP is a serious developmental toxicant, with the ability to cause fetal death or harm to fetal development. As with MC, EPA's assessment shows that MOEs for this end-point are well below the benchmarks EPA has historically used to define "safe' levels. As a result, continued exposure to NMP in paint and coating removal presents risks that are "unreasonable" under TSCA section 6.

A. A Large Population of Workers and Consumers is Exposed to NMP in Paint and Coating Removal

EPA estimates that 9 percent of the total amount of NMP produced and imported in the US (approximately 180 million pounds per year) is used for paint and coating removal. Chemical products for paint and coating removal have broad application across several economic sectors and are used by consumers for home renovation projects, hobbies, automotive and furniture refinishing and other purposes. Many paint removers containing NMP are distributed for multiple purposes and sold through consumer and commercial channels. EPA has identified 64 different NMP-containing products for paint and coating removal, formulated by 21 different firms. Based on the range of commercial activities where these products are used, EPA estimates that 30,300 workers annually are exposed to NMP at 4300 facilities. In view of the wide availability of NMP-containing products to consumers, the Agency projects that consumers exposed to NMP each year number 732,000.[65]

EPA emphasizes that NMP use for paint and coatings is growing because "products containing NMP have in recent years become increasingly popular substitutes for users interested in avoiding the health effects or odors known to be associated with products containing methylene chloride."[66] This trend is encouraged by some retailers and distributors who frequently advise consumers to use products containing NMP without any explanation of its adverse effects. In addition, NMP-containing products may often lack information about personal protection or risk reduction and include labeling highlighting properties (such as "no harsh fumes") that imply safety.

Because of its low volatility and conditions of use, the main route of exposure to NMP in paint and coating removal is dermal, although some inhalation exposure and absorption of vapors through the skin also occur. Minimizing dermal exposure to NMP requires specialized gloves that have been tested for impermeability on the specific formulation to be used and are regularly replaced, plus the wearing of impervious long pants and shirts.

[65] 82 FR 7503.
[66] 82 FR 7466.

B. A Wide Range of Studies Show that NMP Consistently Causes Serious Developmental Effects, including Fetal Death and Reduced Body Weight, from Acute and Chronic Exposures

NMP has been the subject of numerous toxicological studies in a range of test species using different routes of exposure. A number of adverse effects were observed in different studies, including effects on body weight, liver, kidney, spleen, thymus, testes and brain. Based on a comprehensive review, EPA selected developmental toxicity endpoints as the most robust, sensitive and consistent adverse effects for dose-response analysis. As it concluded, "[n]early every study that evaluated developmental toxicity of NMP identified some type of adverse effect" and "these effects are observed within a comparable dose range when administered doses are converted to internal doses" across different routes of administration.[67]

To conduct this internal dose analysis, EPA used a physiologically-based pharmacokinetic (PBPK) model so it could compare doses and effects across routes and aggregate exposures in different studies. This modeling demonstrated "a number of biologically relevant, consistent and sensitive effects, representing a continuum of reproductive and developmental effects", including decreased fetal and postnatal body weight, delayed ossification, skeletal malformations, and increased fetal and postnatal mortality. To develop a Point of Departure (POD) for assessing the safety of human exposure scenarios, EPA picked increased fetal resorptions (fetal death) to examine risks from acute exposures and decreased fetal body weight to examine risks from chronic exposures.

Since fetal death has been shown to result from acute NMP exposures, dermal contact with NMP during the course of a single day may cause adverse effects. According to EPA, "[f]etal death or fetal mortality includes miscarriage, spontaneous abortion, or stillbirth, depending on when in the pregnancy it occurs." A single maternal exposure to NMP at a developmentally critical period may produce these outcomes. EPA estimates that approximately 38,000 of the consumers using NMP-containing paint and coating removal products are pregnant women and that 500 of the estimated 8,800 female workers at commercial paint and coating facilities using NMP are pregnant women as well.[68]

EPA selected decreased birth weight as the most sensitive endpoint for repeated exposures to NMP by women of child-bearing age because these effects were seen consistently among multiple studies with different dosing regimens and routes of administration and decreases in fetal and post-natal body weights were observed at similar doses. According to EPA, "a relatively brief period of maternal repeated exposure to NMP in typical paint and coating removal can cause fetal weight decreases, resulting in life-long impacts." Based on the literature, EPA emphasizes that "[l}ow birth weight can have significant impacts on childhood development and the incidence of future diseases; reduced birth weight can cause serious health problems for some children, as well as long-term impacts on their lives as adults."[69]

EPA's review of the literature also showed that NMP has caused reproductive effects (including testicular impacts) in several rat studies but that "these findings are significantly less frequent or

[67] 82 FR 7498.
[68] 82 FR 7509-10.
[69] Id.

consistent than the occurrence of developmental effects." It also noted other acute and chronic toxicity concerns, including skin, eye and respiratory irritation and liver and kidney toxicity.[70]

SCHF AND NRDC support EPA's selection of developmental toxicity (increased fetal resorptions and reduced body weight) as the most sensitive hazard endpoints to drive the conclusions of the NMP risk assessment. Thus, EPA actions to mitigate NMP harm must protect pregnant women and women of childbearing age who may become pregnant.

C. EPA Properly Used Well-established and Sophisticated Exposure Modeling Methods to Estimate Occupational and Consumer Exposures Under a Wide Range of Conditions of Use

To determine whether workers and consumers are at undue risk from NMP's developmental effects, EPA's risk assessment examined a comprehensive set of exposure scenarios to determine whether Margins of Exposure (MOEs) are below the benchmark level of 30 that represents a "safe" level of exposure.

Occupational Exposure. The Agency developed six worker exposure scenarios reflecting a range of factors, including the weight fraction of NMP in the paint and coating removal formulation, the size of the worker skin area exposed to NMP and the duration of exposure. Within each scenario, EPA examined five permutations, reflecting such variables as respirator and glove use. On top of these evaluations, EPA also examined exposure scenarios resulting from the application of various risk reduction measures. These included reducing the percent of NMP in formulations, reducing the duration of use and installing engineering controls.

SCHF AND NRDC support EPA's approach, which initially focused on small shops as described in the draft workplan, but was extended to include to address all industries and shop sizes. As EPA notes, any of these facilities may have small (less than 10 workers) or large work forces engaged in paint stripping jobs that put workers at high risk of elevated unsafe exposure to NMP and other hazardous solvents.

SCHF AND NRDC also support the inclusion in the final risk assessment of a scenario that includes the use of respirators and gloves to control exposures. These PPE are among the available options to reduce exposure, and their effectiveness should inform the selection of risk management requirements. (However, as EPA elsewhere notes and we discuss below, the theoretical reduction of exposure from PPE does not necessarily mean that exposure will be prevented in practice. For example, in addition to their high failure rate (due to reasons raising from failure to fit to failing to use), use of respirators places additional requirements on employers including providing proper functioning respirators, training, and medical evaluations at no additional cost to the employee (29 CFR 1910.134(c)(4).[71] In reality, these requirements may discourage respirator programs.

SCHF AND NRDC are pleased that EPA/OPPT consulted with OSHA and NIOSH during the development of the NMP risk assessment, and that OSHA and NIOSH comments and suggestions were incorporated into the final assessment. OSHA and NIOSH have expertise in workplace safety and health that is both deep and broad, and collaborations with EPA to improve risk assessment accuracy will better protect workers and their families.

[70] 82 FR 7499.

[71] OSHA Regulations for Personal Protective Equipment, Respiratory Protection, 29 CFR §1910.134(c)(4).

Consumer Exposure. The EPA risk assessment examined seven consumer exposure scenarios reflecting the same factors used to assess occupational exposures plus additional factors like the method of application of the paint and coating remover and extent of ventilation. EPA has considerable expertise in the selection of appropriate exposure models for use in its risk assessments, for example, within the EPA Office of the Science Advisor Council for Regulatory Environmental Modeling (CREM). EPA has publicly accessible websites that provide Guidance Documents regarding the Agency's development and application of environmental models.[72]

The selection of exposure models for use in risk assessment depends on the data that are available for use in the exposure model. In contrast to occupational exposures, no representative air monitoring data were available for consumer exposures, but EPA applied a 1994 chamber study conducted under contract to EPA to generate estimates of NMP air concentrations from consumer paint stripping activities.[73] This was paired with information on usage amounts from a peer-reviewed survey cited in EPA's 2011 Exposure Factors Handbook, along with some additional survey data. With this information as inputs, the Multi- Chamber Concentration and Exposure Model (MCCEM) was used to estimate exposure levels under the consumer exposure scenarios. EPA provides publicly available information about this model in its website (note that the web link provided in the NMP Final Work Plan is outdated and should be corrected).[74] EPA used this model for NMP because it had access to chamber test emission data for NMP that were deemed suitable for fitting this higher tier model. We support EPA's approach.

Industry Concerns. Industry critics have questioned whether EPA's Workplan risk assessments are adequate for regulatory decision-making, arguing that they are simply "screening assessments" that need to be supplemented by additional data and analysis. This criticism does not hold water for the NMP Final Work Plan Risk Assessment (and others conducted by EPA). EPA has employed sophisticated measuring and modeling approaches to incorporate real-world emissions data as well as modeled exposure estimates using high-tiered peer-reviewed publicly available models to estimate exposures under several realistic scenarios. Additionally, EPA has incorporated a revised PBPK model to estimate internal dose, which effectively captures the toxicity data and adds to the precision and reliability of the dose-response assessment. Industry arguments that the Work Plan exposure calculations lack adequate depth and are not adequate for regulatory purposes 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 NMP's risks and considering action to protect the public. While the data gaps are unfortunate, they are unavoidable at this time. The models EPA uses to bridge the data gaps and refine its assessment are sound and scientifically defensible, have cleared peer review, and represent the best available science.

In light of the clear threats to human health and the lack of exposure information from industry, the NMP Work Plan Risk Assessment is reliable for TSCA regulatory purposes. SCHF AND NRDC are pleased

[72] EPA Environmental Modeling. https://www.epa.gov/modeling
[73] EPA. 1994. Consumer Exposure to Paint Stripper Solvents. EPA Contract No 68-DO-0137. MRI, Washington, DC
[74] Multi- Chamber Concentration and Exposure Model (MCCEM) version 1.2. https://www.epa.gov/tsca-screening-tools/multi-chamber-concentration-and-exposure-model-mccem-version-12

that EPA has stated that "all data that form the basis of the quantitative risk assessment are from public sources." [75]

D. The Risks Estimated by EPA Are Below the Benchmark MOE under a Broad Range of Exposure Scenarios

For acute exposures to NMP, EPA's assessment concluded that worker risks were significantly below the MOEs without and even with PPE under several exposure scenarios:[76]

> "[T]he occupational scenarios in which acute risks were identified included four hours of paint removal in one day with no gloves, with or without a respirator, indoors or outdoors, assuming mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (MOEs range from 12 to 15); and four hours of paint removal in one day with or without a respirator and gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (MOEs range from 0.7 to 11.8) (Ref. 3). These risks are present whether the worker is indoors or outdoors, and may be present even in the presence of PPE or ventilation, depending on the duration of use and the concentration of NMP in the product."[77]

EPA reached similar conclusions for chronic exposures by workers:

> "Risk of decreased birth weight was identified for commercial users of NMP for paint and coating removal in several scenarios, including four hours of paint removal during each day in a work week without gloves, with or without a respirator, indoors or outdoors, assuming the mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (MOEs range from 5.4 to 6.1); and eight hours of paint removal during each day in a work week, with or without a respirator or gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (MOEs range from 0.1 to 3.2). Though no risks were identified for occupational bystanders, for workers, these risks are present whether the worker is indoors or outdoors, and may be present even if PPE or ventilation is used, depending on the duration of use and the concentration of NMP in the product (Ref. 3). In some scenarios, this equates to estimated exposures that are more than 10 times greater than those that would produce the benchmark MOE for this endpoint, which assesses risks for fetal death and decreased birth weight."[78]

Importantly, EPA also found that the target MOE benchmarks for workers could not be achieved by reducing the percentage of NMP in formulations and providing local exhaust ventilation. Similarly, the MOE targets could not be met by the use of respirators and special gloves without additional measures.

While conducted using a different methodology, EPA's MOE calculations for consumers show that some use scenarios would exceed the target MOE benchmarks while others would result in inadequate

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[75] EPA Responses to Comments for NMP Work Plan Assessment, p. 5.

[76] NMP is allowed unregulated in pesticides put on food, and although we acknowledge that it may be beyond the scope of this assessment to estimate oral exposure, EPA acknowledges that this data gap could result in an underestimation of exposure.

[77] 82 FR 7505.

[78] Id.

MOEs.[79] As EPA notes in the rule preamble, some consumer use scenarios should closely resemble worker scenarios, resulting in the same estimated exposures and risks.[80]

In sum, EPA's final risk assessment identifies excessive and unacceptable risks from NMP exposures to pregnant women and women of reproductive age through use of paint or coating removal products. Thus, EPA concludes that acute and chronic worker and consumer exposures to NMP in paint and coating removal present unreasonable risks requiring restriction under TSCA section 6(a).[81] We strongly support this conclusion.

VI. EPA SHOULD IMPOSE A BAN ON NMP USE IN PAINT AND COATING REMOVAL AND REJECT THE ALTERNATIVE OF A REFORMULATION, LABELING AND PPE APPROACH

EPA's proposal seeks comment on two alternatives for mitigating the unreasonable risks presented by NMP use in paint and coating removal. The first alternative (Option 1) is a "supply chain" approach that would effectively ban manufacture, processing, distribution and use of NMP for nearly all commercial and consumer paint and coating removal. The second alternative (Option 2) would combine worker protection measures, product reformulation and labeling to achieve reductions in exposure but would allow continued use of NMP in in paint and coating in compliance with these restrictions.

As explained below, we believe Option 1 would achieve the TSCA goal of eliminating unreasonable risks. By contrast, Option 2 would not provide sufficient protection against NMP exposure to satisfy TSCA risk management requirements, would be impractical and difficult to implement and enforce, and would impose greater costs while producing smaller benefits. Thus, we strongly endorse Option 1 and urge that it form the basis for EPA's final rule.

A. Option 1 Will Eliminate the Unreasonable Risk and Provide a Sustainable Path toward Safer Chemistry

Option 1 closely resembles EPA's proposed restrictions on MC use in paint and coating removal. It would (1) prohibit manufacture, processing and distribution in commerce of NMP for consumer or commercial paint and coating removal (except in certain exempt national security applications), (2) prohibit commercial NMP use in these applications, (3) require notification of these restrictions down through the chain of distribution and (4) require that any allowable NMP-containing paint and coating removal products be distributed in containers with a volume no less than 5 gallons.

The rationale for Option 1 closely parallels the justification for EPA's "supply chain" proposal for MC. As it did for MC, EPA rejected labeling and warning requirements, standing alone, as a remedy capable of eliminating the unreasonable risk given the large uncertainty whether these measures would be effective in the numerous workplaces (including many small businesses with little or no worker training) and consumer environments where NMP is used for paint and coating removal.[82]

[79] EPA. Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal. 2016 (Ref. 76 in EPA docket).
[80] 82 FR 7505.
[81] Id.
[82] 82 FR 7502

EPA also rejected limiting restrictions to either commercial or consumer use as opposed to regulating both, concluding that combined use prohibitions for commercial and consumer applications are essential to adequately protect both exposed groups. As it explained, "paint and coating removal products containing NMP frequently are available in the same distribution channels to consumers and professional users. Products are marketed for a variety of projects, and cannot be straightforwardly restricted to a single type of project or user."[83]

EPA also examined whether improving ventilation, requiring special gloves, reducing NMP levels in products or requiring respirators would, in itself, be sufficient to address the unreasonable risks. It concluded that they would not:

> "The results of EPA's assessment of consumer uses, exposures, and risks indicate that regulatory options for consumer uses such as reducing the concentration of NMP in a product or advising the use of specialized gloves or respirators individually could not achieve the target MOE benchmarks for acute exposures. Similarly, the results of EPA's evaluation indicate that regulatory options for occupational exposures such as reducing the concentration of NMP in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures (Refs. 37 and 75). The results also demonstrate that all risk reduction options meeting the benchmark MOEs for NMP in paint and coating removal require the use of specialized gloves, whether used alone or in conjunction with additional levels of respiratory protection such as a respirator of APF 10 or the use of an air exposure limit, even when the concentration of NMP in a product was limited to 25 percent. Therefore, EPA found setting a maximum concentration of NMP in products under TSCA section 6(a)(2) alone would not reduce exposures to levels at which risks would be at or below the risk benchmarks. Further, EPA's analysis found that even with specialized gloves and a respirator, workers would be at risk of NMP exposure if they used products with more than 25 percent NMP."[84]

By contrast, EPA concluded that Option 1 would "ensure that workers and consumers from the general population (as well as workers and consumers who are women of childbearing age) are no longer exposed to unreasonable risks from NMP exposure during paint and coating removal." As a result, "acute and chronic risks would be eliminated."[85]

In combination with a ban on MC use in paint and coating removal, Option 1 would send a clear and consistent message to the marketplace to move away from toxic solvents for this application and substitute non-toxic alternatives. By contrast, if MC is banned but NMP use is allowed, the message will be a mixed and confusing one: the marketplace may conclude that NMP is safer than MC (contrary to EPA's risk assessment) and is a preferred replacement for MC (even though the evidence shows that NMP presents unreasonable risks). The best way to transition the marketplace away from MC and NMP and incentivize development of sustainable chemistry is through an integrated regulatory approach that results in consistent treatment of both chemicals and provides a well-aligned and easily understood path for their concurrent phase-out and replacement with non-toxic methods of paint and coating removal.

[83] 82 FR 7505.
[84] 82 FR 7505
[85] 82 FR 7506.

B. Option 2 Will Provide Less Health Protection than Option 1, Will be Highly Impractical and Will Cost More while Delivering Smaller Benefits

EPA has described the elements of Option 2 as follows:[86]

> "[C]ommercial users of NMP for paint and coating removal would be required to establish a worker protection program for dermal and respiratory protection, including hazard communication, training, and requirements that workers wear clothing covering most of the body, *i.e.,* impervious long pants and shirts with long sleeves, use gloves specified by product formulators (described under formulator requirements below) and a respirator with APF 10, with an alternative air exposure limit of 5 ppm achieved through engineering controls or ventilation. Also under this approach, formulators of products for either commercial or consumer use would be required to (1) Reformulate products such that paint and coating removal products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations under section 6(a)(2) (except for product formulations destined to be used by DOD or its contractors performing work only for DOD projects identified in Unit XVIII.); (2) Test gloves for the product formulations being processed and distributed in commerce to identify specialized gloves that provide protection for users under section 6(a)(4); (3) Label products with information for consumers about reducing risks when using the products, including identifying which specialized gloves provide protection against their specific formulation; and (4) Provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication. Variations of more than 1% in any component of a paint and coating removal product containing NMP would be considered a separate formulation."

In contrast to the simplicity of Option 1, this option is complex and difficult to implement. Its underlying premise is that multiple measures to reduce exposure to NMP that would not be sufficient on their own will in combination be effective in eliminating NMP's unreasonable risks. This is a highly debatable premise which is contradicted by EPA's own strongly stated reservations about the effectiveness of two critical elements of Option 2 -- labeling and warnings (particularly for consumers) and respirators. EPA has consistently cited reliability and effectiveness of implementation as a key factor in whether a remedy will be fully protective yet Option 2 clearly fails to pass muster on this score under the Agency's own analysis.

For example, EPA has described the proposed labeling and warnings to be provided to consumers in these terms:

> "Specifically, for labeling targeted to consumers under section 6(a)(3) formulators would be required to provide the following information to consumers on product labels: A warning that irreversible health effects such as fetal death may occur as a result of using the product; instructions to not use the product without a new (*i.e.,* replaced each time the product is used) pair of the formulation-specific gloves identified on the label; instructions to either use the product outdoors or to adequately ventilate the workspace by opening windows and adding fans; instructions to not spray-apply the product; instructions to wear clothing that covers exposed skin; and instructions to

[86] 82 FR 7507.

use a respirator of APF 10, such as a NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100, R100, or P100 filters."[87]

The odds that untrained and uniformed consumers would grasp and then implement these many recommended protective measures – special NMP-tested gloves, outdoor use or special ventilation, avoidance of spray application, impervious full body clothing and use of a respirator – are extremely small. As EPA acknowledges, "risks to consumers are only addressed to the extent that consumers understand and follow the required label information" Yet "[u]nder real-world conditions, EPA expects that not all consumers will adequately follow the label to reduce risk to a level above the benchmark MOE." This is not only because many consumers may not understand or pay attention to labels but because those who do comprehend them "may not be motivated to follow the label information." Equally important, even well-motivated consumers "may be unable to readily locate the specialized gloves or the respirator indicated on the label," may not "have the fit of their respirator tested," or may not "wear a new pair of specialized gloves for each use of the product containing NMP."[88]

Because respirators are a prerequisite for adequate protection of consumers and workers under Option 2, consistency and effectiveness of respirator use are also critical criteria in judging whether this Option passes muster under TSCA section 6. In the MC portion of its proposal and in its separate section 6 proposals for TCE,[89] EPA has expressed serious misgivings about relying on respirators, even where they are theoretically capable of reducing exposure to a sufficient extent. These misgivings are no less applicable to NMP Option 2. In describing its own concerns about Option 2, EPA cautions that, "[a]lthough respirators in conjunction with the use of appropriate formulation-tested gloves could reduce exposures to levels that are protective of acute and chronic risks, respirators are not EPA's preferred approach to decrease exposures."[90] This is because "[n}ot all workers may be able to wear respirators, even those with a lower APF" and because the training, testing and compliance programs necessary for effective respirator use will be challenging to implement in paint and coating removal operations.

Indeed, with an estimated 64 different NMP-containing paint and coating removal formulations in use, several thousand use sites and over 30,000 exposed workers, there is reason to doubt whether widespread and adequate compliance with Option 2 is realistic and whether EPA would have the resources to effectively enforce its requirements against violators. As EPA acknowledges, many paint

[87] 82 FR 7507

[88] The suggestion in EPA's preamble that "incomplete adherence to the label might still suffice to reduce risks presented by NMP in paint and coating removal so that those risks are no longer unreasonable" is irresponsible. 82 FR 7509. Given widespread lack of adherence to label recommendations, particularly by consumers, there will still be a large population at risk of NMP health effects. To characterize this sizable remaining risk as "no longer unreasonable" would lack any legal or scientific foundation.

Equally indefensible is the suggestion that the "voluntary nature of consumer use . . . should be a factor in determining whether any remaining risk associated with this exposure scenario is unreasonable." Id. The explicit goal of the law is to impose restrictions on product use to protect consumers against unreasonable risks, not assume that the risks are 'reasonable' because they are somehow "freely chosen." Moreover, it's a misnomer to describe use as "voluntary" when label warnings and instructions are complex, confusing, hard to understand and unimplementable even where they are comprehended.

[89] Federal Register 91592 December 16, 2016) (TCE I); .82 Federal Register 7432 (January 19, 2007) (TCE II).

[90] 82 FR 7509.

and coating removal operations are small shops with few employees and a workforce prone to frequent turnover. These firms lack industrial hygiene expertise and are unlikely to have worker training and protection programs. Implementing Option 2's extensive requirements for specialized gloves, impervious full-body clothing and respirators would be costly and operationally difficult for these unsophisticated operators.

While EPA predicts that many of these firms would eliminate NMP rather than incur the burdens of implementation, it is also likely that many will simply fail to comply. Indeed, as noted above, researchers have found widespread non-compliance with the OSHA MC workplace standard during paint and coating removal, resulting in MC exposures above the OSHA standard, despite the mandatory nature of the OSHA requirements.[91] The same behavior can be expected if EPA adopts Option 2 and, like OSHA, EPA will likely fail to mount an effective campaign to ferret out and penalize violators. This will mean continued worker exposures to NMP at levels that are unsafe. Because Option 1 is more straightforward and relies on a set of mutually reinforcing requirements throughout the supply chain to secure compliance, the likelihood is far greater that it will actually achieve the reductions in risk necessary to meet the standards of TSCA.

Not surprisingly in view of its greater complexity, EPA found that Option 2 would impose implementation costs significantly larger than those of Option 1. The Agency's economic analysis concluded that total costs imposed by Option 1 would be between $1,251,000 and $27,668,000 when annualized over 20 years, whereas Option 2's costs would be between $47,098,000 and $56,404,000 on the same basis.[92] At the same time, because of the uncertainties and limited effectiveness of Option 2, its health benefits would be significantly lower than Option 1's, particularly for consumers, who would only be protected if they understood and followed a set of complex and hard to implement labeling instructions. Thus, when compared on a cost-benefit or cost-effectiveness basis, Option 2 is inferior to Option 1, in addition to failing to provide full protection against the unreasonable risk as required by TSCA.

By predicting that many users will decide that it is too costly to implement Option 2 and will shift to alternatives, EPA seems to be hoping that its risk reduction goals will be achieved indirectly and without the stringency of a ban on NMP use for paint and coating removal applications. But if this is in fact the policy outcome EPA seeks to accomplish, a simple prohibition on manufacture, processing, distribution and use of NMP in these applications will offer greater assurance of achieving it and provide a more transparent and less costly path to compliance, particularly if the messages and compliance measures EPA is communicating to the marketplace on MC and NMP are coordinated and well-aligned.

VII. EPA'S ANALYSIS OF SUBSTITUTES DEMONSTRATES THAT A WIDE RANGE OF EFFECTIVE, LOW HAZARD ALTERNATIVES TO MC AND NMP 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 MC AND NMP in paint and coating removal applications. This analysis is primarily informational: under TSCA section 6(a),

[91] 82 FR 7405 (Ref. 70).
[92] 82 FR 7515.

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, if MC and NMP are banned for use in paint and coating removal, a wide range of effective, economical and safer substitutes will be available.

Because they are relatively interchangeable for paint and coating removal uses, EPA's analysis of substitutes was very similar for MC and NMP. Based on its economic assessment, the Agency concluded that "alternatives are technologically feasible, economically feasible, reasonably available, and present fewer hazards to human health than [NMP and MC] in paint and coating removal."[93] The only exceptions to this conclusion were for furniture refinishing (where EPA could not identify replacements for MC) and for military aviation and vessel readiness (for which EPA proposed use exemptions for both MC and NMP under TSCA section 6(g)).

EPA's confidence in the availability of substitutes was based on extensive research by independent experts on the efficacy of replacement chemicals in different product formulations.[94] The Agency also placed weight on the industry track record of voluntarily adopting substitute chemicals or methods based on financial, customer, workplace safety or environmental considerations and the practice of many product suppliers of offering both products containing both MC or NMP and products containing substitute chemicals. EPA also took note of successful bans of MC use in graffiti removal by several states.

According to EPA, the primary chemical substitutes for MC and NMP in paint and coating removal are products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (collectively ATM); and caustic chemicals. EPA evaluated these products for efficacy, toxicity, relative hazards compared to MC and NMP, and other hazards that might be introduced by use of these products (such as environmental toxicity, increased global warming potential, and increased flammability or other hazards to users). Its conclusion was that:

> "[T]he most likely chemical substitutes for {MC and] NMP in paint and coating removal do not pose a risk of acute or chronic developmental effects [or cancer], generally have lower or similar exposure potential than NMP [and MC], and when acute risks are present, as in the case of caustic chemicals, those risks are self-limiting by the nature of the adverse effects. The chemical formulations that seem to present some risks of concern contain toluene and methanol; however, risks from these chemicals can be mitigated by the user more easily than risks presented by NMP. Overall, exclusive use of substitute chemical products for paint and coating

[93] 82 FR 7513.

[94] The Toxic Use Reduction Institute (TURI) provides links to California and EU reports identifying MC substitutes for paint stripper uses.
http://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/Methylene_Chloride_Fact_Sheet
Clean Production Action/BizNGO also produced a detailed guide on MC alternatives. Many of the same are applicable to NMP. The report is available for free after registration at http://www.greenscreenchemicals.org/alternatives-assessment/methylene_report_request

removal instead of NMP [and MC] would remove the risks of chronic effects [,cancer] and acute developmental effects without introducing additional substantial risks to human health."[95]

To the extent additional R&D or product testing is necessary to optimize the efficacy of substitutes, this innovative activity will be incentivized by a clear and coordinated path and timetable for ending the use of MC and NMP for commercial and consumer paint and coating removal. EPA should provide this path and timetable in its final rule.

VIII. THE PROPOSED SECTION 6(g) EXEMPTIONS FOR MILITARY APPLICATIONS OF MC AND NMP REQUIRE A FULLER JUSTIFICATION AND ADDITIONAL CONDITIONS TO ASSURE WORKER PROTECTION AND A RAPID TRANSITION TO SUBSTITUTE CHEMICALS

EPA is proposing to grant exemptions under TSCA section 6(g) for the use of MC and NMP in paint and coating removal from mission-critical corrosion-sensitive components of military aviation and vessels.[96] These exemptions would be for 10 years and would apply only to removal operations conducted at Department of Defense (DOD) installations or DOD-controlled locations or by DOD contractors.

More generally, EPA's proposal also solicits comment on TSCA section 6(g) might be used to for additional exemptions of uses where MC or NMP substitutes are not deployable or compliance with the proposed bans would otherwise cause hardships.[97]

We address these two issues below.

A. The Proposed DOD Exemption Lacks an Adequate Rationale and Necessary Conditions

We agree that section 6(g) is the proper vehicle under TSCA for accommodating difficulties in substitution since the availability of substitutes is not a permissible factor in determining whether a chemical presents an unreasonable risk or in selecting a remedy to eliminate that risk under section 6(a). However, the criteria for granting use exemptions under section 6(g) are stringent and the burden of demonstrating that they are met falls on the Agency (or the entity requesting the exemption).

In this case, EPA seeks to base its proposed exemptions for military-related paint and coating removal with NMP and MC on section 6(g)(1)(B), which applies where compliance with the restrictions under a section 6(a) rule would "significantly disrupt the national economy, national security, or critical infrastructure." To justify granting exemptions under this standard, section 6(g)(2) requires EPA to "analyze the need for the exemption" and "make public the analysis and a statement describing how the analysis was taken into account."

The MC/NMP proposal preamble explains that –

> "[F]or mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. In these critical and essential

[95] 82 FR 7514.
[96] 82 FR 7517-8 (NMP); 82 FR 7489-90 (MC).
[97] 82 FR 7490-91.

applications, currently available substitute chemicals cannot completely remove specific military high performance or chemical resistant coatings, resulting in improperly applied, incompletely adhering replacement coatings. The impacts of this are early coating failure, corrosion of underlying critical parts, shortened service life for critical components (some of which are no longer manufactured), and reduced availability and mission readiness of military aircraft and vessels.

Substitute chemicals currently available are also incompatible with underlying metallic, nonmetallic and composite materials, resulting in material damage to critical components (*e.g.* hydrogen embrittlement) creating immediate damage or longer-term susceptibility to stress fracturing and corrosion. The impacts of this are shortened service life for critical components (some of which are no longer manufactured), reduced availability and mission readiness of military aircraft and vessels, and an increased risk of catastrophic failure of safety critical parts.

Additionally, substitute chemicals or methods currently available do not support the coating removal requirements of safety inspection, non-destructive inspection, material assessment, or field repair processes. This results in an inability to properly perform safety inspections for critical components, leading to undetected fractures and defects. The impacts of this are increased risk of catastrophic failure of safety critical parts."[98]

While this explanation is helpful, it is extremely general and lacks supporting data or other concrete information that would better identify the mission-critical components impacted and the basis for concluding that substitute chemicals fail to deliver the performance necessary for these components to support the mission readiness of aircraft and vessels. Placing this documentation in the record would provide public assurance that DOE's concerns about substitution are grounded in testing or detailed technical analysis that EPA has carefully reviewed and deemed sufficient. Such transparency is essential to assure that the exception process is not abused.

Section 6(g)(4) requires exemptions to include "conditions . . .to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption." The proposed national security exemptions for MC and NMP-based paint removers do not include such conditions. This is a glaring omission given the significant risks that these chemicals pose to workers in paint and coating removal applications. At a minimum, DOD and its contractors should be required to implement worker protection programs that provide meaningful warnings and labeling about the hazards of MC and NMP and require respirators, special gloves and other protections against exposure at unsafe levels. The extensive analysis in the preamble to EPA's proposal provides a detailed roadmap to the elements such programs should include.

Another "condition" to assure health protection that is lacking in EPA's proposal is an enforceable commitment by DOD to aggressively pursue R&D efforts and related testing to validate the acceptability of MC and NMP substitutes for the mission-critical uses covered by the proposed exemption. While the preamble indicates that DOD has previously conducted research into possible alternative chemicals, there is no indication that this research will continue. This could lead to open-ended future extensions of the exemptions – a situation that would perpetuate the risks associated with MC and NMP use. The time-limited nature of extensions under section 6(g) reflects an expectation that they would be

[98] 82 FR 7490.

temporary and remain in place no longer than necessary to find acceptable substitutes. Thus, all exemption holders should be required to agree to enforceable programs to develop substitutes, with clear milestones for documenting and reporting progress. EPA has successfully followed this model for its Significant New Alternatives Policy (SNAP) program for CFC-substitutes under the Clean Air Act and should do so here as well.[99]

B. *Broader Use of Section 6(g) to Alleviate Substitution Concerns is Appropriate but Requires Careful Safeguards and a Strong Supporting Justification*

Under this rule and others issued under TSCA section 6(a), there may be additional occasions to consider exemptions under section 6(g) in order to address the lack of alternatives for specific conditions of use. These potential exemptions will likely not be based on national security concerns and thus would need to be justified under section 6(g)(1)(A), which provides that EPA must find that –

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

The burden of demonstrating that this standard is satisfied should fall on the requesting company and EPA should require that it submit all documentation necessary to demonstrate that the exemption criteria are met. This should include evidence that (1) the use proposed for exemption performs a "critical or essential" function and (2) that possible alternatives are either technically or economically infeasible or less safe than the restricted chemical. Since the exemption must be time-limited as noted above and no longer than necessary to develop alternatives, the exemption applicant should be required to submit a plan and schedule to identify and evaluate acceptable substitutes. This plan should be made a condition of the exemption so it is legally binding. Finally, all exemptions should include as conditions enforceable requirements to reduce worker and consumer exposure to the restricted chemical during the exempt use, employing the most stringent protections practicable and cost-effective.

IX. THERE IS NO BASIS FOR REFERRING RISKS RELATED TO MC OR NMP USE IN PAINT AND COATING REMOVAL TO OSHA OR 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 referral by the date set by EPA or thereafter fails to initiate

[99] In this regard, it is troubling that EPA is proposing that the DOD exemptions remain in effect for 10 years. A five-year limit would be less open-ended and would provide for a more expeditious review of DOD's R&D and worker protection efforts before a decision is made to extend the exemption.

regulatory action within 90 days of that response, EPA "shall initiate or complete appropriate action under section 6."[100]

Determining whether a section 9(a) referral is warranted entails a comparison of the authorities that EPA and the other agency can bring to bear in addressing an unreasonable risk. If TSCA provides for a level of protection that would eliminate the unreasonable risk but the other agency could not afford equivalent protection, then action by that agency could not prevent or reduce the risk "to a sufficient extent." As a result, regulation under TSCA would be the required path and the Administrator would have no basis for making a section 9(a) referral.

With the enhanced protectiveness and stronger risk management authority provided by the LCSA, the burden to justify foregoing regulation under TSCA and relying on another law under section 9(a) is now higher than before. As the Democratic Senators emphasized in their joint statement upon TSCA's enactment, "the interagency referral process . . . established under section 9 of existing TSCA must now be regarded in a new light since TSCA can no longer be construed as a "gap filler" statutory authority of last resort. The changes in section 9 are consistent with this recognition and do not conflict with the fundamental expectation that, where EPA concludes that a chemical presents an unreasonable risk, the Agency should act in a timely manner to ensure that the chemical substance no longer presents such risk."[101]

A. A Section 9(a) Referral to OSHA is Unwarranted

Since workers comprise a large portion of the population exposed to MC and NMP during paint and coating removal, EPA considered whether to refer the unreasonable risks presented by these uses 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 risks of methylene chloride or NMP exposure to a sufficient extent across the range of uses and exposures of concern."[102]

To support this conclusion, EPA pointed out that TSCA requires EPA to evaluate and then protect against unreasonable risks without regard to cost or other non-risk factors, whereas OSHA is limited to addressing "significant risks of harm" (a term interpreted by the courts to impose a high bar) and is constrained in the restrictions it can impose 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 MC or NMP-containing products and that certain categories of workers are outside its jurisdiction, resulting in a narrower scope of regulation than authorized under TSCA. Although not mentioned by EPA, it is also noteworthy that OSHA has limited authority over small businesses, where much of the use of MC and NMP targeted by EPA occurs, further limiting its ability to provide effective protection to exposed workers.

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[100] 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.

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

[102] 82 FR 7521,

The current OSHA time-weighted average 8-hour Permissible Exposure Limit (PEL) for MC is 25 parts per million (ppm), significantly highly than EPA's analysis of the health effects data on MC would warrant. It was adopted in 1997 and has not been updated since. OSHA has no plans to revise the MC PEL. Nor does it plan to issue a workplace standard for NMP, which now does not exist.[103] Thus, OSHA would almost certainly decline 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."[104]

B. A Section 9(a) Referral to CPSC is Unwarranted

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,[105] TSCA provides that costs and other non-risk 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. Thus, while concerned about continued use of commercial paint removers by consumers, CPSC's Executive Director has advised that "[b]ecause TSCA reaches both occupational and consumer uses, we recognize that EPA could address risks associated with these chemicals in a more cohesive and coordinated manner given that CPSC lacks authority to address occupational hazards."[106] Moreover, CPSC has informed EPA that it has no plans to regulate MC and NMP--containing products.[107]

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 MC and NMP and plan to defer to EPA's greater authority, a referral would be a useless gesture that only delays EPA's rulemaking and would lack any basis in law or in fact.

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[103] According to the March 31, 2016 letter from David Michaels to Assistant Administrator James J. Jones (reference 122 in EPA docket), "OSHA's current regulatory agenda does not include updates to the agency's MC and TCE requirements or the issuance of a new standard for NMP, and at this time OSHA does not anticipate such regulatory activity in the near future."

[104] Id.

[105] 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).

[106] Letter dated June 3, 2016, from Patricia Adkins, CPSC Executive Director, to Assistant Administrator James J. Jones (reference 121 in EPA docket),

[107] Id.

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.[108]

X. THE "GOOD SCIENCE" CONSIDERATIONS OF SECTION 26(h) ARE NOT APPLICABLE TO THIS RULEMAKING AND IN ANY CASE EPA HAS PROPERLY USED THEM IN ITS MC and NMP RISK ASSESSMENTS

Section 26(h) of amended TSCA sets out general "standards" for using science in decision-making under the new law. These standards are not absolute requirements; EPA must "consider" them "as applicable" In individual science assessments. The science standards are straightforward, self-executing and generally consistent with current and past agency practice. Therefore, they do not require significant changes in how EPA conducts risk assessments.

Since the MC and NMP risk assessments were developed under the old law, the provisions of section 26(h) are not "applicable" requirements that the assessment must meet under section 26(l)(4). In any case, as EPA notes,[109] all of the section 26(h) considerations are addressed in the risk assessments, rule preamble and other supporting materials for EPA's proposal. For example:

- EPA has explained how the risk assessments use 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 the two chemicals' 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 risk assessments is "documented" in the assessments and backup materials.
- The risk assessments and backup materials fully "evaluate and characterize . . . the variability and uncertainty" in the assessment and its findings.
- The assessments themselves underwent independent peer review and the science relating to MC's risks to human health has been extensively reviewed over many years by several other agencies inside and outside the US and independent bodies.

CONCLUSION

The use of MC and NMP in paint and coating removal presents a significant and widespread risk of multiple serious health effects to over 60,000 exposed workers and 2 million consumers. Those exposed include women of childbearing age who are at increased risk of adverse developmental effects caused by NMP and other vulnerable populations. EPA has used sound and reliable methods to calculate likely levels of exposure to the two chemicals 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

[108] EPA also considered but correctly rejected a referral to other EPA offices implementing other environmental laws. 82 FR 7521.
[109] 82 FR 7521. .

agencies to protect against cancer and non-cancer effects. EPA's analysis persuasively demonstrates that a ban on MC and NMP use in paint and coating removal is the only remedy that will be effective in eliminating the unreasonable risks they pose and that other approaches will not reliably address these risks and will cost more while delivering less.

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 in accordance with these comments by the one-year deadline in the law.

Respectfully submitted,

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On behalf of:

Alaska Community Action on Toxics
Alliance for a Healthy Tomorrow
Asbestos Disease Awareness Organization
Breast Cancer Prevention Partners
Clean and Healthy New York
Clean Water Action- Connecticut
Earthjustice
Ecology Center
Environmental Health Strategy Center
Healthy Legacy
League of Conservation Voters
Learning Disabilities Association
Maryland PIRG
Oregon Environmental Council
Science and Environmental Health Network
U.S. Public Interest Research Group (PIRG)
VPIRG
WE ACT for Environmental Justice