

September 26, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator McCarthy:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened for EPA's planned proposed rulemakings entitled "Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)." This notice of proposed rulemaking is being developed by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA).

Under section 6(a) of TSCA (15 U.S.C. § 2605(a)), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, if EPA determines after risk evaluation 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 risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Based on EPA's risk assessments of methylene chloride and N-methylpyrrolidone (NMP), EPA has determined that the use of methylene chloride and NMP in paint and coating removal presents an unreasonable risk of injury to health. Accordingly, EPA has identified two regulatory approaches that may reduce these risks to the extent that those risks are no longer unreasonable. As described in section 3 of the Panel Report, these approaches are to 1) Prohibit manufacturing (including import), distribution, and use of methylene chloride or NMP in paint and coating removal; or 2) Allow certain commercial uses with personal protective equipment (PPE) and other restrictions. These options are currently being considered and evaluated by EPA, and are not final at this time.

On June 1, 2016, EPA's Small Business Advocacy Chairperson convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). In addition to its 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. It is important to note that the Panel's findings and discussion are based on the information available at the time the report was drafted. EPA is continuing 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 rule's 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 TSCA and its amendments.

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.

While EPA is still evaluating the impacts of the new law on EPA's regulatory authorities, 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 section 6(a) for addressing these unreasonable risks have not been changed by the law.

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 of the Panel report), 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 of the Panel report. 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 the Panel report. Written comments appear in Appendix B of the Panel report.

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 of the Panel

report. 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.

PANEL FINDINGS AND DISCUSSION

Under section 609(b) of the RFA, the Panel is to report its findings related to these four items:

- 1) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.
- 2) A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.
- 3) Identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap or conflict with the proposed rule.
- 4) An initial regulatory flexibility analysis with a description of any significant alternatives to the planned proposed rule which would minimize any significant economic impact of the proposed rule on small entities consistent with the stated objectives of the authorizing statute.

The Panel's most significant findings and discussion with respect to each of these items are summarized below. Section 9 of the Panel report has the full description of the Panel findings and recommendations.

A. Number of Entities and Users Affected

The proposed rule potentially affects commercial users of methylene chloride or NMP in paint and coating removal in a variety of occupational settings such as bathtub refinishing, graffiti removal, autobody repair, and residential renovations. The proposed rule potentially affects a small number of formulators of paint and coating removal products that contain methylene chloride and NMP, for commercial or consumer uses. 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 estimates that the proposed rule would affect approximately 10,300 small entities. Sections 4, 5 and 7 of the Panel report include a complete description of the small entities to which the proposed rule may apply.

B. Recordkeeping, Reporting, and Other 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. The Panel agrees that reporting and recordkeeping requirements should be streamlined to the extent practicable.

C. Related Federal Rules

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.⁵

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.

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, the CPSC issued a fact sheet warning the public about the hazards of paint strippers, including those containing NMP, and included recommendations to use personal protective equipment (PPE) when using products containing this chemical. The factsheet was updated in 2015. CPSC has not regulated NMP.

D. 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 Recommendations

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.

Sincerely,


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Enclosure