

October 28, 2021

The Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Regan:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened for EPA's planned proposed rulemaking entitled "Methylene Chloride Risk Management under the Toxic Substances Control Act." This notice of proposed rulemaking is being developed by the U.S. Environmental Protection Agency (EPA) under section 6(a) of the Toxic Substances Control Act (TSCA), which requires EPA to take action 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.

In December 2016, EPA selected methylene chloride as one of the first 10 chemicals for risk evaluation under section 6 of TSCA. In June 2020, the risk evaluation was finalized. The risk evaluation was conducted pursuant to TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to conduct risk evaluations "to determine whether 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 by the Administrator, under the conditions of use." EPA published the scope of the risk evaluation document¹ in June 2017 (82 FR 31592, July 7, 2017), the methylene chloride problem formulation document² in June 2018 (83 FR 26998, June 11, 2018), and the methylene chloride draft risk evaluation³ in October 2019 (84 FR 57866, October 29, 2019). EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of methylene chloride on December 3-4, 2019. Public comments and external scientific peer review informed the development of the methylene chloride final risk evaluation⁴ (85 FR 37942, June 24, 2020).⁵

In the 2020 final risk evaluation, EPA evaluated 53 conditions of use of methylene chloride and determined that 47 conditions of use present an unreasonable risk. Small businesses may be represented under all 47 conditions of use that present an unreasonable risk. EPA's unreasonable risk determinations for conditions of use of methylene chloride are based on unreasonable risk of injury to health for workers and occupational non-users (ONUs) (workers who do not directly handle methylene chloride but perform work in an area where methylene chloride is present) during occupational exposures, and for consumers and bystanders during exposures to consumer uses. EPA's unreasonable risk determination is due to central nervous system effects from acute inhalation and dermal exposures, non-cancer liver effects from chronic inhalation, and cancer from chronic inhalation exposures to methylene chloride.

On January 7, 2021, 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 (SBREFA). In addition to its chairperson, the Panel consists of the Deputy Director of EPA's Office of Pollution Prevention and Toxics, the Acting Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Acting Chief Counsel for Advocacy of the Small Business Administration (SBA). It is important to note that the

¹ Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0742-0061>

² Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0742-0083>

³ Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0437-0023>

⁴ Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0437-0107>

⁵ The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0437, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0742, on www.regulations.gov.

Panel's findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during this process as well as from public comment on the proposed rule. The options the Panel identified for reducing the rule's economic impact on small entities will require further analysis and/or data collection to ensure that the options are practicable, enforceable, protective of public health, environmentally sound and consistent with TSCA section 6(a).

On June 30, 2021, as the Panel was concluding its report, EPA announced policy changes for risk evaluations and associated risk management actions to protect human health and the environment and align more closely with the statutory requirements. These policy changes include consideration of ambient air and drinking water pathways to the general population and fence-line communities; making the unreasonable risk determination without assuming use of PPE; and making an unreasonable risk determination for the whole chemical rather than condition of use by condition of use. These policy changes follow review of the risk evaluations and are consistent with Executive Orders and other directives including those on environmental justice, scientific integrity, and regulatory review (i.e., Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities through the Federal Government, Executive Order 13990: Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, January 27, 2021 Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking). The Panel's findings and discussion are based on the information available at the time the final Panel report is drafted. As the policy changes are implemented, there is a chance that some impacts of the proposed rulemaking may not have been fully considered by the Panel during its work. In light of these particular and unusual circumstances, if EPA intends to consider additional requirements impacting small business related to conditions of use that were not presented to Small Entity Representatives (SERs) during the January 2021 SBAR Panel Outreach meeting, then EPA will determine whether those additional requirements may have a significant impact on a substantial number of small entities. Under these unique circumstances, EPA would organize a supplemental opportunity for the Panel to consult with the SERs and additional small entities that might be significantly impacted prior to proposal of the rule. EPA continues to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process.

SUMMARY OF SMALL ENTITY OUTREACH

EPA conducted an online solicitation to identify small businesses and trade associations interested in participating in the SBAR Panel process by serving as 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 September 16, 2020 and accepted self-nominations until September 30, 2020. EPA also contacted potential SERs directly throughout the fall of 2020 to generate interest and organized or participated in three events in September 2020 to specifically generate small business interest in engagement during the risk management process.⁶

Prior to convening the Panel, EPA conducted outreach with small entities that will potentially be affected by these regulations. In November 2020, EPA invited SBA, OMB, and 20 potentially affected small entity representatives to a conference call and solicited comments on preliminary information sent to them. EPA shared the small entities' written comments with the Panel as part of the Panel convening document.

After the SBAR Panel was convened, the Panel distributed additional information to the SERs on January 7, 2021, for their review and comment and in preparation for another outreach meeting. On January 28, 2021, the Panel met with the SERs to hear their comments on the information distributed in these mailings. The SERs were asked to provide written feedback on ideas under consideration for the

⁶ Presentation at National Training for Small Business Environmental Assistance Providers (organized by EPA Office of Small and Disadvantaged Business Units, September 9, 2020); SBA Environmental Roundtable (organized by SBA Advocacy, September 11, 2020); and public webinar on the methylene chloride risk evaluation and next steps for risk management (September 16, 2020).

proposed rulemaking and responses to questions regarding their experience with the existing requirements. The Panel received written comments from the SERs in response to the discussions at this meeting and the outreach materials. See Section 8 of the Panel Report for a complete discussion of SER comments. Their full written comments are also included in Appendix B. In light of these comments, the Panel considered the regulatory flexibility issues specified by RFA/SBREFA and developed the findings and discussion summarized below.

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) 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. To read the full discussion of the Panel findings and recommendations, see Section 9 of the Panel Report.

A. Number and Types of Entities Affected

The proposed rule potentially affects commercial users of methylene chloride as well as any business that manufactures (including import), processes, or distributes methylene chloride and methylene chloride-containing products for commercial or consumer use. During the Panel outreach meeting, SERs discussed the number and types of small entities affected and included information on their processing or use of methylene chloride, their customer base, and how their products are used. Specifically, SERs described polycarbonates manufacturing (medical, military, and other applications), chemical manufacturing (chemicals, pharmaceuticals, pesticides, processing agents), paint and coating removal (furnishing industry, antique restoration), and degreasing and adhesives (brake and immersion cleaners, adhesives, automotive and specialty uses). EPA estimates that a total of 3.7 million small firms could be potentially affected by regulations to address the unreasonable risks from methylene chloride.

The Panel notes that a SER provided comments emphasizing that the unique uses of methylene chloride by two other SERs, its member companies, do not resemble those that EPA's TSCA risk evaluation found to present unreasonable risk. EPA acknowledges the SERs concerns related to the risk evaluation and will consider the information provided by SERs to inform the risk management rulemaking.

B. Recordkeeping, Reporting, and Other Compliance Requirements

Several SERs raised concerns regarding compliance with monitoring for an existing chemical exposure limit (ECEL) and the available technology to be able to provide real-time results. Additionally, SERs provided several comments about their concerns with duplicative or overlapping requirements with current OSHA regulations, particularly regarding monitoring and recordkeeping.

The potential reporting, recordkeeping, and compliance requirements are still under development. Reporting and recordkeeping requirements should be aligned with current federal requirements, including monitoring frequency, methods, and procedures, under existing regulations as much as possible.

C. Related Federal Rules

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), the Department of Transportation (DOT), and the Occupational Safety and Health Administration (OSHA). Of these rules, OSHA's methylene chloride standard received the most attention from SERs. During the Panel outreach meeting as well as SER comments, SERs anticipated burden if required to comply with similar, but slightly different, regulations. SERs described concerns with existing OSHA regulations and expressed confusion with the potential regulatory approach of an ECEL and the existing OSHA permissible exposure limit (PEL), among other overlapping or duplicative requirements.

Based on SER comments, EPA will consider existing federal regulations and aligning with existing regulations where it is possible to address the unreasonable risk sufficiently, and existing best practices relative to OSHA standard compliance, monitoring, and exposure reduction, during the development of regulatory options. EPA also communicates regularly with OSHA throughout the development of the regulatory options and proposed rule.

D. Regulatory Flexibility Alternatives

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. Many of the recommended flexibilities may lessen impacts to all entities, and not just small entities

Regulatory Options Based on SER comments:

1. With respect to the possible establishment of an ECEL, the Panel recommends that EPA consult and communicate with OSHA to clearly explain respective regulatory requirements applicable to workers and workplaces who must comply with standards set by both agencies, and to minimize confusion by aligning definitions, reporting intervals, and other requirements where possible. In addition, EPA and OSHA should communicate on implementing or sharing information in instances of duplicative regulatory requirements (ex: record keeping or monitoring). EPA should also provide clear and specific guidance for complying with any potential ECEL. The Panel recommends that EPA request public comment in the notice of proposed rulemaking (NPRM) on the extent to which a regulation under TSCA 6(a) could minimize requirements, such as testing and monitoring protocols, recordkeeping, and reporting requirements, which may exceed those already required under OSHA's regulations for methylene chloride.
2. The Panel recommends that EPA continue to engage with federal partners to work towards establishing a policy on its relationships to other federal laws administered by EPA and/or other federal agencies to ensure transparency and that the statutory obligations under TSCA to address the unreasonable risk are met. Specifically, the panel recommends including a crosswalk of any final regulations to similar, pre-existing regulations, as part of required small entity compliance guides (as in the case of OSHA PELs and EPA ECEs).
3. The Panel recommends that EPA should request comment in the NPRM on feasibility of complying with and monitoring for an ECEL of 2 ppm, and in particular comments on changes that may be needed in order to meet such a standard, for example changes related to elimination of methylene chloride or substitution, engineering controls, process changes, and monitoring frequency.
4. The Panel recommends that EPA should also request comment in the NPRM on reasonable compliance timeframes for small businesses, including timeframes for reformulation of products or processes containing methylene chloride; implementation of new engineering or administrative

controls; changes to labels, SDSs, and packaging; implementation of new PPE, including training and monitoring practices; and supply chain management challenges. The Panel also recommends that EPA request comment in the NPRM on establishing differing compliance or reporting requirements or timetables that take into account the limited resources available to small entities.

5. The Panel recommends that EPA should request comment in the NPRM on workplace monitoring for implementation of an ECEL. EPA should specify that it is soliciting information related to the frequency of monitoring, initial monitoring, and periodic monitoring for workplace exposure levels and how a lower exposure level compared to the OSHA PEL. Specifically, when this may impact the frequency of periodic monitoring where initial monitoring shows that employee exposures are above the level that would initiate requirements for compliance with the ECEL or an OSHA short-term exposure limit.
6. The Panel recommends that EPA request comment in the NPRM on the feasibility and availability of various prescriptive engineering controls to reduce exposure levels, and information on any technologies or prescriptive control options used in combination for addressing the unreasonable risk.
7. The Panel recommends EPA request public comment in the NPRM on providing an option of complying with the ECEL or implementing various administrative and engineering controls, such as those employed in a closed-loop system, including information on how a small business can demonstrate that such controls eliminate the unreasonable risks for that use.
8. The Panel recommends that EPA request public comment in the NPRM on establishing a certification program for the use of methylene chloride by the furniture refinishing industry and take comments on measures to address the unreasonable risks for commercial use of methylene chloride in paint and coating removal for furniture refinishing.
9. The Panel recommends that EPA request public comment in the NPRM on TSCA section 6(g)(1) exemptions for any MIL-SPEC programs where methylene chloride is specified or required for a specific end use application. The Panel also recommends that EPA should continue to engage with SERs whose products may be certified to specific MIL-SPEC programs as well as the Department of Defense to identify circumstances where methylene chloride is specified with no available alternatives.
10. The Panel recommends that if EPA proposes limitations on distribution for consumer uses, then EPA should seek public comment in the NPRM on means by which small businesses can maintain access for industrial and commercial uses including establishing training, certification, and limited access programs.
11. The Panel recommends that EPA request public comment in the NPRM on temporary work practices to allow for limited circumstances, including but not limited to equipment failure or maintenance activity, where monitoring may not be feasible to comply with an ECEL.
12. The Panel recommends that EPA clearly describe when the use of methylene chloride will be subject to risk management regulation under TSCA section 6(a), and also request public comment in the NPRM for information on the extent to which methylene chloride may be used in the same facility for TSCA and non-TSCA uses.

Sincerely,

**WILLIAM
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William Nickerson
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Mark Hartman
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Enclosure