# FINAL REPORT

**of the**

**Small Business Advocacy Review Panel on**
**EPA's Planned Proposed Rule**
**Toxic Substances Control Act (TSCA) Section 6(a) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint Removers**

**September 26, 2016**

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**Small Business Advocacy Review Panel**
**Proposed Rulemaking: Toxic Substances Control Act (TSCA) Section 6(a) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint Removers**

# 1. INTRODUCTION

This report is presented to the Small Business Advocacy Review Panel (SBAR Panel or Panel) that convened to review the planned proposed rulemaking by the U.S. Environmental Protection Agency (EPA) under Section 6(a) of the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA) to regulate the use of methylene chloride and N-Methylpyrrolidone (NMP) in paint removers. Section 6 provides EPA the authority to address unreasonable risks resulting from the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal of chemicals. Under section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Panel is required to be convened prior to publication of the initial regulatory flexibility analysis (IRFA) that an agency may be required to prepare under the RFA. In addition to EPA's Small Business Advocacy Chairperson, the Panel consists of a representative from the Chemical Control Division of the EPA Office of Pollution Prevention and Toxics, a representative of the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and a representative of the Chief Counsel for Advocacy of the Small Business Administration.

This report includes the following:

- Background information on the proposed rule being developed;
- Information on the types of small entities that would be subject to the proposed rule;
- A description of efforts made to obtain the advice and recommendations of representatives of those small entities;
- A summary of the comments that have been received to date from those representatives; and
- Panel findings and discussion, as required by the statue and described below.

Section 609(b) of the RFA directs the Panel to report on the comments of small entity representatives and make findings on issues related to elements of an IRFA under section 603 of the RFA. Those elements of an IRFA are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;

- Projected reporting, record keeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all other relevant federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- Any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

Once completed, the Panel report is provided to the agency issuing the proposed rule and is included in the rulemaking record. The agency is to consider the Panel's findings when completing the draft of the proposed rule. In light of the Panel report, and where appropriate, the agency is also to consider whether changes are needed to the IRFA for the proposed rule or the decision on whether an IRFA is required.

The Panel's findings and discussion will be based on the information available at the time the final Panel report is drafted. EPA will continue to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process.

Any options identified by the Panel for reducing the rules' regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, and consistent with the Toxic Substances Control Act and its amendments.

# 2. BACKGROUND

## *2.1. Regulatory History*

**Methylene Chloride**

Methylene chloride has been the subject of U.S. federal regulations by EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). While many of the statutes that EPA and other agencies are charged with administering provide statutory authority to address specific sources and routes of methylene chloride exposure, none of these can address the serious human health risks from methylene chloride exposure that EPA has identified.

EPA has issued several final rules and notices pertaining to methylene chloride under EPA's various authorities:

- *Clean Air Act*: Methylene chloride has been designated a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1))CAA). EPA issued a final rule in January 2008 that promulgated national emission standards for hazardous air pollutants

(NESHAP) for area sources engaged in paint stripping, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating operations. In this NESHAP, EPA listed "Paint Stripping," "Plastic Parts and Products (Surface Coating)," and "Autobody Refinishing Paint Shops" as area sources of HAPs that contribute to the risk to public health in urban areas. The final rule included emissions standards that reflect the generally available control technology or management practices in each of these area source categories, and applies to paint stripping operations using methylene chloride. In 2015, EPA issued a final rule for Aerospace Manufacturing and Rework Facilities, which updated a NESHAP from 1995 and added limitations to reduce organic and inorganic facility emissions of HAPs, including methylene chloride, from specialty coating application operations; and removed exemptions for periods of startup, shutdown and malfunction so that affected units would be subject to the emission standards at all times.

- *Solid Waste Disposal Act*: Methylene chloride is listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA) (Code U080).
- *Emergency Planning and Community Right-to-Know Act*: Methylene chloride is listed on the Toxics Release Inventory (TRI) pursuant to section 313 of the Emergency Planning and Community Right-to-Know Act.
- *Safe Drinking Water Act*: The Safe Drinking Water Act (SDWA) requires EPA to determine the level of contaminants in drinking water at which no adverse health effects are likely to occur. EPA has set an enforceable maximum contaminant level for methylene chloride at 0.005 mg/L or 5 parts per billion.

Regulation of methylene chloride by other agencies includes:

- In 1987, CPSC issued a decision to require labeling of consumer products that contain methylene chloride. Labels indicated that inhalation of methylene chloride vapor has caused cancer in certain laboratory animals, and the labels specified precautions to be taken during use by consumers.
- In 1989, FDA banned methylene chloride as an ingredient in all cosmetic products because of its animal carcinogenicity and likely hazard to human health. Before 1989, methylene chloride had been used in aerosol cosmetic products, such as hairspray.
- The Occupational Safety and Health Administration (OSHA) has taken steps to reduce exposure to methylene chloride in occupational settings. In 1997, OSHA lowered the permissible exposure limit (PEL) for methylene chloride from an eight-hour time-weighted average (TWA) of 500 parts per million (ppm) to an 8-hour TWA of 25 ppm. This standard also includes provisions for initial exposure monitoring, engineering controls, work practice controls, medical monitoring, and personal protective equipment (PPE).

Additionally, the National Institute for Occupational Safety and Health (NIOSH) considers methylene chloride a potential occupational carcinogen. NIOSH also in 2013 issued a

hazard alert for fatal hazards related to methylene chloride use in bathtub refinishing.[1]

**N-Methylpyrrolidone (NMP)**

While many of the statutes that EPA is charged with administering (such as the Clean Air Act and Resource Conservation and Recovery Act) provide statutory authority to address specific sources and routes of NMP exposure, none of these can address the serious human health risks from NMP exposure in paint and coating removal that EPA has identified.

- NMP is listed on the Toxics Release Inventory (TRI) and is therefore subject to reporting pursuant to Section 313 of the Emergency Planning and Community Right-to-Know Act.
- NMP is currently approved for use by EPA as a solvent and co-solvent inert ingredient in pesticide formulations for both food and non-food uses and is exempt from the requirements of a tolerance limit.

In 2013, CPSC issued a fact sheet warning the public about the hazards of paint strippers, including those containing NMP, and included recommendations to use PPE when using products containing this chemical. The factsheet was updated in 2015.[2] CPSC has not regulated NMP.

## *2.2. Risk Assessments for Methylene Chloride and NMP*

**Methylene Chloride**

The Office of Pollution Prevention and Toxics (OPPT) identified and selected methylene chloride for risk evaluation as part of its TSCA Work Plan for Chemical Assessments. Methylene chloride is a volatile compound that is classified as a human carcinogen. Methylene chloride is used in commercial processes and in consumer products in residential settings.

The final risk assessment for methylene chloride (released in August 2014) evaluated human health risks to consumers and workers, including bystanders, from exposures to methylene chloride in a variety of paint and coating removal scenarios. Table 1 below summarizes the findings of this risk assessment.

[1] *Available at* http://blogs.cdc.gov/niosh-science-blog/2013/02/04/bathtub-refinishing/
[2] *Available at* http://www.cpsc.gov/Global/Safety%20Education/Home-Appliances-Maintenance-Structure/423%20Paint%20Stripper%20Publication.pdf

***Table 1: Summary of Risk Assessment Findings for Methylene Chloride***

| | **Methylene Chloride** |
|---|---|
| **Routes of exposure assessed** | Inhalation exposure |
| **Acute effects and risk** | Acute effects: Confusion, incapacitation, and death. Acute risks of concern were found in most exposure scenarios including when respiratory protection is worn |
| **Chronic effects and risk** | Chronic effects: Cancer and liver toxicity. Cancer risks greater than $1.0x10^{6}$ were identified, and chronic non-cancer margins of exposure (MOEs) were less than 10 from chronic (lifetime) exposure in all except scenarios evaluated except the lowest exposure levels when PPE is worn |
| **Bystander** | Acute MOEs less than 10 were identified for bystanders except in lowest-exposure scenarios |

In this assessment, EPA estimated the size of the occupational population directly exposed to paint removers containing methylene chloride at over 230,000 workers nationwide[5]. This estimate only accounts for workers performing paint removal using methylene chloride and does not include other workers within the facility who may be indirectly exposed. OPPT found limited data on numbers of workers exposed to chemical paint removers in shops conducting these operations; OPPT relied on an estimation approach to estimate the total number of exposed workers from the technical support document for the 2007 National Emission Standards for Hazardous Air Pollutants Paint Stripping Operations at Area Sources proposed rule. This estimate has been revised slightly since the risk assessment. Populations exposed to methylene chloride during paint and coating removal include workers, consumer users, and bystanders to anyone using methylene chloride for paint and coating removal (including children in residences where these activities are conducted). EPA estimates that, annually, there are approximately 45,000 workers at 13,000 commercial operations conducting paint and coating removal with methylene chloride, and approximately 2.5 million consumers who use paint and coating removal products containing methylene chloride each year.

EPA has obtained additional qualitative data on uses and substitutes from other federal agencies, including users (such as the Department of Defense) and regulatory agencies (such as the Occupational Safety and Health Administration) as well as States and regulatory agencies in other countries. Additionally, OPPT engaged in discussions with manufacturers of paint removal products containing methylene chloride or alternatives on several occasions, including a manufacturer's forum in December 2014. OPPT continues to engage with experts and companies to obtain additional information that could help inform rulemaking and other risk reduction actions.

The final risk assessment for methylene chloride focused on occupational and consumer paint and coating removal with methylene chloride. Specifically, EPA evaluated the following exposure scenarios:

Occupational Scenarios

Twenty occupational scenarios for paint removal activities were evaluated in EPA's risk assessments, considering a range of possible air concentrations and user practices, based on measured and modeled data. These scenarios were constructed to evaluate acute and chronic exposure to methylene chloride in occupational paint removal in industries such as:

- Professional contractors;
- Bathtub refinishing;
- Automotive refinishing;
- Furniture refinishing;
- Art restoration and conservation;
- Aircraft paint stripping;
- Ship paint stripping; and
- Graffiti removal.

In these settings, the population of interest consisted of workers using the products and workers nearby not using the products, who may be exposed to the chemicals. The route of exposure evaluated for methylene chloride was inhalation. Some scenarios included assessments of exposure when the worker was wearing PPE.

Consumer Scenarios

Seven scenarios for consumer use of these products were evaluated. These scenarios included variations on:

- how the product was applied (by brush or spray)
- location of use (workshop or a bathroom)
- effects for users and non-users in the residence (including children)

All seven scenarios were constructed to evaluate acute exposure to these chemicals for users and bystanders when used for occasional projects; EPA assumed that consumers would not generally do paint stripping jobs on a regular basis in their residences, allowing sufficient time between exposures to clear methylene chloride metabolites from the body.

**Methylene Chloride Risk Findings**

The EPA risk assessment identified acute, chronic non-cancer, and cancer risks for commercial users of methylene chloride. EPA also found acute risks to consumers.

EPA found acute risks for central nervous system effects in nearly all occupational scenarios, irrespective of the absence or presence of respirators and both in central-tendency and worst-case assumed air concentrations of methylene chloride. Additionally, acute risks for incapacitating central nervous system effects were found for workers who had no respiratory protection in most industries, or with respirators with an assigned protection factor (APF) 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. 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.

EPA also identified risk of liver toxicity following chronic inhalation exposure to methylene chloride during paint and coating removal by commercial users and occupational bystanders. The assumptions varied, such as use of PPE, such as an air-supplied or other respirator, and duration of time spent in contact with the product (days and years). Workers and occupational bystanders in most industries evaluated were identified as 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.

For commercial users and bystanders, EPA also identified cancer risks as a result of chronic exposure to methylene chloride in paint and coating removal. Methylene chloride is a likely human carcinogen; cancer risks determine the incremental probability of an individual developing cancer over a lifetime following exposure to the chemical under specified use scenarios. Common cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk of one in one million or one in one in ten thousand ($1x10^{-6}$ or $1x10^{-4}$). Estimates of cancer risk should be interpreted as the incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen (i.e., incremental or excess individual lifetime cancer risk). Workers and occupational bystanders showed excess cancer risks for all of the industries evaluated when exposed to paint and coating removal with methylene chloride for 250 days per year for 40 years with no respiratory protection.

Following the methylene chloride risk assessment, EPA conducted additional analyses to inform risk management. These analyses were based on the peer-reviewed methodology used in the methylene chloride risk assessment and included identification additional exposure scenarios, addition of local exhaust ventilation, use of different types of PPE, additional consumer exposure scenarios, and methods of monitoring to determine workplace exposures. Results from these analyses were presented to the SERs to inform their advice to EPA; however, the complete analyses were not provided to the SERs. These analyses will be available in the docket for the proposed rule (EPA-HQ-OPPT-2016-0231).

**NMP**

OPPT identified and selected NMP for risk evaluation as part of its TSCA Work Plan for Chemical Assessments. Developmental toxicity effects are associated with certain uses of NMP. NMP is used in commercial processes and in consumer products in residential settings.

The final risk assessment for NMP (released in March 2015) evaluated human health risks to consumers and workers, including bystanders, from exposures to these chemicals when used in a variety of paint removal scenarios. Table 2 below summarizes the findings of this risk assessment.

***Table 2: Summary of Risk Assessment Findings for NMP***

| | NMP |
|---|---|
| **Routes of exposure assessed** | Exposure through dermal, vapor-through skin, and inhalation |
| **Acute effects and risk** | Acute effects: Fetal mortality (developmental effects). Concern is for women of child-bearing age. Acute risks of concern were found if the products were used on a single day, for 8 hours, with or without gloves, or for 4 hours without gloves |
| **Chronic effects and risk** | Chronic effects: Reduced fetal body weight (developmental effects). Concern is for women of child-bearing age. Chronic risks of concern were found if used for 8 hours per day for more than 5 consecutive days, regardless of whether or not gloves are used. Chronic risks of concern were found if used for more than 4 hours per day for more than 5 consecutive days, without gloves |
| **Bystander Routes of exposure** | No risks to bystanders |

In this assessment, EPA estimated the size of the occupational population directly exposed to paint removers containing NMP at over 230,000 workers nationwide. This estimate only accounts for workers performing paint removal using methylene chloride and does not include other workers within the facility who may be indirectly exposed. OPPT found limited data on numbers of workers exposed to chemical paint removers in shops conducting these operations; OPPT relied on an estimation approach to estimate the total number of exposed workers from the technical support document for the 2007 National Emission Standards for Hazardous Air Pollutants Paint Stripping Operations at Area Sources proposed rule. This estimate has been revised slightly since the risk assessment. Populations exposed to NMP during paint and coating removal include workers and consumer users. EPA estimates that, annually, there are approximately 54,000 workers at 2,500 commercial operations conducting paint and coating removal with NMP, and approximately 1.4 million consumers who use paint and coating removal products containing NMP each year.

EPA has obtained additional qualitative data on uses and substitutes from other federal agencies, including users (such as the Department of Defense) and regulatory agencies (such as the Occupational Safety and Health Administration) as well as States and regulatory agencies in other countries. Additionally, OPPT engaged in discussions with manufacturers of paint removal products containing NMP or alternatives on several occasions, including a manufacturer's forum in December 2014. OPPT continues to engage with experts and companies to obtain additional information that could help inform rulemaking and other risk reduction actions.

The final risk assessment for NMP focused on the occupational and consumer uses of paint removers containing these chemicals. Specifically, EPA evaluated the following exposure scenarios:

Occupational Scenarios

Twenty occupational scenarios for paint removal activities were evaluated in EPA's risk assessment, considering a range of possible air concentrations and user practices, based on measured and modeled data. These scenarios were constructed to evaluate acute and chronic exposure to these chemicals when used in occupational paint removal in industries such as:

- Professional contractors;
- Bathtub refinishing;
- Automotive refinishing;
- Furniture refinishing;
- Art restoration and conservation;
- Aircraft paint stripping;
- Ship paint stripping; and
- Graffiti removal.

In these settings, the population of interest consisted of workers using the products and workers nearby not using the products, who may be exposed to the chemicals. The routes of exposure considered for NMP were inhalation, dermal, and vapor-through skin. Some scenarios included assessments of exposure when the worker was wearing PPE.

Consumer Scenarios

Seven scenarios for consumer use of these products were evaluated. These scenarios included variations on:

- how the product was applied (by brush or spray)
- location of use (workshop or a bathroom)
- effects for users and non-users in the residence (including children)

All seven scenarios were constructed to evaluate acute exposure to NMP for users and bystanders when used for occasional projects; EPA assumed that consumers would not generally do paint stripping jobs on a regular basis in their residences, allowing sufficient time between exposures to clear NMP from the body.

**NMP Risk Findings**

The EPA risk assessment identified acute risks through dermal contact, inhalation, and vapor-through-skin exposure for occupational and bystander scenarios of paint and coating removal with NMP. Risks are to pregnant women. Acute risks of fetal death were identified for commercial users of NMP for paint and coating removal in several scenarios. The 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, such as concentration of NMP in the product; 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. 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.

EPA also assessed risks of chronic exposure to NMP by commercial users. This assessment used decreased fetal body weight as the critical endpoint. The selected exposure scenarios represented combined inhalation, dermal, and vapor-through-skin exposures with a range of conservative assumptions. As described earlier, the assumptions were then varied, such as use of PPE (respirator and gloves), duration of time spent in contact with the product, and the concentration of NMP in the product. EPA assessed risks for low birthweight for occupational and bystander exposure scenarios of paint and coating removal with NMP. No risks were identified for occupational bystanders.

Following the NMP risk assessment, EPA conducted additional analyses to inform risk management and to expand on the consumer exposure scenarios. These analyses were based on the peer-reviewed methodology used in the NMP risk assessment and included identification of additional exposure scenarios, addition of local exhaust ventilation, use of different types of PPE, and methods of monitoring to determine workplace exposures. Results from these analyses were presented to the SERs to inform their advice to EPA; however, the complete analyses were not provided to the SERs. These analyses will be available in the docket for the proposed rule (EPA-HQ-OPPT-2016-0231).

## *2.3. The Frank R. Lautenberg Chemical Safety for the 21st Century Act*

By the time the Small Business Advocacy Review Panel met, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (P.L. 114-182) had been passed by Congress. The President subsequently signed the bill into law on June 22, 2016.

The law preserves EPA's ability to address risks presented by the manufacture, processing, distribution in commerce, or use of methylene chloride and NMP that were identified in the 2014 TSCA Work Plan Chemical Risk Assessment for methylene chloride and in the 2015 TSCA Work Plan Chemical Risk Assessment for NMP. Also, the options available to EPA under TSCA § 6(a) for addressing these unreasonable risks have not been changed by the law.

To promulgate a rule under TSCA §6(a), TSCA §6(c)(2)(C) of the new law requires EPA to 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. Additionally, under TSCA §26(h) EPA must use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science. It is important to note that, per TSCA §26(l), because the methylene chloride and NMP risk assessments were completed prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA may publish proposed and final rules under §6(a) that are consistent with the scope of the completed

risk assessments for these chemical substance and consistent with other applicable requirements of §6.

## *2.4. Description of the Rule and Scope*

Given the risks identified by EPA in the *TSCA Work Plan Chemical Risk Assessment for* Methylene Chloride in Paint Removal and in the *TSCA Work Plan Chemical Assessment for NMP in Paint Removal*, EPA is proposing to regulate uses of methylene chloride and NMP in commercial and consumer paint removal under TSCA § 6(a).

Under TSCA § 6(a), if the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the Agency's risk evaluation, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

The table below summarizes the regulatory requirements EPA can utilize, separately or in combination, under TSCA § 6(a).

***Table 1. Regulatory Requirements Available under TSCA § 6(a).***

| TSCA § | Requirement |
|---|---|
| **6(a)(1)** | A requirement **(A)** prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or **(B)** limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce. |
| **6(a)(2)** | A requirement **(A)** prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for **(i)** a particular use or **(ii)** a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or **(B)** limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for **(i)** a particular use or **(ii)** a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement. |
| **6(a)(3)** | A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator. |
| **6(a)(4)** | A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection. |
| **6(a)(5)** | A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture. |

| TSCA § | Requirement |
|---|---|
| **6(a)(6)** | **(A)** A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes. **(B)** A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal. |
| **6(a)(7)** | A requirement directing manufacturers or processors of such substance or mixture **(A)** to give notice of such determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, **(B)** to give public notice of such determination, and **(C)** to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed. |

The options under consideration would not duplicate other federal regulations, and current federal regulations discussed previously in Section 2.1 do not protect adequately against the risks that EPA has identified with use of methylene chloride and NMP in paint removal.

# 3. OVERVIEW OF OPTIONS UNDER CONSIDERATION

EPA has considered a number of regulatory options under section 6(a). In assessing these options, EPA considered a wide range of exposure scenarios and risk reduction practices and options. Through Agency review and stakeholder input, two options have been identified as reducing exposures sufficiently that acute, chronic, and cancer risks are reduced to the extent necessary so that methylene chloride and NMP no longer presents an unreasonable risk with respect to their use in in paint and coating removal. These options are currently being considered and evaluated by EPA, and are not final at this time.

## *3.1. Prohibit manufacturing (including import), distribution, and use of methylene chloride or NMP in paint and coating removal*

Specifically, this option would:

- Prohibit the manufacturing (including import), processing, and distribution in commerce of methylene chloride and NMP in paint and coating removal products under §6(a)(2),
- Prohibit the commercial use of methylene chloride and NMP in paint and coating removal in under §6(a)(5),
- Require downstream notification of the prohibitions and recordkeeping by chemical manufacturers and processors when distributing NMP for other uses under §6(a)(3).

### *3.2. Allow certain commercial uses with personal protective equipment (PPE) and other restrictions under TSCA §6(a)(5)*

For methylene chloride, this option would allow use of methylene chloride for certain types of paint and coating removal with appropriate PPE, such as an air-supplied respirator of APF 1,000 or 10,000, or equivalent air exposure limit, and associated restrictions under TSCA §6(a)(5). Specifically, for any uses of methylene chloride as a paint remover that would continue, this would require:

- Respiratory protection program under §6(a)(5):
  - Training, medical monitoring, re-fitting, and other components of respirator protection programs,
  - A respirator with APF 1,000 would be required in most scenarios, with APF 10,000 when immersion methods of paint removal are used. APF is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees,
  - Workers nearby (occupational bystanders) would be required to wear respirators as well, or be excluded from the area,
  - As an alternative, work places could meet an air exposure limit of 0.2 ppm.
- Also required:
  - Downstream notification and recordkeeping by manufacturers, processors, and distributors (but not retailers) of the prohibitions for this use under §6(a)(3),
  - Packaging of all paint and coating removal products containing methylene chloride in volumes no less than 55 gallon drums, under §6(a)(3), to prevent diversion to prohibited consumer uses.

For NMP, this option would allow use of NMP for certain types of paint and coating removal with appropriate product reformulation and PPE, such as specialized gloves and respiratory protection (e.g., a respirator with APF 10), or equivalent air exposure limit, and associated restrictions under TSCA §6(a)(5). Specifically, for any uses of NMP as a paint remover that would continue, this would require:

- Paint remover products would be required to be reformulated to contain no more than 25% NMP by weight under §6(a)(2),
- Manufacturers would be required to test their formulated product to determine which gloves would be protective under §6(a)(4),
  - Glove breakthrough varies, depending on which solvents are present
- Manufacturers would be required to label their products and SDS with the information about gloves under §6(a)(3),
- Commercial users would be required to wear the specified gloves and a respirator (APF 10) under §6(a)(5),
  - Gloves may not be re-worn; must be replaced after each 8-hour shift (minimum)
  - Workplaces may meet an air exposure limit (of 1 ppm) instead of requiring to wear APF 10

- Also required:
  - Downstream notification and recordkeeping by manufacturers, processors, and distributors of the prohibitions for this use under §6(a)(3),
  - Packaging of all paint and coating removal products containing methylene chloride in volumes no less than 55 gallon drums, under §6(a)(3), to prevent diversion to prohibited consumer uses.

# 4. APPLICABLE SMALL ENTITY DEFINITIONS

The Regulatory Flexibility Act (RFA) defines small entities as including "small businesses," "small governments," and "small organizations" (5 USC 601). The regulatory revisions being considered by EPA for this rulemakings are expected to affect a variety of small businesses, small governments, and small organizations. The RFA references the definition of "small business" found in the Small Business Act, which authorizes the Small Business Administration to further define "small business" by regulation. The SBA definitions of small business by size standards using the North American Industry Classification System (NAICS) can be found at 13 CFR 121.201.

The detailed listing of SBA definitions of small business for affected industries or sectors, by NAICS code, is included in Table 3 in Section 5, below.

# 5. SMALL ENTITIES THAT MAY BE SUBJECT TO THE PROPOSED REGULATION

The following table lists industries/sectors potentially affected by the proposed regulation.

***Table 3: Industry Sectors and Small Entities Potentially Affected by EPA's Planned Action***

| NAICS | NAICS Description | SBA Size Standard[3] |
|---|---|---|
| 336611 | Ship building and repairing | 1,000 employees |
| 336411 | Aircraft manufacturing | 1,500 employees |
| 712110 | Museums | $27.5 million |
| 711510 | Independent Artists, Writers, and Performers | $7.5 million |
| 811420 | Reupholster and furniture repair | $7.5 million |
| 811121 | Automotive body, paint, and interior repair and maintenance | $7.5 million |
| 238330 | Flooring contractors | $15 million |
| 238320 | Painting and wall covering contractors | $15 million |

[3] Source: U. S. Small Business Administration Table of Small Business Size Standards Available at: https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf

# 6. SUMMARY OF SMALL ENTITY OUTREACH

EPA conducted an online solicitation to identify small businesses and trade associations interested in participating in the Small Business Advocacy Review (SBAR) Panel process by serving as Small Entity Representatives (SERs). EPA issued a press release inviting self-nominations by affected small entities to serve as SERs. The press release directed interested small entities to a web page where they could indicate their interest. EPA launched the website on March 30, 2015, and accepted self-nominations until April 10, 2015. EPA also contacted potential SERs directly throughout 2015 to generate interest.

On February 4 and 10, 2016, EPA held kick-off meetings with representatives from the Office of Advocacy of the Small Business Administration (SBA) and the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB). At those meetings, EPA gave a presentation, answered questions on the options being considered for the rule, and provided follow-up information.

After identifying a list of potential SERs (shown in Section 7), EPA conducted a Pre-Panel outreach meeting with potential SERs on March 17, 2016. To help them prepare for the meeting, EPA sent materials to each of the potential SERs via email. The materials shared with the potential SERs during the Pre-panel outreach meeting are included in Appendix A. For the March 17, 2016, Pre-Panel outreach meeting with the potential SERs, EPA also invited representatives from SBA and OMB. A total of 11 potential SERs participated in the meeting. EPA presented an overview of the SBAR Panel process, an explanation of the planned rulemaking, and technical background.

This outreach meeting was held to solicit feedback from the potential SERs on their suggestions for the upcoming rulemaking. EPA asked the potential SERs to provide written comments by March 31, 2016, with an extension to April 6, 2016. Comments made during the March 17, 2016, outreach meeting and written comments submitted by the potential SERS are summarized in section 8 of this document. Written comments appear in Appendix B.

On June 1, 2016, EPA's Small Business Advocacy Chairperson convened this Panel. The Panel outreach meeting was held on June 15, 2016 with 17 SERs in attendance. As with the Pre-Panel outreach meeting, EPA sent materials to each of the SERs via email. The materials shared with the potential SERs during Panel outreach meeting are included in Appendix A. For the Panel meeting, EPA invited representatives from SBA and OMB. EPA presented similar materials at the Pre-Panel meeting with an overview of the SBAR Panel process, an explanation of the planned rulemaking, and technical background.

# 7. LIST OF SMALL ENTITY REPRESENTATIVES

This list of potential SERs was identified at the time of the Pre-panel meeting and prior to the SBAR Panel meeting. See Table 4 below for the list of potential SERs.

***Table 4. Paint Removers Panel Potential SERs***

| ENTITY |
|---|
| Benco Sales Inc (TN) |
| Besway Systems Inc (TN) |
| Consumer Specialty Products Association (Washington DC) |
| Custom Tub and Tile Resurfacing (Washington, DC) |
| Cyphers & Kallander Refinishers (WA) |
| Dennie's Resurfacing LLC (PA) |
| Dumond Chemicals, Inc (PA) |
| Fargo Painting (AZ) |
| Federal Restorations (MD) |
| Finishing Trades Institute (MD) |
| Interlux Paints (MD) |
| International Union of Painters and Allied Trades (MD) |
| Looney and Sons (VA) |
| Macfee Refinishing (KS) |
| Osprey Composites (MD) |
| Professional Bathtub Refinishers Association (TX) |
| Restorations Unlimited (VA) |
| Savogran Company (MA) |
| Sunnyside Corp. (IL) |
| Tub Klass (NJ) |
| WM Barr (TN) |

# 8. SUMMARY OF COMMENTS FROM SMALL ENTITY REPRESENTATIVES

## *8.1. Summary of Oral Comments and Pre-Panel Meeting Discussion, March 17, 2016*

The following is a summary of the oral comments from the Pre-Panel Meeting discussion from the potential SERs, either made by phone or in person. The comments are grouped by use of paint removers.

**Bathtub Refinishers:**

- Bathtub refinishers perform the majority of their work at job sites (e.g., customers' homes).

- Paint stripping a single tub can take up to approximately one hour, and completing an entire job may take two to four hours. A bathtub refinisher may perform paint stripping two or three times per day.
- Bathtub refinishers may use ventilation units or commercial fans at job sites to provide ventilation when using methylene chloride, but most refinishers do not use respirators.
- Some bathtub refinishers find some alternative chemical strippers successful (such as benzyl alcohol). A key requirement for alternative chemical strippers for bathtub refinishing is that they can work within the typical job duration. Strippers that take too long to work, or that must set overnight, are not acceptable.
- Several bathtub refinishers are supportive of banning methylene chloride because they are aware of its health hazards for their workers and their customers.

**Painters:**

- Painters and finishing trades' contractors perform their work at job sites (e.g., customers' homes or commercial sites).
- Paint stripping does not represent a majority of the work performed by this industry.
- While abrasion methods for paint removal find success in this industry, some paint removing applications for wood substrates require chemical stripping because abrasion methods could damage the wood substrate.
- One SER discussed experiencing health effects from using methylene chloride.
- Multiple SERs supported EPA prohibiting the use of methylene chloride for paint removal.
- One SER suggested that, if EPA does not ban methylene chloride, EPA consider limiting the sale of methylene chloride to paint stores or to licensed painters.

**Furniture Refinishers:**

- Furniture refinishing is performed in a shop (not in customer's homes).
- Furniture refinishers are able to install mechanical ventilation to attempt to mitigate methylene chloride exposures during paint stripping.
- Methylene chloride is preferred for paint stripping wood furniture because it works rapidly and well on wood substrates. Abrasion methods are not as acceptable as they can damage the wood substrate. One furniture refinisher expressed concerns about alternative chemical strippers that might pose flammability issues.
- One SER indicated he performs methylene chloride-based paint stripping two to three hours per week on average.
- One SER indicated he has a supplied-air respirator, but only uses it when finishing large furniture pieces, which occurs rarely.

**Manufacturers, Formulators, Distributors and Suppliers:**

- One SER indicated that methylene chloride costs less than benzyl alcohol or NMP paint removers, and works efficiently.
- Abrasive methods are not acceptable for wood substrates as they can damage the wood.

## *8.2. Summary of Written Comments from potential SERs following the Pre-Panel meeting, March 17, 2016*

EPA received written comments from five Small Entity Representatives between March 17 and April 6, 2016. Three comments were from product manufacturers or formulators; two were from paint remover users. The following is a summary of the written comments submitted by the potential SERs. A copy of each of the comments submitted by the potential SERs is included in Appendix B.

**SER Comments on the Utility of Methylene Chloride and NMP as Paint and Coating Removers:**

- Methylene chloride strippers are effective on older coatings such as lacquers, shellac and varnishes, as well as newer cross-linked coatings like conversion finishes, UV finishes, epoxies, polyurethanes, and conversion lacquers.
- Alternative paint/coating removal products have little or no effect on newer coatings, have workplace hazards, and environmental hazards such as flammability and high VOC levels that are not present in methylene chloride strippers.
- Certain conditions, such as stripping a hand-carved door, expensive cabinets, or antique furniture, require a gel or liquid paint stripper in order to not damage the wood profile.
- EPA should further evaluate a preferred alternative to methylene chloride and NMP as paint strippers for bathtub refinishing, as alternatives do not perform as quickly.
- The increased time needed to complete a job using an alternative product increases a worker's exposure duration, which could increase risk of an adverse health outcome.

**SER Comments on the Health Effects:**

- Certain long term epidemiology studies of worker populations exposed to methylene chloride for a long duration at high concentrations do not show the same margins of exposure or inhalation unit risk as EPA's risk assessment calculations. According to the comment, these studies do not support an increase in cancer deaths from exposure to methylene chloride.
- The suggested alternative paint and coating removal products pose as many health hazards as methylene chloride and can be prevented using PPE.

**SER Comments on the Availability of Methylene Chloride and NMP:**

- Paint removers containing methylene chloride are available in pint, quart, and gallon size containers. These paint removers are the most common in today's market, and are the most effective solvents.

- Methylene chloride and NMP should not be available to the general public for paint removal in any size or quantity.
- Methylene chloride and NMP should only be sold through paint stores, not Home Depot or similar stores in order to make it difficult for the average homeowner to be able to purchase these products.

**SER Comments on the Regulatory Approaches:**

- The regulatory approach to limit the sale of methylene chloride paint removers to 55 gallon drums is counterproductive to the objective of reducing the risk of over exposure because an additional hazard is created for the end user when transferring the product to a secondary container.
- States have different paint contractor licensing rules, but a federal license, in order to obtain methylene chloride and NMP, could allow the industry to operate.
- EPA should consider labeling as a regulatory option because the formulating community favors enhanced labeling in order to prevent products from being used in enclosed spaces. SERs would like to see the data showing why enhanced labeling would not be effective.
- One commenter questioned EPA's authority to regulate methylene chloride in the workplace since OSHA conducted a rigorous process in evaluating the workplace standard permissible exposure limit (PEL) of 25 ppm. This commenter is wondering the basis EPA had to propose an alternative workplace limit over 100 times lower than OSHA's standard, which is supposed to address any significant risk.

**SER Comments on the Negative Impacts to Small Businesses:**

- Selling these components only in 55 gallon drums will destroy this sector of the industry since a small business does not have a large budget in order to purchase large quantities of methylene chloride or NMP.
- Most of the formulators of methylene chloride and NMP are small businesses, but EPA did not present enough information about the impact on formulators in the retail paint remover market.
- Sale of methylene chloride is not declining as EPA's industry research claimed; one commenter said sales have been relatively steady for their company.
- Alternatives to methylene chloride paint removers are often cost-prohibitive (some are two or more times as expensive).
- EPA did not calculate cost estimates correctly in the assessment; methylene chloride can be purchased in bulk for $2.00-3.00 per gallon, benzyl alcohol in bulk is about $20.00, and a greater quantity of benzyl alcohol is needed per job because it is not as effective at paint/coating removal as methylene chloride.

## *8.3. Summary of Oral Comments and Panel Meeting Discussion, June 15, 2016*

The following is a summary of the oral comments from the Panel Meeting discussion from the SERs, either made by phone or in person. The comments are grouped by use of paint removers.

**Bathtub Refinishers:**

- Generally, the bathtub refinishers agreed that there is a lack of training and education on how to properly use methylene chloride in their industry. Some bathtub refinishers described poor training among professional bathtub refinishers and lack of education among "fly-by-night" refinishers and consumers.
- Generally, bathtub refinishers felt methylene chloride is the best working product for their industry, and NMP is not an effective product. Alternatives take much longer to remove coatings and time is the driving factor in their business. One bathtub refinisher stated he is committed to using methylene chloride-alternative products (e.g. benzyl alcohol and sanding). Another bathtub refinisher stated soft media abrasive blasting (e.g., walnut shell blasting) is not a viable alternative for bathtub refinishing.
- One SER said common coatings encountered in bathtubs are epoxy and polyurethane coatings and when multiple coats are applied to a bathtub, each coat is removed as a single layer. Therefore, removing multiple coats can take up to three to four hours. The coatings are typically applied by a tradesman.
- Multiple SERs stated they purchase 55-gallon drums of methylene chloride and fill smaller containers to take to job sites, but some smaller companies may work out of their homes and 55-gallon drums are not practical for them given the shelf life of methylene chloride.
- Two SERs indicated that exposure duration to methylene chloride is less than 8 hours per day and that the process takes about half an hour at a time. One SER said they refinish bathtubs about 10 hours per week and another stated 1 hour per day.
- The SERs in attendance said they use ventilation systems, either with a 12-inch or 8-inch hose that cost about $75-$300. One SER said they believe that most refinishers do not know how to properly set up a ventilation system at job sites.
- PPE mentioned by the SERs included use of a respirator, gloves, goggles, and ventilation systems.

**Painters:**

- Methylene chloride is the best-working paint remover product, especially because other products can raise the grain of the wood. The SER did not specifically indicate what other products he was referring to.
- One SER supported keeping methylene chloride out of the hands of the public, but finding ways to continue to make it available to contractors.

- Restricting methylene chloride sales to larger volume containers is not feasible as painters paint strip infrequently and buy one gallon of methylene chloride at a time.
- One SER said that they do not conduct paint stripping frequently and most of the stripping jobs are small, such as a door, or occasionally a larger job (e.g., cabinets), but this SER does not generally need to use ventilation on job sites. However, sometimes it is necessary to use a respirator and a fan.
- The SER noted that while legal employers report injuries appropriately, "fly-by-night" employers may not. Therefore, actual methylene chloride-related injuries may be greater than estimated through employer injury reporting databases.

**Furniture Refinishing:**

- One SER described his furniture refinishing operation in the following way: if the item is coated with a heavy lacquer, he begins with sanding the item with 80 grit sandpaper. He then places the item in a paint stripping tank. He does not remain near the tank during this process. Rather, he periodically checks on the item, approximately every 15 to 20 minutes, to agitate the item in the tank and check on its progress. In addition, he has a system in which methylene chloride is sprayed onto the item while in a trough, and the methylene chloride is drained through the bottom of the trough and recycled.
- Both furniture refinishing SERs operate from a commercial facility with ventilation systems in place but one also performs operations at the customer site when required. Ventilation systems include an "air shower" system in which air pushes downward and "air suckers" near the floor draw air inwards (implying a downdraft ventilation system). Workers wear gloves and respirators for paint stripping operations. One SER said the ventilation and work practices to meet OSHA standards for methylene chloride are cost significant. The SERs supported use of PPE.
- Both furniture refinishing SERs have a separate room they use for paint stripping.
- Both furniture refinishing SERs purchase methylene chloride by the 55-gallon drum. One SER indicated that he purchases 1-gallon of methylene chloride for on-site jobs.
- One furniture refinishing SER estimated that paint stripping is about one-third of their business. The other SER estimated that, while paint stripping is about 20% of a given job, it affects about three-fourths of their business.
- One SER said they previously tried an NMP product but did not find it to be effective. Other alternatives could be effective, though composition of the formulation was not stated.
- One SER said they use dip stripping on furniture to remove lacquers, clear finishing, have received a few radiators but is a long, complicated process to remove paint, and window sills/windows.
- One SER said they had an oxygen bottle with mask in the past that was purchased with a doctor's prescription in case an employee felt light-headed, but no longer have the oxygen bottle.

- One SER supported improving product labeling and considerations to ban 5-gallon and smaller sizes of methylene chloride and to remove methylene chloride from retailers. The other SER supported a regulatory option that restricts methylene chloride use to trained and licensed users while not being available to consumers.
- Furniture refinishing for very small businesses is sometimes performed in the refinishers' home or small warehouse.

**Manufacturers, Formulators, Distributors and Suppliers:**

- One SER indicated that their largest market of methylene chloride-based paint stripper is to consumers. One SER estimates that only 1% of methylene chloride is used in bathtub refinishing.
- One SER stated that their NMP-based products are almost entirely sold to consumers, but acknowledged this product is not effective on all coatings (e.g., chemical-resistant coatings).
- One SER has intentionally kept their products out of big-box stores and sells to dedicated retailers through a distribution network that distinguishes between consumer and professional end-users.
- One SER also stated that they are working with the Consumer Product Safety Commission (CPSC) to redesign their label with improved language and pictograms, with the intention of increasing awareness of the hazards.
- SERs discussed whether the EU methylene chloride regulations have been successful and could serve as a model for EPA. There was disagreement among the SERs and no consensus was reached.
- One SER indicated alternatives are more expensive than methylene chloride and some alternatives have fluctuating prices. They also indicated some alternatives have flammability concerns. Other alternatives have to meet other federal regulations, such as acetone-toluene-methanol (ATM) products have to meet the volatile organic compound (VOC) requirements and this composition has a low flash point, presenting a flammability hazard.
- Multiple SERs indicated alternatives do not perform as well on chemical-resistant coatings, but one SER stated methylene chloride might not be necessary for newer coatings.
- One SER stated that consumers have a low incidence of injury due to methylene chloride.
- One SER stated that EPA did not evaluate the full cost of a potential methylene chloride ban to product formulators because EPA did not account for the complete elimination of product lines that would result from banning methylene chloride. This ban could put some companies out of business, especially small formulating companies.
- One SER indicated that they have worked with NIOSH on ventilation system design, and noted that it is nearly impossible to achieve methylene chloride concentrations of 25 ppm or less using ventilation systems alone.

## *8.4. Summary of Written Comments from SERs following the Panel meeting, June 15, 2016*

EPA received written comments from 9 Small Entity Representatives between June 15 and July 1, 2016. 1 comment was from a painter; 2 comments were from furniture refinishers; 5 comments were from product manufacturers or formulators; 1 comment was from a trade association; 1 comment was claimed as Confidential Business Information. Two companies, W.M Barr & Company Inc. and Savogran Company, submitted a letter from the Consumer Product Safety Commission (CPSC) titled Cautionary Labeling of Methylene Chloride-Containing Paint Stripper Products, which is included in Appendix B. The following is a summary of the written comments submitted by the potential SERs. A copy of each of the comments submitted by the potential SERs is included in Appendix B.

**Painters:**

- One SER believes methylene chloride and NMP should not be available to the general public in any size or quantity.
- One SER stated that certain conditions exist, such as stripping a hand-carved door, expensive cabinets, or antique furniture that require a gel/liquid stripper such as methylene chloride products to not damage the wood profile as other methods would.
- One SER described how states handle paint contractor licensing in a separate fashion, if at all. Having a federal licensing program could allow a small segment of the industry to exist. Licensing could be similar to the EPA Lead Renovation, Repair, and Painting (RRP) Rule. The licensing process annually could be somewhat costly (e.g., $400-$500) which could possibly keep the average homeowner at bay.
- One SER said that for smaller businesses, 1 gallon containers are critical. 55 gallon drums are impractical for most painting contractors and would destroy this industry.

**Furniture Refinishers:**

- Approximately 20 to 25% of one SER's total annual revenue is attributed to the paint and varnish removal (stripping) portion of any finishing product.
- One SER has protocols and has implemented ventilations systems, air showers, and personal protective equipment to protect the health and safety of its workers.
- One SER stated that methylene chloride is inherently dangerous and it is the nature of this business to be around hazardous materials, but with proper training and adequate safety systems installed, risks over exposure can be greatly if not completely mitigated.
- One SER recommended that methylene chloride be regulated by permits for purchase and use by licensed and qualified persons.

**Manufacturers, Formulators, Distributors and Suppliers:**

- Many SERs stated that EPA should consider additional labeling as the primary regulatory option for the consumer market in order to mitigate the acute risk associated with the

misuse in the bathtub refinishing trade or use in confined spaces. This will entail supporting the revisions by CPSC to their September 14, 1987 Notice of Interpretation and Enforcement Policy for Labeling of Certain Household Products containing methylene chloride to include warnings about the acute and chronic hazard associated with the use of methylene chloride.

- One SER stated that EPA continues to ignore the financial impact on formulators and has not presented any cost estimates for the impact on formulators, most of which are small businesses.
- One SER said EPA seems to think the products containing methylene chloride can be reformulated easily, but this is incorrect and a ban would cause entire product lines to disappear as there are no drop-in replacements for methylene chloride. Costs would increase and would cause small entities to go out of business.
- One SER said that the alternatives that EPA suggested are not practical and demonstrates EPA has a lack of knowledge of the market. As an example, ATM removers would need to contain 50% acetone in order to be VOC compliant. A paint remover formulation with 50% acetone would present an unacceptable acute fire hazard. Furthermore, caustic removers are products used by trained professionals due to the products' corrosive characteristic. DBE removers are not effective unless formulated with n-methylpyrrolidone. Benzyl alcohol products simply don't work and haven't been able to establish any significant consumer acceptance.
- One SER said that methylene chloride strippers are effective on older coatings like lacquers, shellac, and varnishes. This SER also said that methylene chloride strippers also work well on newer cross-linked coatings like conversion finishes, UV finishes, epoxies, polyurethanes, and conversion lacquers. This SER also said that as coating technology improves, methylene chloride strippers offer the only effective product for finish removal which is needed to extend the life of coated materials and aid in recycling and reuse.
- One SER said that there is significant data from studies in 1992 and 1995 that confirm that the metabolic pathway for methylene chloride in humans differs from mice and rats, and that the incident of potential cancer of the lung or liver in humans does not correlate with the animal studies. This SER also said that there have been significant epidemiology studies of workers at Eastman Kodak, Hoescht Celanese, and ICI fiber that involve thousands of workers exposed at levels of 200 ppm or more for decades.
- One SER said they are not aware of any occupational deaths from use of their methylene chloride products.
- One SER questioned the data that EPA used to determine exposure estimates over 8 hour days and compared to the current OSHA exposure limit of 25 ppm for a TWA 8-hour day. They asked if there are any documented cancers from 25 ppm TWA exposures.
- One SER said that packaging in 55 gallon quantities is not practical for all facilities.

- One SER said that cost for companies would increase with the proposed regulation more than the cost estimates due to increased labor, increased costs for waste removal, need for multiple coatings, reduced effectiveness of other formulations, etc.
- One SER said 85% of their customers are commercial users on larger projects and 15% are either homeowners or small contractors on small projects or home projects. They supply to paint stores, hardware stores, safety supply, big box stores, construction supply, and marine supply stores.
- One SER said the main function for a methylene chloride paint remover is to get antique furniture into a functioning use and not cut down more trees to make new furniture.
- One SER that manufactures and formulates products for consumer use would support a prohibition on the consumer use and DIY uses of methylene chloride-containing coating removers for bath tub stripping. This targeted restriction can be implemented in a timely and effective way and can address the most critical consumer, home, and DIY uses for which no effective substitutes exist. Other consumer uses should not be prohibited as EPA overestimated the risk to consumers who buy small quantities and short-duration uses of coating removal products.
- One SER mentioned that paint removal products containing methylene chloride outperform all of the alternatives that EPA identified, particularly for consumer, do-it-yourself (DIY) and limited duration use applications. Therefore, it is not technically nor economically feasible for SERs to shift production of products to alternative-based products. EPA's own materials support the conclusion that methylene chloride-based products are the most effective for paint and coating removal.
- A SER described how EPA's proposal is not economically feasible. The cost of alternatives varies and prices to consumers could be much more expensive than methylene-based products, both up front and in the long run if the customer has to use more volume of product to remove a coating than they would using methylene chloride-based products. The SER said that "EPA has not performed the kind of economic analysis required under the amended TSCA in which the costs of a potential regulatory intervention should be vetted." EPA should assess and consider the cost of reformulating, packaging, purchasing and using paint and coating removal products.
- One of the SERs stated that EPA has not adequately considered the environmental consequences as well as risks to human health of the various regulatory alternatives. The SER said that consumers and DIY users purchase and use small quantities on an as-needed basis so exposures to these products are episodic and short-lived. If an alternative product does not remove paint or coating as quickly as methylene-chloride based products, there is potential for a longer exposure time for the user.
- Multiple SERs commented on the flammability and other toxicity concerns of alternative paint and coating removal products as other risk factors for EPA to consider.
- One SER provided a study that compared methylene chloride-based coating removers with alternative coating removers to test the removal of alkyd and epoxy removed at the

given time and this showed that methylene chloride-based products work faster than alternatives.

- One SER submitted an analysis of how the Frank R. Lautenberg Chemical Safety for the 21st Century Act would impact the risk evaluation for methylene chloride and NMP in paint and coating removal, the consideration of alternatives, consideration of other federal statutes that regulate the chemicals, and the gap filling purpose of TSCA.
    - Gap filling purpose of TSCA: According to the SER, the amended TSCA § 9 requires EPA to consult and coordinate with other federal agencies and impose the least burdens of duplicative requirements. According to the SER the use of methylene chloride and NMP in paint removers are already more than adequately regulated under the Occupational Safety and Health Act as well as by EPA under the Clean Air Act.
        - Occupational Safety and Health Administration (OSHA) Regulation: One SER stated that OSHA regulates chemical use in workplaces. OSHA has regulated occupational exposure to methylene chloride at a level of 25 ppm as an 8-hour time-weighted average (TWA) and a short-term (15 minute) exposure limit (STEL) of 125 ppm and an action level for concentrations of airborne methylene chloride of 12.5 ppm (8-hr TWA). The SER stated that therefore there is no basis for EPA to assume that methylene chloride is being used in what would be a flagrant violation of the OSHA standard.
        - Consumer Product Safety Commission (CPSC) Regulation: One SER stated that CPSC regulates labeling of consumer products. This SER stated that use of methylene chloride in paint stripping is already more than adequately regulated under the Federal Hazardous Substances Act.
        - EPA Regulation: one SER said EPA should review the National Emission Standards for Hazardous Air Pollutants for Paint Stripping and Miscellaneous Surface Coating Operations and Area Sources (NESHAP) under the Clean Air Act (CAA) §112 as this standard must ensure an "ample margin of safety to protect public health." Methylene chloride is listed as a Hazardous Air Pollutant (HAP) under the CAA §112. The NESHAP has specific requirements applicable to facilities that conduct paint stripping operations to minimize evaporative emissions of methylene chloride. The SER stated it is unclear how action under TSCA realistically could achieve greater public health protection for paint stripping sources of methylene chloride than EPA is already required to achieve under the Clean Air Act. The SER stated that EPA has not taken the extensive NESHAP requirements into account when proposing this rule under TSCA.
    - TSCA § 9 Requirements: one SER provided background information about TSCA § 9, including the House Committee Report and several quotes from members of

the House of Representatives to highlight the SER's position on the limitations on EPA's authority, and stated that TSCA was strengthened by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and said it was clear from the outset that TSCA is to be used only when other statues fail to provide a remedy for unreasonable risks. Specifically, the SER quoted report language that "EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New Section 9(b)(2) will force the Agency to do just that." This SER mentioned that there could be potential for conflicting or overlapping regulation with OSHA regulations, and OSHA should be given an opportunity to consider whether a lower workplace standard would be appropriate. The SER indicates that there is no evidence that EPA submitted to OSHA a report describing the risk and the specific activities that present such risk, as required by TSCA Section 9(a)(1). According to the SER, the non-existent report obviously did not include a statement of the information on which it is based or was published in the Federal Register, as required. The SER indicates that the letter from OSHA dated April 2016 does not meet the requirements of TSCA, and furthermore, does not identify a gap specific to vapor degreasing, rather, the letter states overall limitations of OSHA and therefore seems that EPA is assuming authority over the use of hazardous substances in the workplace. This SER said that OSHA would be unable to enforce EPA's regulations even if the EPA regulation afforded greater protection. This SER also said that EPA also is not authorized to establish ambient concentration limits under TSCA § 6 and therefore cannot limit employee exposure directly, but can indirectly, e.g., by controlling the amount of substance used in a product or prohibiting a particular use of the substance. This SER said that this is potentially more economically burdensome than ambient standards.

- One SER commented about the EPA Risk Assessments for methylene chloride and NMP: Under TSCA § 6(b)(4)(F), as revised by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA must evaluate the risk and, according to one SER, among other things:
  - "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified by the Administrator,"
  - "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance," and
  - "describe the weight of the scientific evidence for the identified hazard and exposure."

- One SER commented that new TSCA § 26(h) requires a risk evaluation that "the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science…" This SER said that the screening level risk evaluation that supports the current TSCA § 6 rule is not robust enough to meet the requirements of new TSCA §26(h). This SER also said that it comply with Office of Management and Budget guidelines implementing the Information Quality Act.
    - One SER said that the risk assessment indicates that the NESHAP described above was taken into account, but the exposure data predates the compliance dates of the NESHAP ranging from January 2008 to January 2011. This SER also said that the risk assessment does not reference the reporting and recordkeeping requirements of the NESHAP.
    - A SER stated that the August 2014 assessment on methylene chloride includes the incorrect baseline for exposure to methylene chloride in paint stripping, particularly the occupational exposure scenarios. This incorrect baseline is a limitation of the risk assessment. See comment for excerpts from the uncertainties within the draft risk assessment.
    - A different SER said that EPA should reconsider the scientific bases for the methylene chloride risk assessment and the risk of exposure to consumer and DIY users under realistic exposure scenarios. This would allow the Agency to have a better basis to reasonably determine whether a proposal to further limit use of methylene chloride-containing paint removal products is warranted under TSCA.
- One SER mentioned that during the discussion, many SERs were vocal about EPA's consideration of viable and technically feasible alternatives to methylene chloride in paint removal applications. See above comment summaries from other SERs with their specific concerns. Some SERs that formulate both methylene chloride-based and non-methylene chloride-based paint removers said that they have been trying to promote the latter for years but customer acceptance was poor because the alternatives are not as effective as methylene chloride-based products. This SER said a true substitute is not available at this time.

# 9. PANEL FINDINGS AND DISCUSSION

## *9.1. Number and Types of Entities Affected*

For a complete description of the small entities to which the proposed rule may apply, see Sections 4, 5 and 7 of this document.

## *9.2. Potential Reporting, Recordkeeping, and Compliance Requirements*

The potential reporting, recordkeeping, and compliance requirements are still under development. However, the Panel anticipates that the requirements will be the minimum necessary to ensure compliance with the regulatory option chosen. Reporting and recordkeeping requirements should be streamlined to the extent practicable.

## *9.3. Related Federal Rules*

See Section 2.1 of this document for a discussion of related federal rules. Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that an unreasonable risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. If the other agency responds by declaring that the activities described do not present an unreasonable risk or if that agency initiates action under its own law to protect against the risk, EPA is precluded from acting against the risk under sections 6 or 7 of TSCA.

Section 9(d) of TSCA instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. EPA has consulted with CPSC and OSHA. These consultations included numerous meetings at the staff and management level, to discuss technical, legal, and public health issues related to this rulemaking.

CPSC protects the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction. Though CPSC has provided guidance to consumers when using products containing NMP, there are no CPSC regulations regarding NMP in paint and coating removal. CPSC currently requires that all consumer products containing methylene chloride identify that they contain that chemical. In a letter supporting EPA’s proposed rulemaking, CPSC stated that “Some paint removers are distributed for sale to, and use by, consumers and thus would likely fall within CPSC’s jurisdiction. However, because TSCA gives EPA the ability to reach both occupational and consumer uses, we recognize that EPA may address risks associated with these chemicals in a more cohesive and coordinated manner given that CPSC lacks authority to address occupational hazards.” The CPSC letter was not discussed nor shared with the SERs during the panel process. CPSC’s letter will be available in the docket for the proposed rule (EPA-HQ-OPPT-2016-0231).

OSHA assures safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA’s methylene chloride standard, 29 C.F.R. 1910.1052, was issued in 1997 and applies to general industry, construction, and shipyard employment. It sets the PEL for airborne MC to an eight-hour TWA of 25 parts per ppm. OSHA has not set a standard for NMP. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace. OSHA’s current regulatory agenda does not include revision to the methylene chloride PEL, establishment of a PEL for NMP, or other regulations addressing the risks EPA has identified when methylene chloride or NMP are used in paint and

coating removal. OSHA supports EPA's proposed regulation of methylene chloride and NMP in paint and coating removal under Section 6 of TSCA, and has provided a letter documenting this support (Appendix A).

With the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce the cross-cutting exposure to these chemicals in paint and coating removal in workplaces and consumer settings. For example, OSHA may set exposure limits for workers but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals. Other Federal regulatory authorities, such as CPSC, have the authority to only regulate pieces of the risks posed by methylene chloride and NMP when used in consumer products. TSCA is the only regulatory authority able to prevent or reduce risk from these uses of methylene chloride and NMP to a sufficient extent across the range of uses and exposures of concern. In addition, these risks can be addressed in a more coordinated, efficient and effective manner under TSCA than under two or more different laws implemented by different agencies. Accordingly, EPA determines that referral to other Federal authorities for risk management is inappropriate.

If EPA determines that actions under other Federal authorities administered in whole or in part by EPA may eliminate or sufficiently reduce unreasonable risk, section 9(b) of TSCA instructs EPA to use these other statutes unless the Administrator determines in the Administrator's discretion that it is in the public interest to protect against such risk under TSCA. In making such a public interest finding, section 9(b)(2) of TSCA states: "the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk."

Although several EPA statutes have been used to limit methylene chloride exposure, regulations under these EPA statutes have limitations because they largely regulate releases to the environment, rather than direct human exposure. SDWA only applies to drinking water. CAA does not apply directly to worker exposures or consumer settings where methylene chloride or NMP are is used. Under RCRA, methylene chloride that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of methylene chloride to air, land and water. RCRA does not address exposures during use of products containing methylene chloride or NMP. Only TSCA provides EPA the authority to regulate the manufacture (including import), processing, and distribution in commerce, and use of chemicals substances.

## *9.4. Regulatory Flexibility Alternatives*

Panel Recommendations

The Panel recommends that EPA consider additional activities listed below to determine if they are appropriate to provide flexibility to lessen impacts to small entities as well as entities not classified as small:

**Exposure Information**

Based upon SER comments, the Panel recommends that EPA should request workplace monitoring information during the comment period for worker exposure levels from companies for methylene chloride and NMP in paint and coating removal.

Based upon SER comments, EPA should request additional information regarding the frequency of use currently of PPE, and consider that information when weighing alternative options in the proposed rulemaking for methylene chloride and NMP in paint and coating removal.

**Regulatory Options**

Based upon SER comments, the Panel recommends that EPA should consider and seek public comments on enhanced labeling requirements for consumer paint removal products containing methylene chloride or NMP to reduce exposure to methylene chloride and NMP.

Based upon SER comments, the Panel recommends that EPA should consider and seek public comments on a control option such as a certification program similar to the Lead Renovation, Repair and Painting program with increased training and education for commercial users of paint removers.

Based upon SER comments, the Panel recommends that EPA should delay any proposed regulatory action on methylene chloride for the commercial furniture refinishing industry while it gathers additional information to characterize the impacts on this industry of restrictions on use of methylene chloride in paint and coating removal. EPA should request comment on current practices in the furniture refinishing industry on limiting exposure to methylene chloride used in paint and coating removal.

Based upon SER comments, the Panel recommends that EPA should request comment on the feasibility of methylene chloride only being sold in 30-55 gallon drums.

The panel recommends that EPA should address the proposed regulatory actions as distinctly as possible in the one proposed rulemaking addressing both methylene chloride and NMP in paint and coating removal.

**Alternatives**

The Panel recommends that EPA ensure that its analysis of the available alternatives to methylene chloride and NMP in paint and coating removal comply with the requirements of TSCA § 6(c)(2)(C) and include consideration, to the extent legally permissible and practicable, of whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect. Specifically, the Panel recommends that EPA:

- evaluate the feasibility of using alternatives, including the cost, relative safety, and other barriers

- take into consideration the current and future planned regulation of compounds the agency has listed as alternatives

**Cost information**

The Panel recommends that EPA request additional information on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

**Risk Assessment**

The Panel recommends that EPA recognize the concerns that the SERs had on the risk assessments by referring readers to the risk assessments and the Agency's Summary of External Peer Review and Public Comments and Disposition document for each risk assessment, which addresses those concerns, in the preamble of the proposed rulemaking.

SBA Office of Advocacy Recommendation

The SBA Office of Advocacy recommends that EPA address the concerns expressed by the SERs on the final risk assessments for methylene chloride and NMP in the preamble of the proposal for this rulemaking. Moreover, based on the SERs comments, Advocacy recommends that EPA revise the final risk assessments to specifically address concerns regarding the baseline for occupational exposure and the risk of exposure to consumers. Finally, Advocacy recommends that EPA revise the risk assessments to incorporate the supplemental analyses conducted after the final risk assessments. These recommendations are included to ensure that the risk assessments provide sufficient basis for EPA's regulatory action with regard to commercial and consumer use of methylene chloride and NMP in paint and coating removal.

The SBA Office of Advocacy recommends that EPA conduct peer review for any supplemental analysis completed after the final risk assessments for methylene chloride and NMP and to specifically seek public comments on the supplemental analysis especially since the SERs did not review these analyses during the panel process.

EPA Response

EPA disagrees with the recommendation by Advocacy to revise the risk assessments for methylene chloride and NMP and to have the supplemental analyses peer reviewed. The methylene chloride and NMP risk assessments were already open for public comment and have been peer reviewed, and that peer-reviewed methodology was used for the supplemental analyses. The current final risk assessments and supplemental analyses provide the necessary scientific support for the rule. EPA believes that additional comments relating to the completed risk assessment are most appropriately addressed during the public comment period for the proposed rule on methylene chloride and NMP in paint and coating removal.

# APPENDICES

## Appendix A: Materials EPA shared with Small Entity Representatives

Materials shared with Small Entity Representatives (SERs) for EPA's Planned Proposed Rule under the Toxic Substances Control Act (TSCA) Section 6(a) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint Removers

### *Appendix A1. Materials EPA shared with potential SERs before the Pre-Panel outreach meeting, March 17, 2016*

- Agenda for Pre-Panel Outreach Meeting, March 17, 2016
- Power Point Presentation: An Overview of the Small Business Advocacy Review Panel Process
- Power Point Presentation: Rulemaking for Methylene Chloride and N-Methylpyrrolidone (NMP) under the Toxic Substances Control Act (TSCA), March 17, 2016
- SBAR Pre-Panel Discussion Questions

### *Appendix A2. Materials EPA shared with SERs before the Panel outreach meeting, June 15, 2016*

- Agenda for Panel Outreach meeting, June 15, 2016
- Power Point Presentation: Small Business Advocacy Review Panel Process Recap, June 15, 2016
- Power Point Presentation: Rulemaking for Methylene Chloride and N-Methylpyrrolidone (NMP) under the Toxic Substances Control Act (TSCA), June 15, 2016
- Panel questions for Small Entity Representatives (SERs)
- Regulatory history and international actions for Methylene Chloride and N-Methylpyrrolidone (NMP)
- Additional Cost Information
- Additional Information on the Efficacy of Alternative Paint Removers
- U.S. Department of Labor Letter to EPA in Support of Rulemaking
- Articles on Methylene Chloride in Paint Removers
- List of Alternative Paint Removal Products
- OSHA Assigned Protection Factors for the Revised Respiratory Standard

# Appendix B: Written Comments Submitted by Small Entity Representatives

The U.S. Environmental Protection Agency (EPA) conducted a Pre-Panel outreach meeting with potential Small Entity Representatives (SERs) on March 17, 2016. EPA, along with Panel partners, Small Business Administration's Office of Advocacy (SBA), and Office of Management and Budget's Office of Information and Regulation Affairs (OMB), hosted a Panel outreach meeting with SERs on June 15, 2016.

## *Appendix B1. Written Comments from Potential SERs following the March 17, 2016 Pre-Panel outreach meeting*

After the March 17, 2016 Pre-Panel outreach meeting, potential SERs submitted five sets of written comments, which are provided in this Appendix:

- Benco Sales, Inc., Benny Bixenman
- Fargo Painting, Donny Fargo
- Savogran Company, Mark Monique
- Tub Klass, Kris Estrada
- W.M. Barr & Company, Inc., Lisa M. Sloan

## *Appendix B2. Written Comments from SERs following the June 15, 2016 Panel outreach meeting*

After the June 15, 2016 Panel outreach meeting, the following SER submitted 10 sets of written comments, which are provided in this Appendix:

- Benco Sales, Inc., Benny Bixenman
- Cyphers & Kallander Refinishers, John Moran
- Dumond Chemicals, Inc., Erik Gertsen
- Fargo Painting, Donny Fargo
- Green Products Co., Guy Woods
- Painting & Decorating Contractors of America (PDCA), Mark Casale
- Restorations Unlimited, William Shotwell
- Savogran Company, Mark Monique
- W.M. Barr & Company, Inc., Lisa M. Sloan
- Confidential Business Information comment from 1 company