

**EPN Comments on Methylene Chloride;
Draft Revision to Toxic Substances Control Act Risk Determination**

Docket No.: EPA-HQ-OPPT-2016-0742

August 4, 2022

Founded in 2017, the [Environmental Protection Network](https://www.environmentalprotectionnetwork.org) (EPN) harnesses the expertise of more than 550 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

We are pleased to comment on EPA's Draft Revision to the Toxic Substances Control Act (TSCA) Risk Determination for Methylene Chloride.

In accordance with TSCA section 6(b)(2)(A), EPA published a final risk evaluation for methylene chloride on November 23, 2020, based on 1) making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation, and 2) the assumption, for several conditions of use, that personal protective equipment (PPE) would always be provided to and used by workers potentially exposed to methylene chloride. On July 5, 2022, in accordance with Executive Order 13990 and based on recent policy changes to ensure the public is protected from unreasonable risks from chemicals in a way supported by science and law, EPA published a draft revision to its risk determination for methylene chloride. The draft revision, when final, would supersede the condition of use-specific no unreasonable risk determinations in the November 2020 risk evaluation (and withdraw the associated order). Specifically, EPA is replacing its condition of use-specific unreasonable risk determinations with a determination of unreasonable risk for methylene chloride as a whole chemical substance and is removing the assumption of PPE use by workers. PPE use would be considered during the risk management phase following the finalization of the draft revised risk evaluation. Finally, the draft revised risk evaluation does not attempt to alter underlying technical or scientific information that informs methylene chloride-specific risk characterization other than assumptions about PPE use.

On November 26, 2019, EPN submitted comments¹ to the Science Advisory Committee on Chemicals (SACC) to assist in their review of EPA's October 29, 2019, draft risk evaluation of methylene chloride. Among other concerns, we disagreed with the evaluation of risk from dermal and inhalation exposures to methylene chloride separately, rather than aggregately, even though exposures were likely to occur simultaneously, potentially leading to an incorrect conclusion of "no unreasonable risk." On December 3, 2019, we presented testimony² on the draft risk evaluation of methylene chloride at the public meeting of the SACC. Concerns presented included timing of public meetings of the committee; the use of draft, flawed guidance; inadequate use of available information regarding benchmark margins of exposure; the lack of appropriate aggregate risk assessment; and worker exposure and risk. EPN also sent a letter³ to then-EPA Administrator Andrew Wheeler expressing concerns about serious health risks demonstrated in EPA's

¹ https://www.environmentalprotectionnetwork.org/wp-content/uploads/2019/11/Methylene-Chloride-Written-Comments-11_26_19.pdf

² <https://www.environmentalprotectionnetwork.org/wp-content/uploads/2019/12/EPN-Oral-Comments-Dec-2019-SACC-Meeting-.pdf>

³ <https://www.environmentalprotectionnetwork.org/wp-content/uploads/2019/11/Methylene-Chloride-support-letter-Administrator-Wheeler-1.pdf>

October 29, 2019, draft risk evaluation of methylene chloride. Although this risk evaluation was only a draft, EPA had already determined that methylene chloride poses an unreasonable risk in its 2014 risk evaluation and in a 2019 ban on paint removers for consumer use. Therefore, in our view, it would have been irresponsible for EPA to further delay taking protective action. To ensure that the acute effects are addressed as soon as possible, we urged the agency to regulate the hazards of methylene chloride in two separate stages, the first stage to begin at once, focusing on the risks posed by acute neurotoxicity. The first stage was described in the letter:

- Use an immediately effective final rule under section 6(d) to ban methylene chloride from all consumer products in addition to the paint removers banned earlier this year.
- Ban methylene chloride from commercial applications where the margin of exposure exceeds safe levels, such as vapor degreasing, cold cleaning, adhesives and sealants, paint and coating removal, and dry-cleaning solvent applications.
- Require downstream notification of this prohibition throughout the supply chain.
- Require strong warnings of the risks of death and brain damage on labels and safety data sheets for the remaining methylene chloride-containing products in commerce.
- Place methylene chloride on the TSCA section 5(b)(4) list as a chemical that “present[s] or may present an unreasonable risk to human health and the environment.”

We recommended that the second stage of regulation focus on the chronic exposures and cancer endpoints and any remaining uses of methylene chloride that present an unreasonable risk that are not restricted in the first stage. These uses should be regulated to the extent necessary to eliminate unreasonable risks, to be imposed through the normal TSCA section 6(a) rulemaking process.

We continue to have concerns about a number of issues involved in the risk evaluation of methylene chloride, but concur with EPA's July 5, 2022, draft revision to the risk determination of methylene chloride. Specifically, we agree with the logical and scientific reasoning behind using a whole chemical approach for methylene chloride exposure and for declining to rely on the use of PPE for workers exposed to methylene chloride. We promote prompt risk management actions once the draft methylene chloride risk evaluation is finalized, including those actions outlined in our November 22, 2019, letter to the former EPA Administrator, as described above.