Critical Legal Issues: WORKING PAPER SERIES

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

METHYLENE CHLORIDE PROPOSAL: AN EPA TEMPLATE FOR SUPERSEDING OSHA ON WORKPLACE CHEMICAL REGULATION

Lawrence P. Halprin
Keller and Heckman LLP

Washington Legal Foundation
Critical Legal Issues WORKING PAPER Series

Number 227
June 2023

TABLE OF CONTENTS

ABOUT OUR LEGAL STUDIES DIVISION

Since 1986, WLF's Legal Studies Division has served as the preeminent publisher of persuasive, expertly researched, and highly respected legal publications that explore cutting-edge and timely legal issues. These articles do more than inform the legal community and the public about issues vital to the fundamental rights of Americans—they are the very substance that tips the scales in favor of those rights. Legal Studies publications are marketed to an expansive audience, which includes judges, policymakers, government officials, the media, and other key legal audiences.

The Legal Studies Division focuses on matters related to the protection and advancement of economic liberty. Our publications tackle legal and policy questions implicating principles of free enterprise, individual and business civil liberties, limited government, and the rule of law.

WLF's publications target a select legal policy-making audience, with thousands of decision makers and top legal minds relying on our publications for analysis of timely issues. Our authors include the nation's most versed legal professionals, such as expert attorneys at major law firms, judges, law professors, business executives, and senior government officials who contribute on a strictly *pro bono* basis.

Our eight publication formats include the concise COUNSEL'S ADVISORY, succinct LEGAL OPINION LETTER, provocative LEGAL BACKGROUNDER, in-depth WORKING PAPER and CONTEMPORARY LEGAL NOTE, topical CIRCULATING OPINION, informal CONVERSATIONS WITH, balanced ON THE MERITS, and comprehensive MONOGRAPH. Each format presents single-issue advocacy on discrete legal topics.

In addition to WLF's own distribution network, full texts of LEGAL OPINION LETTERS and LEGAL BACKGROUNDERS appear on the LEXIS/NEXIS® online information service under the filename "*WLF*," and every WLF publication since 2002 appears on our website at www.wlf.org. You can also subscribe to receive select publications at www.WLF.org.

To receive information about WLF publications, or to obtain permission to republish this publication, please contact Glenn Lammi, Vice President of Legal Studies, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, DC 20036, (202) 588-0302, glammi@wlf.org.

ABOUT THE AUTHOR

Lawrence P. Halprin is a partner in the Washington, D.C. office of Keller & Heckman LLP. He is nationally recognized for his work in the areas of occupational safety and health and chemical regulation, representing companies and trade associations at the federal and state levels. His hands-on familiarity with the manufacturing and construction environments, and his engineering and financial background have been invaluable to his clients in handling enforcement actions, in providing compliance counseling, and in evaluating and critiquing rulemaking proposals and policy initiatives before the Occupational Safety and Health Administration (OSHA), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), the Chemical Safety Board, the Department of Treasury (TTB licensing and formula approval, and ethanol and Superfund excise taxes), and corresponding state agencies.

Mr. Halprin's practice includes:

- Federal and state investigations and enforcement proceedings;
- Compliance counseling;
- Incident investigations, mandatory incident reporting, and audits;
- Federal and state agency rulemakings and stakeholders processes;
- Pre-enforcement challenges to final agency rules; and
- Participation in the development of national consensus standards related to workplace safety, process safety, product safety, product stewardship, and sustainability.

His chemical regulation practice, supported by the expertise of Keller & Heckman chemists and toxicologists, includes:

- Chemical hazard classification, risk evaluation and analysis of control measures in connection with TSCA premanufacturing notifications and rulemaking;
- Determining threshold effect levels for chemicals, recommending occupational exposure limits (OELs), and developing and reviewing chemical risk evaluation and risk management programs;
- Developing and advising on the implementation of product stewardship programs;
- Advising on the regulation and taxation of ethanol by the U.S. Tax and Trade Bureau and state alcoholic beverage commissions, and the taxation of chemicals under the Superfund excise tax; and
- Advising on incident investigations conducted by the OSHA, EPA and the Chemical Safety Board.

METHYLENE CHLORIDE PROPOSAL: AN EPA TEMPLATE FOR SUPERSEDING OSHA ON WORKPLACE CHEMICAL REGULATION

Reflecting on the implementation of the Toxic Substances Control Act (TSCA) under the Biden Administration, it appears the Environmental Protection Agency (EPA) will eventually supersede and largely replace the Occupational Safety and Health Administration (OSHA) as the agency with primary responsibility for establishing substance-specific toxic chemical standards for the workplace.

With respect to "existing chemicals," this is important for three reasons. First, Section 6 of TSCA generally grants EPA the authority to impose (by rule) a *complete ban* or virtually any lesser restrictions on the manufacture, processing, distribution, and use of toxic chemicals that EPA demonstrates to be necessary to eliminate "*unreasonable risk*" to human health or the environment. In contrast, Section 6 of the Occupational Safety and Health (OSH) Act generally grants OSHA the authority to impose (by rule) *control measures* on employers that OSHA demonstrates to be necessary to eliminate or reduce "*significant risk*" to employees in the workplace, but only to the extent OSHA also demonstrates that compliance is technically and economically feasible for each affected commercial/industrial sector or condition of use. Second, for two reasons, as explained below, EPA's threshold for "unreasonable risk" from exposure to a toxic chemical is likely to be at least an order of magnitude below OSHA's threshold for "significant risk." Finally, the civil and criminal sanctions

available under TSCA far exceed those applicable to OSHA Act violations.

These differences and their likely impact are discussed below in the context of EPA's proposed Risk Management Rule for methylene chloride, which is likely to be at least the initial template for all future TSCA Section 6 Risk Management Rules.

I. STATUTORY AUTHORITY FOR SUBSTANCE-SPECIFIC REGULATION OF "EXISTING" TOXIC CHEMICALS UNDER THE OSH ACT AND TSCA

Section 6(b)(5) of the OSH Act states:

> The Secretary [of Labor], in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

Integrating the relevant provisions, Sections 6, 8, and 26 of TSCA provide substantially as follows with respect to human health:

> If [EPA] determines [, based on "reasonably available information,[1] and without consideration of costs or other non-risk factors,] … that the … [circumstances under which a chemical substance or mixture is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of [2]] … present[

[1] Section 26(k) of TSCA, titled "Reasonably available information, states that in performing its duties under Section 6 of TSCA, EPA "shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, which is reasonably available to the Administrator." For purposes of conducting risk evaluations, EPA defined that phrase as follows: "Reasonably available information means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation …" 40 C.F.R. § 702.33.

[2] The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

>] an unreasonable risk of injury to health [including an unreasonable risk to a potentially exposed or susceptible subpopulation,[3] such as workers, identified as relevant by EPA] … [and that such risk cannot be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in other Federal laws,] … [EPA] shall by rule … [prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substance or mixture] … to the extent necessary so that the chemical substance or mixture no longer presents such risk….
> ….
> In selecting among prohibitions and other restrictions, [EPA] shall factor in, to the extent practicable … [the following Additional Considerations] …
> (i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
> (ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
> (iii) the benefits of the chemical substance or mixture for various uses; and
> (iv) the reasonably ascertainable economic consequences of the rule, including consideration of—
> (I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
> (II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
> (III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by [EPA].

Based on the applicable statutory language of the two statutes, court decisions, and agency interpretations, the burden of proof to sustain a rule under

[3] The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

judicial review, with respect to human health, appears to be as follows:

Statute	OSH Act Section 6(b)(5) Standard	TSCA Section 6 Risk Management Rule
Standard for Judicial Review	OSHA must demonstrate by substantial evidence in the record taken as a whole:	EPA must demonstrate by substantial evidence in the record taken as a whole:
1. Existing Risk	1. Current conditions present a "significant risk" of harm to covered employees.	1. Current conditions present an "unreasonable risk" to human health, either in general or with respect to any "potentially exposed or susceptible subpopulation," such as workers or subpopulations of workers involved in a particular condition of use.
2. Required Impact of the Rule	2. The proposed measures will eliminate or significantly reduce that significant risk for all covered employees, subject to items 3 and 4.	2. The proposed measures will eliminate that unreasonable risk for the relevant population/subpopulation.
3. Technical Feasibility	3. The proposed measures are technically feasible for employers to implement (for each affected industrial sector or condition of use, such as the use of hexavalent chromium in stainless-steel welding).	3. Not applicable
4. Economic Feasibility	4. The proposed measures are economically feasible for employers to implement (for each affected industrial sector or condition of use).	4. Not applicable
5. Most Cost-Effective Alternative	5. The regulatory alternative selected by the agency represents the most cost-effective alternative	5. The regulatory alternative selected by the agency represents the most cost-effective alternative (from a

	(from a reasonably developed selection of options, arguably including any variation that a rulemaking comment demonstrates to be more cost-effective) that achieves the objectives of the rule.	reasonably developed selection of options, arguably including any variation that a rulemaking comment demonstrates to be more cost-effective) that achieves the objectives of the rule.
6. "Additional Considerations" as defined above	6. Not applicable	6. Applicable
7. Depth of Evidentiary Investigation Required[4]	7. The agency action is based on "the best available evidence."	7. The agency action is based on "reasonably available evidence." Decisions based on science, shall use the available information in a manner consistent with the best available science and based on the weight of the scientific evidence.
8. "Unreasonable risk" cannot be "prevented or reduced to a sufficient extent"[5] by actions taken under the authorities contained in other Federal laws.	8. Not applicable	8. Applicable

[4] It is unclear whether the variance in the statutory language would make a difference but for the fact that EPA is subject to statutory deadlines for developing risk evaluations and issuing rules whereas OSHA generally operates without legal deadlines for developing rules (OSHA took over 20 years to develop a comprehensive rule governing exposure to crystalline silica) or issuing final rules (the overhaul of the HCS to incorporate the Globally Harmonized System was proposed in September of 2009 and adopted in March 2012).

[5] TSCA Section 9(a). The use of the phrase "reduced to a sufficient extent" appears inconsistent with the mandate in Section 6(a) to eliminate "unreasonable risk" except to the extent agencies may be quibbling over nominal differences in risk assessments or the presence or terms of the requirements in auxiliary program provisions that supplement the mandatory exposure limits.

II. EPA'S PROPOSED METHYLENE CHLORIDE RISK MANAGEMENT RULE

In addition to the material difference in the criteria for adoption of a substance-specific toxic chemical rule under the two statutes, EPA's methylene chloride proposal further demonstrates there is also a material difference in the approach EPA and OSHA take when evaluating and quantifying significant risk and unreasonable risk, and in selecting appropriate control measures, with potentially momentous consequences.

EPA policy has been that 1 in 10,000 generally represents the upper bound of acceptability for estimated excess cancer risk. EPA noted that is the level recommended by the National Institute for Occupational Safety and Health (NIOSH)[6] for workplace exposures and has, in effect, proposed to adopt it for Section 6 Risk Management Rules covering commercial and industrial activities. EPA also noted: "OSHA acknowledges that the 10^{-3} threshold is "100 to 1000 times higher than the risk levels generally regarded by other Federal Agencies as on the boundary between significant and insignificant risk."[7]

---

[6] NIOSH Chemical Carcinogen Policy. https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf?id=10.26616/NIOSHPUB2017100revised.

[7] 88 Fed. Reg. 28291, col. 1. The following excerpt from the Preamble to the 1997 Amendment to OSHA's methylene chloride standard is instructive background for this issue:

> The Supreme Court has noted that a reasonable person would consider a fatality risk of 1/1000 to be a significant risk, and would consider a risk of one in one billion to be insignificant. Industrial Union Department v. American Petroleum Institute, 448 U.S. 607, 646 (1980) (the "Benzene decision"). So a risk of 1/1000 (10(-

Statute	OSH Act Section 6(b)(5) Standard	TSCA Section 6 Risk Management Rule
Health Endpoints Evaluated	Cancer and infrequently other endpoints unique to the chemical.	All significant health endpoints.
Determination of Significant/Unreasonable Risk for Cancer Endpoints	1/1,000 (10E-3) excess risk over a working lifetime of (2,000 hours per year) for 45 years.	1/10,000 (10E-4) excess risk over a working lifetime of (2,000 hours per year) for 40 years.
Determination of Significant/Unreasonable Risk for Non-Cancer Endpoints	1/1,000 incremental risk over a working lifetime of (2,000 hours per year) for 45 years.	No more than negligible concerns for adverse human health effects through application of a benchmark dose (BMD) analysis and uncertainty factors designed to generate an ECEL below the threshold effect level for the most sensitive subpopulation.

As stated above, to adopt a Section 6 Risk Management Rule governing employees, EPA must demonstrate that the "unreasonable risk" cannot be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in other Federal laws, such as the OSH Act. Solely for purposes of assessing this issue, one can assume EPA's scientific analysis and policy choices for establishing "unreasonable risk" are supported by the evidence and generally recognized principles of toxicology, and consistent with the language and objectives of TSCA—

3)) represents the uppermost end of a million-fold range suggested by the Supreme Court, somewhere below which the boundary of acceptable versus unacceptable risk must fall. The Court further stated that "while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is significant will be based largely on policy considerations."

i.e., the most sensitive health endpoint is liver toxicity, liver toxicity is an unreasonable risk, and compliance with the ECEL and STEL is necessary to eliminate that unreasonable risk. Under those assumptions and current circumstances, as explained below, it would appear impossible to demonstrate that "unreasonable risk" can be eliminated or reduced to a sufficient extent by actions taken under the OSH Act[8] and difficult to demonstrate that a coordinated set of rules issued by multiple agencies under multiple statutes would, collectively, be adequate to eliminate "unreasonable risk."

The OSH Act provides lesser worker protections as compared to TSCA if one considers the OSH Act does not apply to state and local employees in approximately 25 states and does not apply to any self-employed individuals. The statutes provide different level of protections in additional ways as follows:[9]

---

[8] In effect, OSHA gave EPA the green light to assume responsibility for the development of substance-specific workplace chemical standards through a letter from former OSHA Administrator David Michaels to James Jones, former EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, which stated:

> Given certain limitations imposed on OSHA's authority under the OSH Act, this agency believes TSCA provides the Environmental Protection Agency (EPA) with a means of eliminating or reducing the risks associated with the[ ] chemical uses [of methylene chloride, N-methyl pyrrolidone and trichloroethylene] in a more coordinated fashion, across both consumer and occupational settings…. OSHA supports the goals of EPA to broadly address the hazards associated with these chemicals and looks forward to collaborating with you on activities that will reduce occupational risk.

[9] The OSH Act provides greater workplace protection when toxic chemical products are both exempt from TSCA and not subject to worker safety protection requirements enforced by the agency with primary jurisdiction over those products. For example, for diacetyl and other food ingredients, FDA focuses on food safety from the standpoint of consumer exposure, not worker exposure to the chemical at much higher concentrations.

1. Different Excess Risk Threshold

Given EPA's excess risk threshold of 1 per 10,000 (40-year exposure) and OSHA's excess risk threshold of 1 per 1,000 (45-year exposure), one would expect the EPA ECEL to consistently be almost an order of magnitude lower than the OSHA PEL for the most sensitive of the chronic health endpoints targeted by both agencies, assuming they followed the same risk assessment procedures.[10] However, there is a potential for a much more significant difference between the OSHA PEL and EPA ECEL.

2. Targeting a Different Endpoint

In developing PELS, OSHA generally does not address and apparently does not have the resources to address all significant non-cancer endpoints resulting from chronic exposure,[11] methylene chloride being one example. OSHA established a PEL of 25 ppm for methylene chloride to address the chronic risk of work-related lung cancer and liver cancer[12] but did not address chronic liver toxicity. In EPA's pending methylene chloride proposal, EPA determined that an ECEL of 42 ppm would be adequate to control the excess risk of lung cancer but that an ECEL of 2 ppm was needed to address the excess risk of chronic liver toxicity.

---

[10] Oddly, this difference was not relevant with respect to the excess cancer risk in the pending methylene chloride proposal. The OSHA PEL is 25 ppm as an eight-hour time-weighted-average (TWA) and EPA determined that an ECEL of 42 ppm as an eight-hour TWA would be adequate to reduce the excess risk of cancer to 1/10,000 (based on exposure over a 40-year working life). Apparently based on different modeling, OSHA determined that its PEL of 25 ppm would only reduce the excess risk of cancer to 36/10,000 (over a 45-year working life).

[11] Two exceptions are the OSHA standards for lead and beryllium were two of the few OSHA standards to address non-cancer endpoints.

[12] 68 Fed. Reg. 1494-1619 (Jan. 10, 1997).

3. OSH Act Feasibility and Enforcement Constraints

Due to feasibility constraints, according to OSHA's risk estimates, OSHA has rarely been able to set a PEL low enough to reduce the excess cancer risk to 1 in 1,000.[13]

In adopting a PEL of 25 ppm for methylene chloride in 1997, OSHA determined that a PEL significantly lower than 25 ppm would be required to reduce the excess risk to 1 in 1,000 but that 25 ppm was the limit of feasibility. There would be no point in OSHA using its limited resources to initiate a PEL rulemaking that would identify a significant risk it could not address through reduction of the current PEL due to feasibility constraints.

Furthermore, even if there was no feasibility constraint in the OSH Act and the law covered self-employed individuals, the enormous regulatory power (to ban a condition of use) and enforcement sanctions (strict liability and significant criminal sanctions) TSCA grants to EPA go well beyond the authority the OSH Act provides to OSHA. If OSHA could adopt the EPA ECEL, that would not come close to the effect of a ban. Manufacturers and distributors would be free to sell methylene chloride to any commercial purchaser without restrictions.

For several reasons, enforcement of the ECEL under the OSH Act would be an extremely challenging if not impossible task. First, given the agency's level of staffing, OSHA inspectors can only inspect fixed establishments subject to OSHA jurisdiction on the average of once per hundred years. Second, OSHA would face the challenging task of effectively targeting locations where methylene chloride exposures are likely to be out of compliance. Third, for

[13] *See* Table VI-4: Selected OSHA Risk Estimates for Prior and Current PELs (Excess Cancers per 1,000 Workers), 81 Fed. Reg. 16393 (Mar. 25, 2016), which does not reflect the1994 amendment to the OSHA asbestos standard.

some conditions of use, the methylene chloride activity may be quickly shut down and the methylene chloride vented when the inspector arrives. Fourth, some of the worst methylene chloride exposure situations are likely to be work performed by a contractor in a private home where the ventilation is likely to be inadequate. One can imagine the outcry if OSHA inspectors were to attempt to enter private homes to inspect a contractor's work, interview homeowners, take photographs, and conduct air monitoring for eight hours. Fifth, to sustain a challenged citation, OSHA would have to prove all elements of a violation, including noncompliance and employer knowledge of the violative condition.

4. OSHA's Limited Regulatory Resources

OSHA adopted its initial PELs for hundreds of chemicals in 1971 through a special process established under Section 6(a) of the OSH Act. That provision gave OSHA a two-year window in which it could adopt any appropriate established Federal standard without traditional rulemaking. Since then, OSHA has been able to adopt or amend PELs for only 18 chemicals. By an undated letter, with a reported date of March 31, 2016, OSHA advised EPA that it had no plans or resources to initiate a further revision to the OSHA PEL or STEL for MC and two other chemicals targeted by EPA.[14]

A Federal regulatory czar, not limited by political silos, would logically assess the situation, and quickly conclude that TSCA provides an opportunity to reduce the excess risk of workplace exposure to 1 in 10,000, or even lower, and create a level playing field within the Unites States, with a far lower burden of proof than would be required to reduce the excess risk of workplace exposure to 1 in 1,000 under the OSH

[14] *See* fn. 11 [David Michaels letter].

Act. Furthermore, the arsenal of civil and criminal enforcement remedies available under TSCA would be expected to result in a higher level of compliance.

At the same time, EPA apparently recognizes that the development and implementation of Section 6 Risk Management Rules for existing chemicals is part of a "grand experiment" to determine whether it is possible to reduce the incremental risk from workplace chemical exposures to 1 in 10,000 without severe disruption of national employment and the economy. EPA also apparently recognizes that it is not conducting this grand experiment in isolation but contemporaneous with EPA's consideration of the application of cumulative risk assessment principles, and with the other government mandates, competitive pressures, and social pressures driving far-reaching ESG/sustainability initiatives on a global basis. Possibly, given these considerations, EPA also determined, in a break from OSHA policy, that potentially widespread use of respiratory protection (at least when using supplied air respirators) to reduce ambient exposures by a factor of up to 50 is more appropriate than OSHA's policy that widespread use of respirators should be viewed as infeasible. This may be a concept employers should support.

With the proposed ECEL and STEL for methylene chloride established, EPA reviewed the exposure data it had collected on the various conditions of use and made determinations on which conditions of use would be expected to operate in compliance with the ECEL and STEL without primary reliance on respiratory

protection ("the Compliance Criterion"). EPA interpreted the Compliance Criterion to mean reliably achieving compliance without respiratory protection or with respiratory protection having an assigned protection factor of no more than 50. Under the EPA proposal, the agency would permit businesses whose conditions of use are expected to meet the Compliance Criterion to continue such operations; those conditions of use not expected to meet the Compliance Criterion would be banned.

EPA identified ten broad conditions of use that it concluded would meet the Compliance Criterion. It then reviewed the conditions of use that would be banned to determine whether, per TSCA Section 6(g), any should be granted an exemption to avoid eliminating a critical use for which no safer alternative is available or to avoid significant disruption to the national economy, national security, or critical infrastructure. EPA determined that a particular use of methylene chloride in maintaining commercial aircraft merited a ten-year exemption and proposed a relatively quick phaseout for all other banned uses. The EPA proposal also would require implementation of a comprehensive Workplace Chemical Protection Program (WCPP)—substantially like the program required by OSHA's methylene chloride standard and incorporating the lower EPA ECEL, Action Level, and STEL—for the continuing conditions of use and the condition of use covered by the ten-year exemption.

III. SOME AREAS OF CONCERN WITH THE EPA PROPOSAL

When EPA evaluates occupational uses against the Compliance Criterion, it considers both the individuals who actively work with the chemical and others who have incidental exposure from being in an area when the chemical is present (referred to as occupational non-users or "ONUs"). EPA proposed to ban some conditions of use based solely on the questionable assumption that the ONUs currently do not use respiratory protection and would not use respiratory protection (or be excluded from the areas of exposure) even if the result would be to ban the condition of use.

In determining whether a condition of use would meet the Compliance Criterion, EPA relied on data from OSHA compliance inspections conducted over a period of approximately 40 years and a variety of exposure monitoring reports from other sources. Whether that data is representative for the 34 industrial and commercial conditions EPA identifies is unclear. Inevitably, some better performing facilities meet the Compliance Criteria but operate a condition of use that EPA would ban based on generic data the agency relied upon for the condition of use. The agency's use of this collective judgment approach to create an irrebuttable assumption against a condition of use appears inappropriate and open to a legal challenge. The policy would be on much firmer legal and policy grounds if the proposed rule created a rebuttable presumption and allowed each facility that

believes it can meet the Compliance Criterion to rebut that presumption by filing with EPA, by a certain date, either: (a) an appropriate certification of compliance with the ECEL and STEL, supported by an independent certified industrial hygienist's report; or (b) an appropriate notice of a good faith belief of a business's ability to comply followed up with the required certification.

On the same general theme, the proposed rule would preclude either an existing site, or a site not yet built, from installing new technology that would allow the site to meet the Compliance Criterion for a banned condition of use. The proposed rule should be revised to include a cost-efficient exemption through a variance process like the certification of compliance described above.

The proposed rule would apply to methylene chloride and all materials containing it, apparently meaning any material with detectable methylene chloride. The proposed rule makes no exception for *de minimis* concentrations/amounts of methylene chloride. This would include undisclosed levels below the 0.1 % threshold cut-off value under OSHA Hazard Communication Standard, which may or may not generate a Proposition 65 warning in Section 15 of a safety data sheet. Practically, that approach is probably unworkable. Legally, that approach does not appear to satisfy EPA's obligation under Section 6 of TSCA to demonstrate that a product containing any concentration/amount of methylene chloride presents an unreasonable risk to health.

The failure of a facility to inform EPA that it meets the Compliance Criterion for one or more conditions of use that EPA proposes to ban, or to persuade EPA to establish an appropriate *de minimis* exemption, could result in an unexpected and inappropriate ban of a broad range of commercial activities. EPA outreach does not appear adequate to make facilities aware of the importance of addressing these issues.

Finally, the following excerpt from the Preamble to the methylene chloride proposal suggests that EPA's determinations on the availability of alternatives to methylene chloride need to be carefully scrutinized, and that EPA's analysis would benefit from more extensive EPA consultation with OSHA:

> EPA's consideration of alternatives, including for safety and flammability, is discussed further in … the Economic Analysis, and Alternatives Assessment …. Mechanical or thermal methods (i.e., sanding, media blasting, or heat guns) are also potential alternatives for this sector, though likewise they may damage the substrate, require different processes, and often requires more time ….[88 Fed. Reg. 28313.]

Standing alone, EPA's summary discussion of "mechanical or thermal methods" as alternatives to methylene chloride appears substantially incomplete. Sanding of wood will generate significant quantities of wood dust, which, depending on its properties, can be both an explosive combustible dust and a carcinogen by inhalation. Media blasting poses significant inhalation hazards and heat guns are ignition sources.

IV. THE ROLE OF EPA AND TSCA IN REGULATING WORKPLACE EXPOSURES TO HAZARDOUS CHEMICALS

Some industry interests advance a good-faith view that Congress intended Section 6 of TSCA to be a gap-filling statute that provides protection from toxic chemicals for those who would otherwise be unprotected, and that it would not infringe on areas regulated by OSHA. While that view has a certain appeal, it appears to overlook some important considerations. First, the Lautenberg Safe Chemical Act[15] repeatedly directs EPA to eliminate unreasonable risk with an emphasis on any "potentially exposed or susceptible subpopulation," which is explicitly defined to include workers. The phrase "potentially exposed or susceptible subpopulation" appears 21 times in the LSCA; the word "workers" appears only once in the LSCA, in the Section 3 definition of the phrase "potentially exposed or susceptible subpopulation," and once in the accompanying House Committee Report.[16] Second, Section 9(c) of TSCA explicitly states that TSCA rules adopted by EPA will *not* preempt OSHA's authority to adopt a rule on that matter; there is no language in that section addressing whether or how rules adopted by OSHA might affect EPA. The simple answer appears to be that if an OSHA rule eliminates unreasonable risk, EPA has no

[15] https://www.congress.gov/114/plaws/publ182/PLAW-114publ182.pdf.

[16] H. Rept. 114-176. https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf. While this may reflect a subtle deftness in drafting, one would be hard pressed to demonstrate this was an elephant hidden in a mousehole. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

authority to propose any additional requirements. Finally, there is the history of many failed attempts by organized labor, aligned NGOs, and their supporters in Congress to amend the OSH Act. It appears those proponents of OSH Act reform recognized that, rather than competing with the environmental and consumer interests for congressional support, the viable approach was a bill (LSCA) that would advance all their interests at a time when the chemical industry was working to amend TSCA. For those OSH Act reform supporters, the stars aligned.

CONCLUSION

Rulemakings to develop substance-specific exposure limits for toxic chemicals are highly complex and require an early and ongoing substantial commitment of resources by stakeholders to effectively inform the agency and influence the outcome on its merits. Historically, the OSHA PELs process is relatively closed, secretive, and marginally functional. The data collection, scoping, and risk-assessment functions are largely conducted in secret and their outcomes, and the underlying information relied upon by the agency, are not shared with stakeholders until the agency issues the Notice of Proposed Rulemaking. By that time, it is generally too late to address many of the data collection, data analysis, modeling, and risk assessment issues.

In contrast, the TSCA Section 6 framework for Risk Management Rules provides for early stakeholder participation in the development of both the scoping

document identifying the conditions of use and the risk evaluation for the identified conditions of use, which includes an assessment of compliance with the proposed ECEL and STEL. Stakeholders must take advantage of those opportunities to provide EPA timely input. Waiting for EPA to issue a Notice of Proposed Rulemaking before determining whether and how to participate in the process is a risky and generally far less effective approach that will, due to time constraints, generally preclude a rigorous evaluation of the data and scientific analysis underlying the agency's proposal. Where the potential outcome of a toxic chemical rulemaking is a ban (under TSCA) of an important commercial activity rather than imposition of a significant but feasible control measure (under the OSH Act), it seems prudent for industry to reevaluate the timing and level of resources committed to these rulemakings.

This is the first TSCA Section 6 Risk Management Rule to provide for continuing uses rather than a ban of the regulated chemical. As such, EPA is expected to use the methylene chloride rulemaking to establish guiding principles, if not a blueprint, for future Risk Management Rules. Given the competing demands for limited resources, trade associations and their members may be inclined to wait for EPA to address a chemical of significant interest rather than participating in the methylene chloride rulemaking. A potentially countervailing risk is that lack of broad industry participation in the methylene chloride rulemaking could mean the loss of input

critical to the development of an appropriate rule and precedent for future rules.[17] Finally, it seems likely that EPA and OSHA are going to find a way to integrate their enforcement functions so that EPA and OSHA are not enforcing different exposure limits for the same chemical in the same facility.

[17] EPA's proposed TSCA Section 6 Risk Management Rule for perchloroethylene was approved for publication by the OMB Office of Information and Regulatory Affairs on June 1, 2023. https://www.reginfo.gov/public/do/eoDetails?rrid=299861 Another concern for the regulated community is whether it has the capacity to effectively participate in what could become a steady flow of proposed Risk Management Rules (at possibly 50 times the annual volume of OSHA PELs rulemaking) with overlapping comment periods.

