What are the key elements and likely impact of the EPA's proposed rule for methylene chloride?

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POn 20 April the US EPA announced a proposed rule under section 6(a) of the Toxic Substances Control Act (TSCA) that would prohibit most uses of methylene chloride and require a workplace chemical protection program (WCPP) for non-prohibited uses. We will outline the key elements of the EPA's proposal and discuss the likely impact on industry. We also look at what this portends for the agency's future rulemaking activities on chemical substances undergoing risk evaluation.

The proposed rule

The EPA published its proposed rule on methylene chloride on 3 May, beginning a 60-day comment period which ends on 3 July. According to the proposal, pursuant to TSCA section 6(b), the agency determined that the substance presents an unreasonable risk of injury to health (without consideration of costs or other non-risk factors) including to potentially exposed, or susceptible, subpopulations as identified in the June 2020 risk evaluation for the substance, under the conditions of use (COU).

To address the unreasonable risk, the EPA's proposal under TSCA section 6(a) includes the following key elements:

1. Prohibition of the manufacture, processing and distribution of methylene chloride for all consumer use;

2. Prohibition of most industrial and commercial use of the substance;

3. For ten COUs that will be permitted, a WCPP, including inhalation exposure concentration limits and related workplace exposure monitoring and controls, will also be required. The conditions of use include:

- manufacture;
- processing as a reactant;
- aboratory use;
- industrial or commercial use in aerospace and military paint and coating removal from safety-critical, corrosion-sensitive components by federal agencies and their contractors; and
- industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of speciality batteries for such by federal agencies and their contractors, and disposal.

The WCPP lowers the enforceable exposure limit from the current US Occupational Safety and Health Administration (OSHA) eight-hour time-weighted average (TWA) permissible exposure limit (PEL) of 25ppm, and a short-term exposure limit (STEL) of 125 ppm, to an eight-hour TWA existing chemical exposure limit (ECEL) of 2ppm and an EPA STEL of 16ppm.

4. Provision of a ten-year time-limited exemption under TSCA section 6(g) for civilian aviation from the prohibition addressing its use for paint and coating removal to avoid significant disruptions to critical

infrastructure, including required compliance with the WCPP;

5. Provision of a ten-year time-limited exemption under TSCA section 6(g) for emergency use of methylene chloride, in furtherance of the National Aeronautics and Space Administration's mission, for specific conditions which are critical, or essential, and for which no technically and economically feasible safer alternative is available, including required compliance with the WCPP; and

6. Recordkeeping and downstream notification requirements for manufacturing, processing and distribution in commerce of the substance.

The EPA says that all TSCA COUs of methylene chloride (other than its use in consumer paint and coating removers, subject to separate action in 2019) are subject to this proposal, including the circumstances intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of according to Methylene Chloride: Regulation of Paint and Coating Removal for Consumer Use under TSCA section 6(a). Non-TSCA uses (for example, uses regulated under the Federal Food, Drug, and Cosmetic Act) are not subject to these limitations.

Impacts

The two key elements that are expected to cause the greatest impact on entities that use methylene chloride are the prohibition of most industrial and commercial uses and the WCPP requirements.

The WCPP is likely to be the most impactful requirement on regulated entities that use methylene chloride for non-prohibited or time-limited exempt COUs. The EPA's proposal requires compliance with it for continued use of the substance. It concluded "as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate- any unreasonable risk of injury to health." We quote this specific language because in TSCA section 6(a), it states that the agency must address unreasonable risks "to the extent necessary so that the chemical substance or mixture no longer presents such risk." If a WCPP with an ECEL is protective of health and the environment, as the EPA states, it is questionable how it can justify a ban on uses in which a company can meet these requirements. Imposing a ban in addition to them suggests that the EPA's proposal goes beyond the "extent necessary" provision. It may be true that consumers do not have the technical expertise or ability to meet a WCPP, so a ban on these uses is justified. But employers could reasonably expect to be able to continue to use methylene chloride if they can document compliance with the WCPP.

The EPA does not explain why a company that can comply with the WCPP during the phase-out period cannot continue with this past the deadline, thereby guarding against unreasonable risk. Its view that it must ban uses that it views as non-critical may be a result of its whole chemical approach – that having found the whole chemical to pose an unreasonable risk, it must ban the chemical. We do not see a basis for this view in the statutory language.

Under TSCA section 6(c)(2)(C), the agency is required to consider alternatives when deciding whether to prohibit specific conditions of use for a chemical substance. To meet this requirement, the EPA performed an assessment of alternatives to methylene chloride and identified products with similar costs and efficacy for most of the uses it intends to prohibit. The agency identified products that contain chemical substances that are subject to risk evaluation and undergoing risk management (for example, N-methylpyrrolidone) or will undergo risk evaluation and possible risk management at some point (for example, benzene and ethyl benzene). This presents a challenge for industries that use methylene chloride for a COU proposed for phase-out when EPA will evaluate and may prohibit the alternative chemical substances in the future. A company may find itself selecting a series of alternatives that will be subject to risk evaluations – and potential bans – at a later date.

We also note that the EPA identified various alternative solvents as having 'No Information Available' on hazards. In these cases, a company may be faced with changing from protecting from well-characterised hazards of methylene chloride to protecting from unknown or poorly characterised hazards.

One of the solvents the EPA identified as having no information available is xylene (Chemical Abstracts Service Registry Number® (CAS RN®) 1330-20-7). We mention this solvent for two reasons. First, it is subject to a harmonised classification in the European Union, according to Annex VI of Regulation (EC) No 1272/2008. Furthermore, xylene is a combination of m-, o- and p-xylene. Second, each of these isomers is on EPA's TSCA Work Plan for Chemical Assessments: 2014 Update with identified hazard concerns for 'reproductive toxicity and developmental toxicity' (m-xylene CAS RN 108-38-3), 'chronic toxicity' (o-xylene CAS RN 95-47-6) and 'reproductive toxicity' (p-xylene CAS RN 106-42-3). Given the information available from ECHA and the EPA's concerns over the individual isomers, the agency's conclusion that there was no information available on xylene's hazards is puzzling.

We also remind readers that in the EPA's assessment of

alternatives to chrysotile asbestos in diaphragms used in the chlor-alkali industry, the agency acknowledged that the substitute for asbestos is per- and polyfluoroalkyl substances (PFASs). It does not further compare the potential hazards and risks of the PFAS alternatives, nor the legal and regulatory vulnerabilities of companies shifting to PFAS-based technologies.

The EPA's apparent lack of rigour in its alternatives assessment further begs the question whether a ban for uses is justifiable, or even advisable, when a WCPP and ECEL can be met. Workers may be better off using methylene chloride under a WCPP than using another solvent that the agency may consider hazardous but has not evaluated yet under the new TSCA standard. At least the EPA is confident that the WCPP for methylene chloride is protective. Given this rather than banning the substance, the agency might consider working with OSHA to extend the proposed WCPP to all uses. This will reduce the over-regulation under TSCA and under-regulation under other authorities.

Future TSCA rulemakings

The EPA's two proposed regulations under TSCA section 6(a) (methylene chloride and chrysotile asbestos) provide some insight on the direction that the agency may take on the proposed risk management rules for future risk evaluations, in which it finds unreasonable risks for COUs. Industries that manufacture, process, and use substances undergoing risk evaluations should be prepared for WCPPs. It may be that for most section 6 risk evaluations, the EPA will identify COUs that necessitate workplace protections, such as ECELs that are lower than existing PELs. It is less clear that the agency will have a basis to impose bans or phase-outs for COUs that can meet the protective limits. Such proposed actions should be scrutinised along with EPA's alternative assessments that it uses in its justification for prohibitions. We encourage readers to review closely the proposed regulation on methylene chloride, even if they do not use the substance, and provide comments as appropriate. We expect that this rule is likely to be the standard for EPA's future rulemaking on existing chemical substances.

The views expressed in this article are those of the author and are not necessarily shared by Chemical Watch. The author transparency statement can be seen here.

FURTHER INFORMATION

Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA) →

Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a) →

Xylene: Harmonised classification – Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) →

TSCA Work Plan for Chemical Assessments 2014 update →