BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

Comments on Methylene Chloride; Regulation Under
the Toxic Substances Control Act
(TSCA)
88 Fed. Reg. 28284 (May 3, 2023)
EPA-HQ-OPPT-2020-0465

Halogenated Solvents Industry Alliance, Inc.
3033 Wilson Boulevard, Suite 700
Arlington, VA 22201

Of Counsel:

W. Caffey Norman
Squire Patton Boggs (US) LLP
2550 M Street, NW
Washington, DC 20037

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The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents manufacturers and users of chlorinated solvents, including methylene chloride (dichloromethane or DCM). A list of HSIA's members is attached (Attachment A). We appreciate the opportunity to provide these comments in response to the proposed rule governing the manufacture, processing, and use of DCM under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 28284 (May 3, 2023). The proposed rule would greatly restrict the permissible uses of DCM and impose limits on worker exposure which are much more restrictive than those imposed by the Occupational Health & Safety Administration (OSHA). We address in turn below a number of significant deficiencies in the proposed rule that show it is not based on best available science or supported by substantial evidence, as required by TSCA.

As will be discussed more fully below, the proposed rule breaks down into (i) 34 conditions of DCM use where EPA found unreasonable risk to workers and proposes to ban the use and (ii) specific requirements for ten conditions of use not prohibited. The ten allowed uses would be subject to Workplace Chemical Protection Program (WCPP) requirements to be implemented by employers.[1] Most notably, these include an Existing Chemical Exposure Limit (ECEL) of 2 parts per million (ppm) (8-hour time weighted average) and a 15-Minute Short-Term Exposure Limit (STEL) of 16 ppm.

EPA's assumption that the 34 prohibited commercial use sectors would not be able to achieve limits is unprecedented and illogical. It is also unlawful. TSCA § 6(a) states that EPA should apply requirements for addressing unreasonable risks "to the extent necessary so that the chemical substance or mixture no longer presents such risk." EPA asserts that compliance with the WCPP will protect health and the environment. To go further and ban a use without giving the employer an opportunity to implement a WCPP goes far beyond EPA's authority to regulate "to the extent necessary."

In a case of similar overreach by OSHA, involving comparable language in the Occupational Safety and Health Act ("OSH Act") defining an occupational safety and health standard as one "reasonably necessary or appropriate to provide safe or healthful employment," the Supreme Court found a duty on OSHA's part to make a finding that a workplace exposure

[1] Table 3, 88 Fed. Reg. at 28317, provides a complete listing of prohibited and allowed uses.

was unsafe before adopting a workplace standard.[2] OSHA must quantify a "certain" level of risk and conclude that it is "significant" before regulating.[3] These findings must be supported by substantial evidence. The comments that follow show how EPA, in implementing a statute of similar vintage and wording (the OSH Act was enacted in 1970; TSCA in 1976) has departed from the TSCA statutory directive.

By raising the *Benzene* decision, HSIA does not mean to imply that the risks of DCM are in any way comparable to those of benzene. As will be discussed below, DCM does present very significant risks of asphyxiation in overexposure situations, and it is presumably due to its conclusion that these risks cannot effectively be managed that EPA proposes to ban consumer use. No such reasoning can apply to the workplace, however, where DCM has been used by hundreds of thousands of workers in dozens of different applications for many decades, with no evidence of liver toxicity or increased cancer risk in the exposed workers where the OSHA limits have been observed. EPA's Risk Evaluation is based entirely on health effects extrapolated from studies in animals, not from any studies of exposed workers showing an increased incidence of those effects. Benzene, on the other hand, is a known human leukemogen. The concerns expressed by the Court in *Benzene* apply many times over to the regulation of DCM.

As discussed more fully below, the comprehensive OSHA standard for DCM, in effect for the past 25 years, has ensured against health risks in exposed workers. Substantial evidence in the record shows no liver toxicity in the hundreds of workers studied to detect just such effects using the standard tests employed by all physicians (occupational and otherwise), even at exposures for longer than 10 years at levels nearly 20-fold greater than the current 25 ppm OSHA PEL (these studies precede lowering of the PEL from 500 ppm to 25 ppm in 1997). EPA discounted this evidence based on an effect seen in a rat study that was not seen in any of the workers. Thus, the proposed rule would supplant existing workplace requirements and drastically affect the competitiveness of American manufacturing by imposing limits far below

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[2] *Industrial Union Department, AFL-CIO v. American Petroleum Institute, et al.,* 448 U.S. 607 (1980) (*"Benzene"*).

[3] "By empowering the Secretary to promulgate standards that are 'reasonably necessary or appropriate to provide safe or healthful employment and places of employment,' the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But 'safe' is not the equivalent of 'risk-free.' There are many activities that we engage in every day -- such as driving a car or even breathing city air -- that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.' Similarly, a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm." *Id.* at 642.

those in other countries, ostensibly to protect workers from an effect that has never been documented.

I. SUMMARY LEGAL FRAMEWORK

TSCA provides EPA authority to regulate the use of chemical substances, to impose reporting, record-keeping and testing requirements, and to limit conditions of use. Section 6(a), relevant here, requires EPA to promulgate regulations to restrict the use of chemical substances where they "present[] an unreasonable risk of injury to health or the environment." Section 6(a) permits EPA to limit, condition, and prohibit the use of any chemical substance where it presents an unreasonable risk. As noted above, Section 6(a) further states that EPA should apply requirements for addressing unreasonable risks "to the extent necessary so that the chemical substance or mixture no longer presents such risk."

TSCA § 6(c) provides that "In selecting among . . . restrictions," EPA "shall factor in, to the extent practicable," considerations such as "the effects of the chemical . . . on the environment," "the benefits of the chemical substance or mixture for various uses," and "the reasonably ascertainable economic consequences of the rule. The assessment of economic consequences must include the "costs and benefits" and the "cost effectiveness" of the "proposed and final regulatory action" as well as of at least one alternative. EPA must publish a statement discussing those factors. If a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute."

The 2016 Lautenberg Act also added substantive requirements that appear in TSCA § 26.

TSCA § 26(h): "In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information . . . employed in a manner consistent with the best available science . . . and shall consider as applicable—(5) the extent of independent verification or peer review of the information . . . " TSCA § 26(i): "The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence."

Finally, TSCA § 17(c) makes clear that both the final rule and the associated determination of unreasonable risk shall be held unlawful and set aside "if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole."

II. DCM USE IN ACCORDANCE WITH CURRENT OSHA LIMITS DOES NOT PRESENT AN UNREASONABLE RISK TO WORKER POPULATIONS

In 1997, OSHA adopted a comprehensive standard under § 6(b)(5) of the Occupational Safety & Health Act regulating use of DCM in workplaces and providing the following exposure limits:

- 8-Hour Time-Weighted Average (TWA) Permissible Exposure Limit (PEL) -- 25 ppm
- 15- Minute Short-Term Exposure Limit (STEL) -- 125 ppm

OSHA requires airborne monitoring and engineering controls to achieve PEL/STEL limits, further provides that employers must implement a respiratory protection program, and requires the provision of personal protective equipment and hygiene facilities. OSHA also imposes extensive medical surveillance requirements, tracking employee health and wellness and monitoring for changes that could be attributable to DCM exposure.[4]

Among the thousands of pages in the docket of the instant rulemaking, nowhere is there any evidence that workplace exposures in accordance with these limits have caused any material health impairment or indeed any health effect at all in the hundreds of thousands of workers so exposed over the preceding decades. The only reported incidents are the unfortunate fatalities associated with asphyxiation, all over-exposure scenarios at concentrations much higher than the legal limits. Thus, the proposed rule lacks the fundamental statutory prerequisite that it address an "unreasonable risk." Although that term is undefined, it cannot mean a risk that has never been identified. Major epidemiology studies of thousands of workers exposed at DCM levels of 200 ppm or more for decades at US industrial facilities have shown no overall increased health risk. The best available review of these and other epidemiology studies makes clear that no overall cancer risk was found:

> "No strong or consistent finding for any site of cancer was apparent despite several studies of large occupational cohorts of workers potentially exposed to high concentrations of methylene chloride. Sporadic and weak associations were reported for cancers of the pancreas, liver and biliary passages, breast, and brain. Although these studies collectively cannot rule out the possibility of any cancer

[4] 29 C.F.R. § 1910.1052.

> risk associated with methylene chloride exposure, they do support a conclusion of no substantive cancer risk."[5]

To its credit, the Risk Evaluation has recognized the limitations in the evidence of carcinogenicity, and cancer is not the driver of the proposed ECEL: "EPA used a benchmark of 1 in 10,000 (10^{-4}) for individuals in industrial and commercial work environments for purposes of the unreasonable risk determination for methylene chloride (Ref. 2), and at that cancer risk level EPA calculates the exposure limit based on cancer to be approximately 42 ppm—almost double the OSHA PEL."[6] It is important that this be kept in mind in connection with the estimation of benefits in the Economic Analysis, however, as there can no benefit from reduction in cancer risk below the level at which that risk is deemed insignificant. In any event, we may turn our attention to the driver of the ECEL – liver toxicity – which as shown below clearly is not a health risk even at exposures well above the 25 ppm PEL.

A. The OSHA PEL of 25 ppm as an 8-hour TWA is protective against liver toxicity

EPA proposes a chronic non-cancer ECEL value of 2 ppm as an 8-hour TWA to protect workers against liver toxicity from airborne DCM exposures. This value was determined from the two-year inhalation study by Nitschke *et al.* (1988), in which there was a statistically significant increase in liver vacuolation (fatty change) in female rats exposed to 500, but not 200, ppm DCM.[7] This same endpoint was used previously by EPA to derive a Reference Concentration (RfC) for its 2011 DCM IRIS assessment.[8] The 2020 TSCA Risk Evaluation[9] does not discuss in detail why rat liver vacuolation from the Nitschke *et al.* study is an endpoint of concern from chronic exposure to DCM. However, it is discussed in the IRIS Assessment where EPA considered hepatic vacuolation in the liver of DCM-exposed rats a toxicologically

[5] Dell, LD, Mundt, KA, McDonald, M, Tritschler II, JP, Mundt, DJ, Critical Review of the Epidemiology Literature on the Potential Cancer Risks of Methylene Chloride, *Int Arch Occup Environ Health* 72: 429-442 (1999) (Attachment B).

[6] 88 Fed. Reg. at 28291.

[7] Nitschke, KD, Burek, JD, Bell TJ, Kociba, RJ, Rampy, LW, McKenna, MJ, Methylene chloride: a 2-year inhalation toxicity and oncogenicity study in rats, *Fundam Appl Toxicol* 11: 48-59 (1988).

[8] EPA Integrated Risk Information System (IRIS) Review of Toxicological Information on Methylene Chloride (2011) (hereafter the "IRIS Assessment").

[9] EPA-HQ-OPPT-2019-0437-0107 (hereafter the "Risk Evaluation").

relevant and adverse effect because it could be a "precursor of toxicity," leading to hepatic steatosis (fatty liver). Since EPA is extrapolating human health risks from studies involving laboratory animals, it is important to know whether liver toxicity also occurs in DCM-exposed workers.

There are three human epidemiology studies that have investigated liver toxicity in DCM-exposed in workers at U.S. plants.[10] The workers were assessed in a medical surveillance program that consisted of a health history, clinical chemical testing, and a physical examination – the completeness of this assessment is comparable to that of annual physical examinations by health care providers. For two of the studies, the median DCM exposures reached as high as 475 ppm as an 8-hour TWA (about 20- and 240-fold higher than the current OSHA PEL and the proposed ECEL, respectively). These epidemiology studies were reviewed by EPA in its 2011 IRIS assessment as well as the 2020 TSCA Risk Evaluation. The Risk Evaluation states that EPA did not use the human data to derive the POD for chronic non-cancer effects because these studies "are not conclusive with respective to DCM's association with liver effects."

At the request of HSIA, Dr. Jonathon Borak, a Clinical Professor of Medicine at Yale University and a faculty member of the Yale Occupational and Environmental Medicine Program, reviewed these three epidemiology studies and evaluated whether they provide evidence that DCM causes liver toxicity in workers. (Dr. Borak's report and CV are provided as Attachments C and D, respectively.) Besides a review of the studies, the report discusses the interpretation of serum enzyme measurements. Dr. Borak concludes that "the three studies discussed by EPA provide *no evidence* of hepatic effects, even at exposures for longer than 10 years at levels nearly 20-fold greater than the current OSHA PEL of 25 ppm. They also contain no evidence of dose-related hepatic effects of exposures." Accordingly, Dr. Borak found "no evidence, based on reported studies of liver function in workers, that the current OSHA PEL is not adequately protective."

The interpretation of serum enzyme tests, as discussed in Dr. Borak's report, is commonly misunderstood; that misunderstanding may have resulted in some misleading

[10] Ott, MG, Skory, LK, Holder, BB, Bronson, JM, Williams, PR, Health evaluation of employees occupationally exposed to methylene chloride, *Scand. J. Work Environ Health* 9: 1-38 (1983); Soden, KJ, An evaluation of chronic methylene chloride exposure, *J. Occup. Med.* 35: 282-286 (1993); Kolodner, K, Cameron, L, Gittlesohn, A, Berney, B, Emmett, EA, Morbidity study of occupational exposure to methylene chloride using a computerized surveillance system (final report) with cover sheets and letter dated 041190, OTS 0522984. *The Center for Occupational and Environmental Health, The Johns Hopkins School of Hygiene and Public Health* (1990).

statements by EPA in the Risk Evaluation and the 2011 IRIS assessment. Serum enzyme test data should be evaluated by the statistical distribution of the serum enzyme tests, and not whether, for instance, the results are normal versus abnormal. In Soden *et al.* (1993), which is a follow-up study of the same DCM-exposed workers reported in the study by Ott *et al.* (1983), both the mean values of the serum tests were reported for both the DCM-exposed and control workers, and the distribution of the values was present graphically. In general, the serum liver enzyme distribution curves in the control group had wider dispersion and greater maximum levels than did the corresponding distribution curves in the DCM-exposed workers. The distribution curves between the two groups of workers were not statistically different, with the exception of AST levels which were borderline significant ($p=0.06$) in the controls versus the DCM-exposed workers; a finding that is opposite to what would be expected if DCM caused liver toxicity. Both studies involved workers exposed to median DCM exposures of up to 475 ppm for at least 10 years of employment.

EPA chose to use liver effects from a two-year rat inhalation study in its human health risk assessment on DCM even though the existing human data on DCM-exposed workers showed no liver toxicity even at high DCM exposures (about 20- and 240-fold higher than the OSHA PEL and proposed ECEL, respectively). We submit that EPA did not use "the best available science" in the DCM Risk Evaluation when it relied upon the rat data, as the information collected in the human epidemiology studies (clinical health history, clinical chemical testing, and a physical examination) are considered sufficiently robust to detect liver toxicity and are indeed the standard measures in routine annual physical examinations conducted by medical doctors for the general public. EPA's disregard of robust human data for determining the chronic, non-cancer risk from DCM exposure implies that the same type of information is also insufficient for health care providers to assess liver toxicity in routine or annual physical examinations, as is universally the case. As noted above, EPA speculates in the 2011 IRIS assessment that the liver vacuolation in chronically exposed rats is toxicologically relevant and an adverse effect because it can lead to liver steatosis. EPA also considers humans in the IRIS assessment to be 10-fold more sensitive to the effects of DCM than rats. Yet, the human studies showed no exposure-related increase in serum liver enzymes, which is key diagnostically for liver steatosis, as well as no concerns for liver toxicity from the medical history or physical examination.

HSIA has raised concerns on several occasions regarding EPA's choice of liver vacuolation from the two-year rat inhalation by Nitschke *et al.* (1988) for chronic, non-cancer effects in the DCM risk assessment, including in comments on the draft Risk Evaluation and the draft Revised Risk Determination.[11] In comments on the draft Risk Evaluation, HSIA stated:

> HSIA considers hepatocyte vacuolation in female rats from the two-year inhalation study by Nitschke *et al.* (1988)[12] an inappropriate endpoint for EPA's POD for chronic non-cancer inhalation exposure. In the draft Risk Evaluation, EPA reviewed the evidence for liver effects in workers exposed to high levels of DCM by inhalation and identified two studies that reported increased serum bilirubin.[13] In the absence of any other serum chemistry changes, increased serum bilirubin alone does not suggest an adverse liver effect from methylene chloride exposure."[14]

EPA's response was conclusory and indirect: "EPA considers hepatocyte vacuolation to be an adverse outcome relevant for humans. Therefore, the study is appropriate for inclusion in the risk evaluation of MC."[15]

For the draft Revised Risk Determination, HSIA even provided evidence in its comments to EPA of mischaracterization of the human studies that investigated liver toxicity in DCM-exposed workers, including inaccurate information on the serum enzyme data. Specific examples provided include the following:

- Serum γ-glutamyl transferase (GGT) was evaluated only in the study by Kolodner *et al.* (1990); there was no statistically significant difference in serum GGT among the exposure groups even after age adjustment.
- All three studies consistently showed no association with DCM exposure and AST levels. The mean values were all within the normal range.
- There was no positive association with increasing DCM exposures and serum ALT levels in two of the studies; a follow-up of one of these studies

[11] Although EPA referred to the ECEL during the Small Business Advisory Review (SBAR), the ECEL was not actually referenced in the draft Risk Evaluation; it was quietly placed in the docket in 2021 after release of the final Risk Evaluation. HSIA did comment extensively on the ECEL in comments on the draft Revised Risk Determination, but as noted there has been no response from EPA to these comments.

[12] Nitschke, KD, Burek, JD, Bell TJ, Kociba, RJ, Rampy, LW, McKenna, MJ, Methylene chloride: a 2-year inhalation toxicity and oncogenicity study in rats, *Fundam Appl Toxicol* 11: 48-59 (1988).

[13] General Electric Co., *Morbidity study of occupational exposure to methylene chloride using a computerized surveillance system (final report) with cover sheets and letter dated 041190* (1990); Ott, M.G., Skory, L.K., Holder, B.B., Bronson, JM, Williams, PR, Health evaluation of employees occupationally exposed to methylene chloride, *Scand. J. Work Environ Health* 9: 1-38 (1983).

[14] EPA-HQ-OPPT-2016-0742-0131, at 16.

[15] EPA-HQ-OPPT-2019-0437-0083, at 132.

confirmed that serum ALT levels were not associated with DCM exposure (no statistically significant difference between DCM-exposed and non-exposed workers).

- A positive association with serum bilirubin levels and increased DCM exposures (up to median of 475 ppm 8-hr TWA) was reported by Ott *et al.* (1983); there were no other indicators of liver injury. This association was not substantiated in a follow-up study involving the same workers ten years later (Soden *et al.*, 1993). A third study at a different facility with DCM exposures also showed no association with serum bilirubin levels and DCM exposures.[16]

Remarkably, EPA has never addressed these comments at all, in spite of the fact that they provide clear (and so far uncontroverted) evidence that there is no liver toxicity at the OSHA PEL of 25 ppm and certainly not at the proposed EPA ECEL of 2 ppm. Although it is well-established that "[a]n agency must consider and respond to significant comments received during the period for public comment,"[17] EPA has not explained why it considers the rat data to be more relevant to the evaluation of liver toxicity in DCM-exposed workers when there is no evidence of liver toxicity in these workers even at relatively high (up to the pre-1997 OSHA PEL) DCM exposures.[18]

In summary, EPA's Risk Evaluation disregarded the robust human data from the epidemiology studies that investigated liver toxicity in DCM-exposed workers; this is inconsistent with the use of "best available science" required by TSCA §§ 6 and 26(h). The human data provide *no evidence* of liver effects in the DCM-exposed workers even at exposures for longer than 10 years at levels nearly 20-fold greater than the current OSHA PEL of 25 ppm. Therefore, the existing OSHA PEL of 25 ppm as an 8-hour TWA adequately protects workers from liver toxicity. EPA's proposed lowering of the workplace exposure limit an additional 12.5-fold to the ECEL value of 2 ppm as an 8-hour TWA cannot be scientifically justified.

[16] EPA-HQ-OPPT-2016-0742-0131.

[17] *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015).

[18] EPA provided no information on these human studies in the Risk Evaluation except for a brief mention that "two of these studies found some evidence of increasing levels of serum bilirubin with increasing exposure, but no consistent trends for other serum hepatic enzyme levels."

B. The proposed 15-minute STEL of 16 ppm to protect workers from the acute neurotoxicity effects of DCM is overly conservative and not scientifically justified

EPA has proposed a 15-minute STEL of 16 ppm for DCM based on a study by Putz *et al.* (1979),[19] in which human subjects exposed to 195 ppm DCM for 4 hours showed a statistically significant decrease (7%) after 1-1/2 hours of exposure to one of three performance tasks and only in the tasks with the more difficult conditions. While this study was considered by EPA to be of medium quality in the systematic review, only one exposure concentration was tested, which is a significant issue for assessing the acute neurobehavioral effects of DCM because the dose-response curve cannot be determined. Furthermore, the variability or response among the subjects was not reported by the authors in the publication. Thus, a no-observed-adverse-effect-concentration (NOAEC) cannot be determined from this study. To derive the STEL, EPA used an equation developed by ten Berge *et al.* (1986)[20] (with n = 2) to convert the exposure duration of 1-1/2 hours to a 15-minute exposure, resulting in the DCM exposure level increasing from 195 to 478 ppm. The 15-minute STEL was determined by dividing 478 ppm by two uncertainty factors (UFs): 3 for extrapolating a Lowest-Observed-Adverse-Effect-Concentration (LOAEC) to a NOAEC; and 10 to account for variability in the human response to DCM exposure.

EPA claims in the proposed rule that "the ECEL incorporates advanced modeling and peer-reviewed methodologies, including accounting for exposures to potentially exposed or susceptible populations"[21] This is certainly not the case. The ten Berge equation used by EPA describes the exposure concentration and exposure duration relationship for lethality from 20 acute inhalation studies involving predominantly rats, but also mice, guinea pigs, rabbits, dogs, and a monkey. The 20 chemicals included both local irritants and systemically acting toxicants; it did not, however, include DCM. Importantly, the ten Berge equation was validated only for lethality and not for other health-related endpoints, such as the acute neurobehavioral effects used to derive the ECEL value, as reported by Putz *et al.* (1979). In their publication, ten Berge

[19] Putz, VR, Johnson, B, Setzer, JV, A comparative study of the effects of carbon monoxide and methylene chloride on human performance, *J. Environ. Pathol. Toxicol.* 2: 97-112 (1979).

[20] ten Berge, WF, Zwart, A, Appelman, LM, Concentration-time mortality response relationship of irritant and systematically acting vapours and gases, *J. Hazard Materials* 13: 301-309 (1986) (hereafter the "ten Berge equation").

[21] 88 Fed. Reg. at 28290

et al. (1986) wrote that "a general rule concerning the value of the exponent *n* [in the equation] does not exist. The exponent should always be derived *empirically* from acute inhalation toxicity experiments, in which both the concentration and exposure period are variable [italics added]."

The performance decrement effect reported in the Putz study is an outcome of the central nervous system (CNS) effects of DCM. While the ten Berge equation included chlorinated hydrocarbons and solvents that are also CNS depressants, DCM is unique in that CNS depression can occur from both the direct effects of DCM in the brain (common mode of action for many solvents) and as a result of its oxidative metabolism by CYP450 enzymes, which can form carbon monoxide (CO) and thus carboxyhemoglobin (COHb), leading to hypoxia. These two mechanisms have different exposure concentration and exposure duration relationships. A further complexity unique to DCM metabolism is that there is another competing metabolic pathway of DCM that involves its conjugation with glutathione (GSH) by the enzyme GSH-S-transferase (GSTT1-1 isozyme in humans). The human population can be subdivided into three groups based on the polymorphism of GSTT-1: non-conjugators that lack the GSTT-1 enzyme; low-conjugators that have one positive allele and one null allele; and high-conjugators that are homozygous for the GSTT-1 gene. Thus, a percentage of the human population is not able to conjugate DCM with GSH (non-conjugators) based on the polymorphism of GSTT1-1. This is important with respect to assessing the acute toxicity risk of DCM because there will be greater amounts of CO (and thus COHb) formed in individuals that are non-conjugators compared to conjugators for a given DCM exposure as DCM will only be metabolized by the pathway which forms CO (the CYP450-mediated oxidation pathway).

The toxicity of DCM from short-term (acute) exposures was reviewed by the National Advisory Committee (NAC) for Acute Exposure Guideline Levels (AEGLs) for hazardous chemicals.[22] This committee is under the auspices of the National Research Council (NRC) and is composed of members from EPA, Department of Defense, and many other federal and state agencies, industry, academia, and other organizations. The AEGL values established by the NAC/AEGL committee are threshold exposure limits for the general public that range from 10 minutes to 8 hours. AEGL-2 values are established to protect against irreversible or other

[22] AEGL, Methylene Chloride CAS Reg. No. 75-09-2), Interim Acute Exposure Guideline Levels (AEGLs), for NAS/COT Subcommittee for AEGLs (2009).

serious, long-lasting adverse effects, or an impaired ability to escape. While there are three levels of AEGL values that vary in severity of toxic effects, it is how the AEGL-2 values were derived for DCM that is relevant to the discussion of EPA's methodology for deriving the DCM ECEL value for short-term acute effects.

Given the complexity of issues with setting AEGL values for DCM, the NAC/AEGL committee considered physiologically-based pharmacokinetic (PBPK) modeling as the most appropriate way to develop AEGL values for DCM. This model, published by Bos *et al.*,[23] combined the ability to calculate the concentration of DCM in the brain and the COHb levels from the formation of CO from DCM metabolism. The PBPK model also incorporates the polymorphism of the GSH pathway (the ten Berge equation does not) and it has been validated with data obtained from human volunteers. The AEGL-2 value that was derived from the PBPK model was based on a COHb level of 4%, which was considered unlikely to cause cardiovascular effects in patients with coronary heart disease or a significant increase in the frequency of exercise-induced arrhythmias.[24] Thus, it is important to note that the AEGL-2 value was derived to protect sensitive subpopulations (those who are both non-conjugators of DCM metabolism and have severe coronary artery disease) with respect to COHb formation.

Why EPA chose to disregard this PBPK model for the Risk Evaluation and for the development of the ECEL value is unclear, as the EPA Office of Pollution Prevention and Toxics was directly involved in the development of the DCM AEGL values, and EPA accepted the PBPK model for the DCM AEGL values. HSIA, along with others, raised this issue in comments on the draft Risk Evaluation, and EPA responded by claiming that it chose the ten Berge equation instead of the PBPK model because of several sources of uncertainty. Sean Hays and Chris Kirman of SciPinion have critiqued EPA's response regarding the uncertainty of the PBPK model, as well as reviewed both the use of the ten Berge equation and the PBPK model for purposes of the DCM Risk Evaluation and ECEL value (see Attachment E).[25] SciPinion

[23] Bos, PMJ, Zeilmaker, MJ, van Eijkeren, JCH, Application of physiologically based pharmacokinetic modeling in setting acute exposure guideline levels for methylene chloride, *Toxicol. Sci.* 91: 576-585 (2006).

[24] EPA, National Advisory Committee for Acute Exposure Guideline Levels (AEGLs) for Hazardous Substances; Proposed AEGL values. 66 Fed. Reg. 21940-21964 (May 2, 2001).

[25] Drs. Hays and Kirman are recognized experts in pharmacokinetics, dose response and PBPK modeling, and human health risk assessment, and have considerable technical knowledge in these areas with DCM (Attachments F and G).

found that the uncertainties with the Bos *et al.* (2006) PBPK model appear to be "relatively modest, and generally consistent with those associated with other PBPK model applications by USEPA." SciPinion concludes that EPA did not use "the best available science" and that EPA should reconsider its decision to use the ten Berge equation and adopt the PBPK model to support time-scaling of the acute toxicity effects of DCM.

Based on the acute neurobehavioral effect reported in the Putz study following a 1-1/2 hour exposure to 195 ppm DCM, SciPinion used the PBPK model to determine that the equivalent effect – the point-of-departure (POD) in the risk assessment - would occur at 270 ppm DCM if the length of exposure was reduced to 15 minutes (EPA calculated the POD to be 478 ppm using the ten Berge equation). EPA used a total uncertainty factor (UF) of 30 to benchmark the acute toxicity risk in the Risk Evaluation and to derive the 15-minute STEL value for DCM -- this includes an UF of 10 for variability in the human response to be protective of susceptible individuals. Yet, again, EPA did not use "the best available science" when it adopted this UF. At such a short time point, the PBPK model predicts that the acute neurotoxicity of DCM is driven almost exclusively by the concentration of DCM in the brain, not from hypoxia from COHb. The drivers for variability in DCM in the brain and change in COHb are the partition coefficients and the degree of metabolism, respectively, which are expected to be very small in a 15-minute timeframe. Human studies have also shown minimal changes in COHb levels following DCM exposures up to 200 ppm for 15 minutes.[26]

Moreover, there is substantial inter- and intraindividual variability in normal COHb levels in populations of healthy, non-smoking adults.[27] SciPinion, as well as the NAC/AEGL committee for the AEGL-2 values, concluded that a default UF value of 10, for variability in the human response and to protect susceptible individuals, was unnecessary. Thus, only an UF of 3 (to account for use of a LOAEC) is needed to benchmark the acute toxicity risk in the Risk Evaluation and to derive the 15-minute STEL value for DCM. Based on these considerations,

[26] DiVincenzo, GD, Kaplan, CJ, Uptake, metabolism, and elimination of methylene chloride vapor by humans, *Toxicol. Appl. Pharmacol.* 59: 130-140 (1981a); DiVincenzo, GD, Kaplan, CJ, Effect of exercise or smoking on the uptake, metabolism, and excretion of methylene chloride vapor, *Toxicol. Appl. Pharmacol.* 59: 141-148 (1981b).

[27] Radford, EP. Blood carbon monoxide levels in persons 3-74 years of age: United States, 1976-1980. Advance Data from Vital and Health Statistics, Issue 76. National Center for Health Statistics, US Department of Health and Human Services, Public Health Service, Office of Health Research Statistics, and Technology (1982).

the 15-minute STEL for DCM would be 90 ppm DCM, which is considerably higher than EPA's proposed value of 16 ppm DCM.

The current OSHA PEL of 25 ppm as an 8-hour TWA is also adequately protective of workers against acute neurotoxicity. As presented in the report from SciPinion, if the neurobehavioral effect seen in the Putz study at 1-1/2 hours is time adjusted to a longer exposure period, such as an 8-hour exposure, the equivalent effect (the POD in the risk assessment) would occur at a DCM exposure of 60 ppm. This value was derived using the Bos *et al.* (2006) PBPK model based on a 4% COHb level being protective of workers against hypoxia-derived acute neurotoxicity as well as any cardiovascular effects in patients with coronary heart disease. As with the 15-minute STEL, a default UF value of 10 for variability in the human response and to be protective of susceptible individuals is unnecessary and only an UF of 3 (to account for use of a LOAEC) is needed. Based on these considerations, an 8-hour TWA for DCM would be 20 ppm DCM, which is quite close to the OSHA PEL for DCM.

In summary, EPA did not use the "the best available science" under TSCA § 26(h) in assessing the acute neurotoxicity risk of DCM. EPA's approach is not consistent with the current science; developing benchmarks for duration extrapolation should use PBPK modeling when appropriate and incorporate mode of action knowledge for assessing potential response variability among potentially susceptible populations. Such processes have already been acknowledged by EPA as the best available science in setting acute limits for DCM (*e.g.*, AEGL values). Indeed, the notice announcing the AEGLs states:

> "EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS) provided notice on October 31, 1995 (60 FR 55376) (FRL–4987–3) of the establishment of the NAC/AEGL Committee with the stated charter objective as 'the efficient and effective development of Acute Exposure Guideline Levels (AEGLs) and the preparation of supplementary qualitative information on the hazardous substances for federal, state, and local agencies and organizations in the private sector concerned with [chemical] emergency planning, prevention, and response.' The NAC/ AEGL Committee is a discretionary Federal advisory committee formed with the intent to develop AEGLs for chemicals through the combined efforts of stakeholder members from both the public and private sectors in a cost-effective approach that avoids duplication of efforts and provides uniform values, while employing the most scientifically sound methods available. . . . While the development of AEGLs for chemicals are currently not statutorily based, at least one rulemaking references their planned adoption. The Clean Air Act and Amendments Section 112(r) Risk Management Program states, ''EPA recognizes potential limitations associated with the Emergency Response Planning

> Guidelines and Level of Concern and is working with other agencies to develop AEGLs. When these values have been developed and peer reviewed, EPA intends to adopt them, through rulemaking, as the toxic endpoint for substances under this rule (see 61 FR 31685).''[28]

Using the best available science, a 15-minute STEL of 125 ppm should be adequately protective of workers against the acute neurotoxicity of DCM.

C. EPA did not use best available science in its occupational exposure assessments

EPA proposed prohibition, rather than compliance with a WCPP, of most industrial and commercial uses of DCM because it concluded that there is a high degree of uncertainty regarding whether compliance is possible with the proposed ECEL/STEL. As this approach relies, at least in part, on the exposure assessments in the DCM Risk Evaluation for these COUs, flaws in the exposure assessments are discussed below.

1. Inhalation Exposure Assessment

To prohibit certain conditions of use, EPA appears to have relied in the Risk Evaluation on workplace inhalation exposure data that were of low quantity or were not representative of current industry practices for certain commercial or industry uses.[29] Despite these inadequacies, EPA utilized these exposure data in the Risk Evaluation rather than considering alternative approaches that would result in a higher confidence in estimating workplace exposures. Generally, for these COUs there was a lack of workplace inhalation exposure data, or the data were of low quality or not representative of current industry practices. There are numerous ways in which EPA's occupational exposure assessment methodologies could have been refined to better characterize exposures with high confidence, particularly for historical and small data sets, as described in a recent publication by Lynch *et al*.[30] Had EPA developed more robust exposure estimates consistent with best practices for occupational risk

[28] AEGL, Methylene Chloride CAS Reg. No. 75-09-2), Interim Acute Exposure Guideline Levels (AEGLs), for NAS/COT Subcommittee for AEGLs (2009).

[29] HSIA provided industrial hygiene (IH) data for manufacturing and feedstock use indicating that they did not pose unreasonable risk for chronic exposure (or for acute exposure with a 25 APF), EPA-HQ-OPPT-2020-0465-0099, and hopefully these were taken into account.

[30] Lynch, HN, Allen, LH, Hamaji, CM, Maier, A, Strategies for refinement of occupational inhalation exposure evaluation in the EPA TSCA risk evaluation process, *Toxicol Ind Health* 39: 169-182 (2023a) (Attachment H).

assessment,[31] it would have been better able to gauge the likelihood that specific industry sectors would be able to meet the proposed ECEL/STEL for DCM.

Combining multiple exposure information sources for COUs and COU subcategories with limited information, rather than relying strictly on empirical data, also would have allowed EPA to better understand potential occupational exposures to DCM for the purposes of risk management. Owing to EPA's hierarchy of data sources, empirical data are typically preferred over modeling, regardless of the number of data points. Small datasets were a limitation of the exposure estimates for many of the COU subcategories in the DCM risk assessment. AIHA and other occupational health professional associations recommend that if empirical data are limited or of low quality, these data should be supplemented by exposure modeling, or the data be used to parameterize a model.[32] Alternatively, empirical data can be used as a method to validate exposure modeling. Regardless of specific approach, integrating several sources of exposure information generally increases the confidence in the resulting exposure estimate. For example, in the Risk Evaluation EPA used a small empirical dataset for aerosol spray degreasing with significant uncertainties (*i.e.,* it could not be specifically attributed to aerosol production application). To demonstrate an alternative approach that integrates empirical data and modeling, Lynch *et al*. (2023) characterized potential DCM exposures from this activity using DCM-specific information and a published model that had been validated using toluene-based automotive spray cleaners. Again, had EPA followed best practices recommendations for handling small industrial hygiene datasets, it would have been able to better characterize the likelihood of exceedance of the ECEL/STEL for specific uses and base its risk management recommendations on this understanding. In any event, allowing use in compliance with a WCPP, in lieu of prohibition, is the appropriate risk management response to TSCA's mandate that EPA regulate "to the extent necessary" so that the substance no longer presents an unreasonable risk, particularly where the data relied upon by EPA are of low quality.

[31] For example, a 2015 textbook from the American Industrial Hygiene Association: Jahn SD, Bullock WH, Ignacio JS, et al. A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. AIHA (2015).

[32] Mulhausen J, Milz, S, Hewett, P, et al. Chapter 8: Quantitative Exposure Data: Interpretation, Decision-Making, and Statistical Tools. A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. AIHA, pp. 124-141 (2015).

2. Dermal Exposure Assessment

DCM manufacture and its use in the production of other chemicals (*i.e.*, refrigerants) are conditions of use (COUs) that occur in closed system process units where potential dermal contact is limited to short-term tasks in the operation of unit activities. EPA used worst case scenarios in the Risk Evaluation to estimate dermal exposure to DCM for workers from a model by Kasting and Miller (2006), but this model is unrealistic and clearly inapplicable to facilities that manufacture DCM or use DCM as a process reactant or intermediate. As a result, EPA very substantially overestimated worker exposure to DCM from dermal contact at these facilities.

Lynch *et al*.[33] reviewed the methodology in the Risk Evaluation for estimating dermal exposures of workers to several chlorinated chemicals for the COUs involving manufacturing and feedstock use. They also provided best practice recommendations which can be broadly applied to any of the exposure scenarios used in the Risk Evaluation. The authors recommended a "tiered, integrated approach to dermal exposure assessment that emphasizes collecting qualitative data; employing validated, peer-reviewed models that align with current industrial practices; and gathering empirical sampling data when needed." They also recommended that a more realistic approach to estimating the dermal dose of DCM in workers in closed system facilities (manufacturing and process reactant/intermediate use) be obtained by using the IH Skin Perm model.[34] This tool is commonly used by practitioners of IH and exposure assessment to produce reliable estimates of dermal exposure. And, as noted in the Risk Evaluation, "this model takes into account losses to evaporation and estimates the mass that is absorbed." In addition, IH SkinPerm can be used to evaluate the impacts of differing patterns of exposure on fractional and total dose of absorption (*i.e.*, it allows for the incorporation of realistic exposure patterns).

According to EPA, risk evaluations under TSCA § 6(b) are not screening level risk assessments, but are intended to use scientific information, technical procedures, measures, protocols, methodologies, and models consistent with the best available science. Therefore,

[33] Lynch, HN, Gloekler, LE, Allen, LH, Maskrey, JR, Bevan, C, Maier, Analysis of dermal exposure assessment in the US Environmental Protection Agency Toxic Substances Control Act risk evaluations of chemical manufacturing, *Toxicol Ind Health* 39: 49-65 (2023b) (Attachment I).

[34] IH SkinPerm is a peer-reviewed exposure assessment tool published by the American Industrial Hygiene Association (AIHA) Exposure Assessment Strategies Committee.

instead of assuming a theoretical worst-case scenario, EPA must use in its dermal exposure models data and assumptions that are relevant and appropriate to actual workplace practices for the COUs being evaluated.

D. EPA did not use best available science in its systematic review

Strangely, the preamble states "EPA considers the methylene chloride ECEL to represent the best available science under TSCA section 26(h), since it was derived from information in the 2020 Risk Evaluation for Methylene Chloride, which is the result of a rigorous systematic review process that investigated the entirety of the reasonably available current literature in order to identify all relevant adverse health effects."[35] This was most emphatically not the view of the outside peer reviewers, who have been generally critical of the systematic review process EPA employed in the Risk Evaluation.

TSCA §§ 6 and 26 require EPA to use the best available science and weight of the scientific evidence when considering study quality and relevance for multiple lines of evidence. EPA developed its fit-for-purpose systematic review approach because other existing approaches did not satisfy these TSCA statutory requirements. However, the TSCA systematic review approach used for the Risk Evaluation does not include sufficiently detailed guidance for evidence integration and weight of evidence methodology, and EPA did not consistently apply a weight of evidence approaches in the Risk Evaluation.

EPA's Scientific Advisory Committee on Chemicals (SACC) recommended a number of improvements in the systematic review process, as did many commenters on the draft Risk Evaluation.[36] More specifically, the Committee to Review EPA's TSCA Systematic Review Guidance Document convened by the Board on Environmental Studies and Toxicology of the National Academy of Sciences was unable to conclude that the TSCA systematic review process is comprehensive, workable, objective, and transparent.[37]

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[35] 88 Fed. Reg. at 28290.

[36] EPA-HQ-OPPT-2019-0437-0078, 0083. *See* a summary and EPA's response at EPA-HQ-OPPT-2016-0742-0122.

[37] The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, National Academy Press (2021).

III. EPA FAILED TO CONSIDER THE IMPACTS OF THE PROPOSED PROHIBITIONS ON SMALL BUSINESSES OR TO DETERMINE WHETHER EFFECTIVE ALTERNATIVES ARE AVAILABLE, AS REQUIRED BY TSCA AND SBREFA

A. The proposed rule discriminates against small businesses

EPA has adopted an unprecedented reading of TSCA that allows it actively to discriminate against small businesses, by prohibiting almost all small business uses outright without even providing an opportunity to those businesses to continue to use DCM in compliance with a WCPP:

> "Because both EPA's 8-hour ECEL and 15-minute EPA STEL are significantly lower than the OSHA PEL and STEL, there is a high degree of uncertainty as to whether most industrial and commercial users will be able to comply with such a level and thus whether the unreasonable risk would be addressed. As discussed earlier in this Unit, this uncertainty, combined with the severity of the risks of methylene chloride and the prevalence of cost-effective alternative processes and products (Ref. 3), has led EPA to propose prohibitions, rather than compliance with the WCPP, for most industrial and commercial uses of methylene chloride."[38]

This statement contains two misrepresentations: DCM has not been shown to pose any risks to workers when used in compliance with the existing OSHA PEL/STEL, and there is, as EPA acknowledges elsewhere, a dearth, not a prevalence, of cost-effective alternative processes and products. Most significantly, however, EPA's "uncertainty" as to whether most users can comply with its ECEL/STEL is not a sufficient reason to eliminate any compliance option for these users, most of which are small businesses. Also problematic is the paragraph following the one just quoted:

> "EPA also considered the potential for methylene chloride use to increase in particular sectors, such as vapor degreasing applications, where it has largely been phased out because of the well-established hazard (Refs. 3, 49). In order to prevent the potential for use of methylene chloride to increase in a sector that has already moved away from it, use of methylene chloride in vapor degreasing would be prohibited under the proposed regulatory and primary alternative regulatory action. The decline in use of methylene chloride was one of several considerations that led EPA to propose to prohibit use of methylene chloride in vapor degreasing."[39]

[38] 88 Fed. Reg. at 28321.

[39] *Id*.

Leaving aside the fact that DCM continues to be used in vapor degreasing, nowhere does TSCA authorize EPA to ban a chemical because its use has declined in a particular sector. The only justification for such a ban is that it would present an "unreasonable risk," which EPA has determined is not present where the user is in compliance with a WCPP.

Perhaps in recognition of the patent inequity of peremptorily shutting down thousands of small businesses, EPA offers an alternative regulatory option:

> "EPA acknowledges that for some of the occupational uses that it is proposing to prohibit, there may be some activities or facilities that could implement workplace protection requirements necessary to ensure that exposure remain below the ECEL and EPA STEL. In some cases, they may be able to undertake more extensive risk reduction measures than EPA currently anticipates. Therefore, for EPA's primary alternative regulatory action described in Unit IV.B., EPA is considering and requesting comment on a WCPP, including requirements to ensure exposures remain below an ECEL and EPA STEL, for some conditions of use of methylene chloride in addition to those conditions of use which are proposed to be subject to a WCPP under the proposed regulatory action (i.e., those additional uses listed in Unit IV.B.). This includes conditions of use that have not resulted in documented acute fatalities, where reasonably available information suggests minimal ongoing use, where reasonably available information suggests use of methylene chloride may increase if other solvents are significantly restricted for that use such as for other solvents undergoing risk evaluation under TSCA section 6(b), and where the regulated entities may have fewer challenges implementing requirements to meet an ECEL and EPA STEL because work activities may occur in sophisticated facilities or take place in a closed system. The additional conditions of use which would be subject to WCPP under the primary alternative regulatory action described in this notice meet all of these criteria. However, EPA was not able to identify reasonably available information such as monitoring data or detailed activity descriptions to indicate with certainty that relevant regulated entities for these conditions of use could sufficiently mitigate identified unreasonable risk through a WCPP."[40]

HSIA supports this option, but there is no rationale for it to be limited to these eight uses specified in Table 3: Industrial and commercial use in paint and coating removers from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators; Industrial and commercial use as solvent that becomes part of a formulation or mixture; Industrial and commercial use as a processing aid; Industrial and commercial use for electrical equipment, appliance, and component manufacturing; Industrial and commercial use for plastic and rubber products manufacturing; Industrial and commercial

[40] *Id.* at 28322.

use in cellulose triacetate film production; Industrial and commercial use for oil and gas drilling, extraction, and support activities; Industrial and commercial use in finishing products for fabric, textiles and leather. Nor is it realistic for EPA to expect the small businesses that predominate in these and the other sectors where it proposes to ban DCM use to be able to provide in two months the kind of information requested that would "indicate with certainty that relevant regulated entities for these conditions of use could sufficiently mitigate identified unreasonable risk through a WCPP."[41]

Where other options are available to regulate "to the extent necessary so that chemical no longer presents such risk," it is inconsistent with TSCA to allow only "regulated entities [that] may have fewer challenges implementing requirements to meet an ECEL and EPA STEL because work activities may occur in sophisticated facilities or take place in a closed system."[42] Elsewhere, EPA's inappropriate exclusion of small businesses in the absence of data confirming their ability to comply is manifest:

> "EPA believes a WCPP may be a viable alternative to the proposed prohibition for these additional industrial and commercial conditions of use because, as discussed in Unit V.A., these conditions of use are generally industrial in nature; owners or operators are likely currently complying with the OSHA methylene chloride standard, so they should be familiar with what is being required to meet the ECEL; and, as far as the Agency is aware, these conditions of use have not resulted in any documented fatalities. Because of the industrial nature of the sectors relevant to these conditions of use, the owner or operator may have the capability to successfully implement a WCPP to ensure that the unreasonable risk, as a result of exposure to methylene chloride, are prevented.
>
> However, at the time of proposal, EPA has not yet received any monitoring data or detailed description of methylene chloride involving activities for these conditions of use to confirm that compliance with an ECEL of 2 ppm is possible. Therefore, concerns about the feasibility of implementing an ECEL for these additional industrial and commercial conditions of use, as discussed in Unit V.3., led EPA to propose that they be prohibited (see Unit IV.A.2.). EPA does not have sufficient information to confidently conclude that facilities engaged in these conditions of use could meet the ECEL for methylene chloride."[43]

[41] *Id.*

[42] *Id.*

[43] *Id*. at 28314.

Finally, in passing the Regulatory Flexibility Act, subsequently amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), Congress stated:

> ‘‘(a) The Congress finds and declares that—
>
> ‘‘(1) when adopting regulations to protect the health, safety and economic welfare of the Nation, Federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public;
>
> ‘‘(2) laws and regulations designed for application to large scale entities have been applied uniformly to small businesses, small organizations, and small governmental jurisdictions even though the problems that gave rise to government action may not have been caused by those smaller entities;
>
> ‘‘(3) uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands including legal, accounting and consulting costs upon small businesses, small organizations, and small governmental jurisdictions with limited resources;
>
> ‘‘(4) the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace, discouraged innovation and restricted improvements in productivity;
>
> ‘‘(5) unnecessary regulations create entry barriers in many industries and discourage potential entrepreneurs from introducing beneficial products and processes;
>
> ‘‘(6) the practice of treating all regulated businesses, organizations, and governmental jurisdictions as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems, and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation;
>
> ‘‘(7) alternative regulatory approaches which do not conflict with the stated objectives of applicable statutes may be available which minimize the significant economic impact of rules on small businesses, small organizations, and small governmental jurisdictions;
>
> ‘‘(8) the process by which Federal regulations are developed and adopted should be reformed to require agencies to solicit the ideas and comments of small businesses, small organizations, and small governmental jurisdictions to examine the impact of proposed and existing rules on such entities, and to review the continued need for existing rules.
>
> ‘‘(b) It is the purpose of this Act [enacting this chapter] to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational

> requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.''[44]

The instant proposal is a case study of an agency completely ignoring this law. The docket includes 57 pages of comments submitted by small businesses representing several use sectors.[45] Nowhere in the docket or the preamble to the proposed rule is there any discussion of these comments, although as noted above it is axiomatic that an agency must consider and respond to significant comments received during the period for public comment.

B. EPA's consideration of alternatives is inadequate

In the absence of a meaningful review of alternatives, it is to be expected that EPA would "not have sufficient information to confidently conclude that facilities engaged in these conditions of use could meet the ECEL for methylene chloride."[46] EPA's failure to meet its obligation adequately to consider alternatives cannot, however, justify its exclusion of thousands of users from the opportunity to implement a WCPP. TSCA contains no authorization for EPA to consider "concerns about the feasibility of implementing an ECEL" to prohibit a use. Just the

[44] Regulatory Flexibility Act, Pub. L. 96-351, as amended by Small Business Regulatory Enforcement Fairness Act (SBREFA), Pub. L. 96–354, Section 2; see note following 5 USC § 601.

[45] Final Report of the Small Business Advocacy Review Panel on EPA's Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a), EPA-HQ-OPPT-2020-0465-0119. EPA's proposed bans are predicated on its conclusion that there are viable alternatives to DCM in most of these applications. Several small entity representatives (SERs) provided compelling arguments as to why the available alternatives are not technically or economically feasible. The SERs that formulate both DCM-based and non-DCM-based alternatives made clear that, in spite of years of effort to promote the latter, customer acceptance was poor because the alternatives do not effectively strip many substrates. Their statements are more credible than those of SERs trying to market only alternatives. They noted that the chemical solvent alternatives such as toluene, acetone, methanol and benzyl alcohol did not completely remove alkyd or epoxy paints in fewer than four hours and in some cases not at all. In contrast, DCM-based products removed both kinds of coatings from substrates within five minutes on all painted surfaces tested, and within 15 minutes on cured coatings. Similarly, Benco Sales Inc. disagreed with EPA's assessment that there would be cost savings by switching from a DCM-based product, in particular that less product is required because of lower volatility, noting that this does not take into account the reduced effectiveness of other formulations, the need for multiple coatings, the increase in cost, the increase in labor, or the increase in costs for waste removal. Benco stated that costs would increase substantially for every industry sector, and that increased costs and reduced effectiveness would be substantial enough to cause closure of many small businesses. SERs pointed out that, due to the longer duration necessary to remove coatings, exposure time necessarily increases, as does the risk of flammability. In sum, given the information EPA has received from small businesses, the alternatives on the market constitute neither technically nor economically feasible alternatives.

[46] 88 Fed. Reg. at 28314.

opposite: it affirmatively requires EPA to consider "whether technically and economically feasible alternatives . . . will be reasonably available." As discussed below, this analysis is inadequate.

As noted above, TSCA § 6(c) provides that if a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute." Here EPA proposes to eliminate uses constituting 30% of the DCM market, including uses such as commercial paint stripping and degreasing that originated decades ago and continue to be important to American manufacturing. EPA's economic analysis, however, completely fails to consider the impact on American manufacturing competitiveness of eliminating such uses by adopting a workplace limit much lower than those of other countries.

EPA's Alternatives Analysis fails to identify technically and economically feasible alternatives because it does not consider whether any particular alternative will work effectively in a given use. Rather, the Alternatives Analysis simply presents "(1) a representative list of reasonably available alternatives for consideration by EPA, to the extent practicable and based on reasonably available information, to form a snapshot of the current market; and (2) where practicable, to enable EPA to compare the human health hazards, environmental hazards, potential persistence, and bioaccumulative properties of each chemical for each product in each product category":

> "In general, EPA identified products containing ingredients with a lower hazard screening rating than methylene chloride for certain endpoints, while some ingredients presented higher hazard screening ratings than methylene chloride (Ref. 40). These alternative hazard screening ratings are described in detail in the Alternatives Assessment grouped under common product use categories (Ref. 40). EPA has therefore, pursuant to TSCA section 6(c)(2)(C), considered, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction becomes effective."[47]

[47] An Alternatives Assessment for Use of Methylene Chloride (November 2022), EPA-HQ-OPPT-2020-0465-0082/0118 at 7.

Thus, EPA's Alternatives Analysis does not address the fundamental question of whether the alternatives identified are "reasonably available" "technically and economically feasible alternatives." Indeed, it acknowledges that:

> "EPA did not find it practicable to consider alternative processes that may be reasonably available as a substitute for processes involving methylene chloride when the proposed prohibitions or restrictions would take effect. This is due to considerable uncertainties about alternative processes that may be reasonably available, and the limited time to conduct research on alternative processes in light of the statutory timeframe for completing the TSCA section 6(a) risk management rule for methylene chloride, the difficulty of ascertaining whether any alternative processes may be technically and economically feasible, the challenges of comparing the benefits of alternative processes to the benefits of the methylene chloride-containing processes, and other relevant considerations."[48]

Rather, the analysis is intended "to enable EPA to compare the human health hazards, environmental hazards, potential persistence, and bioaccumulative properties of each chemical for each product in each product category," an exercise of no practical utility if the alternatives considered do not perform the functions for which DCM is used.

> Such alternatives analysis as there is appears in the Economic Analysis:
>
> "Consideration of whether there are technically and economically feasible alternatives, when compared with methylene chloride for the uses proposed to be prohibited or restricted, is discussed in the Economic Analysis of the Proposed Regulation of Methylene Chloride Under TSCA Section 6(a)."

The Economic Analysis, however, does not remedy the shortcomings of the Alternatives Analysis.[49] On the automotive refinishing condition of use, for example, it is silent. An earlier economic analysis, issued in connection with EPA's rule on consumer paint stripping, states: "The main use of methylene chloride is in aftermarket refinishing and wheel paint and coating removal, where it comprises 75 percent and 90 percent of the removal methods used, respectively (Wolf, 2015). . . . As Table 3-1 indicates, for all types of work performed, there are readily available removal technologies that could replace 100 percent of methylene chloride use."[50] In reality, the automotive wheel and parts refinishing industry uses millions of pounds of various metals each year. Wheel remanufacturers use DCM to strip the wheels to bare substrate,

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[48] *Id*. at 8.

[49] EPA-HQ-OPPT 2020-0465-0175 (hereafter "Economic Analysis").

[50] EPA-HQ-OPPT 2020-0465-0037, at 3-2.

which they then straighten, repair, and re-powder. DCM is dominant in stripping aluminum and magnesium wheels because it is effective in removing coatings without damaging the metal substrate. There is no viable alternative that will not destroy the integrity of the substrate; obviously safety is of great concern when it comes to wheels. Benco Sales has customers that strip parts from paint/powder coat lines at Ford, Volkswagen, and John Deere, among others, that then get returned to those manufacturers after stripping for re-powder. If the industry is unable to recycle, refurbish, and re-use these parts, millions more pounds will have to be mined and processed to address the market demand. The regulation EPA is proposing would affect over 23,000 refurbishing and powder coating businesses that employ over 100,000 American workers.

Automotive parts are actually only part of a larger powder coating market valued at $2.37 billion.[51] We estimate that 10-15% of that sector is refinishers and re-manufacturers that rely on DCM-based strippers. These are the only products that will remove coatings safely from automotive wheels and parts.[52] They are also used to strip hooks and racks and spray booths that are used in the powder coating process. The only alternative is to incinerate, which can damage or weaken the hooks and racks and is not viable for larger items. If these items had to be disposed of rather than re-painted/powdered, there would be a large increase in waste as well as a significant increase in cost of manufacturing to be passed on to consumers. Yet EPA's analyses are either silent or conclude, without further discussion, that DCM can be 100% replaced.

Another glaring omission from the Economic Analysis is the widespread use by paint stripper formulators of recycled DCM that was initially used to manufacture pharmaceuticals. If drug manufacturers are no longer able to sell this recycled material it will require disposal as a hazardous chemical. The only effective means of disposal is incineration, and the cost to incinerate DCM is approximately $5/lb. For just one formulator, Benco Sales, the cost to incinerate the recycled DCM that it purchases would be $11 to $15 million. This cost is nowhere reflected in the analysis.

As in the Alternatives Analysis, the Economic Analysis is mostly limited to a comparison of hazards and physical properties, not an evaluation of the actual feasibility of replacement. It

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[51] https://www.expertmarketresearch.com/reports/us-powder-coatings-market#:~:text=In%202022%2C%20the%20United%20States,of%20nearly%20USD%202.37%20billion.

[52] DCM is also used extensively to reclaim lawn/patio furniture. Powder coated furniture with its intricate designs is submerged in DCM for stripping. Abrasives and sand blasting will damage the substrate, are time-intensive, and may endanger the workers.

compares physical characteristics and health effects of potential alternatives, and even customer satisfaction, but does not consider the physical/chemical properties of DCM that make it *uniquely* suited to many uses. Given the limitations of the analysis, it is hardly surprising that the analysis concludes that a majority of small business will have cost impacts of less than 1 percent of annual revenue. Again, nowhere does EPA address the myriad reasons that small businesses told it in the Small Business Advocacy Review (SBAR) that alternatives are not suitable.[53]

The Agency's proposed rule also fails to meet the requirements of TSCA § 6(c)(2)(A), which requires that EPA consider fully the benefits of chemical products it seeks to prohibit in one or more conditions of use. EPA's analysis is flawed because it assumes benefits based on tenuous evidence and ignores nearly certain costs. EPA may not assume benefits while ignoring costs. *Michigan v. EPA*, 576 U.S. 743, 757 (2015). Many small business participants at the SBAR submitted information demonstrating that DCM-based formulations are the most efficient and cost-effective paint remover products available at retail. Equally, they submitted information demonstrating that the alternative paint strippers currently available do not work effectively. Only by ignoring these submissions was EPA able to conclude, incorrectly, that alternative products are technically and economically feasible.

The flammability risk of alternative products has been well documented. For example, the Consumer Product Safety Commission (CPSC) advised EPA that:

> "Changes to the availability of this product [DCM-based paint removers] for consumer use and the use of alternatives that may present different acute hazards must be carefully considered. The use of more flammable coating removers may present the potential for a greater fire risk, loss of furnishings, and risk of injury to consumers."[54]

However, EPA did not assess the comparative fire risks of DCM-based products and alternatives, dismissing such an assessment in its previous rulemaking on paint stripping as "impracticable."[55] Rather, EPA asserted that since paint remover products contain multiple chemicals of varying flammability, EPA cannot forecast whether the products that might replace DCM-based products

[53] Final Report of the Small Business Advocacy Review Panel on EPA's Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a), EPA-HQ-OPPT-2020-0465-0119.

[54] EPA-HQ-OPPT-2016-0231-0154 at 3.

[55] 82 Fed. Reg. 7464, 7487.

would be more or less flammable. This ignores the history of safety concerns in the market, where DCM-based products became dominant in part because they are not flammable.

As noted, EPA was advised by the CPSC that banning consumer use of DCM-based paint strippers could increase use of more flammable alternative products. The Agency did not act on this warning. We submit that EPA has failed to meet its obligations under TSCA § 26 to use the best available by science by failing to heed this warning and by proceeding with a rulemaking that fails to take into account the documented greater flammability risk posed by alternative products.

Finally, in addition to its other shortcomings, the Economic Analysis fails accurately to present a true picture of economic costs. The preamble states "EPA's analysis of the incremental, *non-closure-related costs* of this proposed rule is estimated to be $13.2 million annualized. . . ."[56] Having concluded that some or all of the 5,000 furniture refinishing shops would be forced to close, it would seem that any analysis of the economic impact of the proposed rule would include the costs of these (and other) anticipated closures. And it includes no analysis of the impact of eliminating DCM on restoration of historic buildings/structures, or on recycling generally, even though this is sure to be significant.

1. Flawed Alternatives Analysis Example – Processing Aid

The category of processing aid includes many longstanding uses where DCM is highly controlled, fundamentally safe, and commercially valuable. One such example is that of LANXESS Corporation's use of DCM for manufacturing plastics additives. Specifically, LANXESS uses DCM as a solvent in the reaction steps of two processes for manufacturing brominated flame retardants. This is considered to be a processing aid as DCM is not used as a reactant to manufacture these products and is not incorporated into or otherwise present in them.,

The brominated flame retardants are commercially useful and beneficial to society: customers process them into many types of plastics to prevent burning, slow the spread of fire, or both. One (EI 3000) replaces the persistent organic pollutant hexabromocyclododecane (HBCD) in extruded polystyrene and expanded polystyrene foams used primarily as insulation in building and construction and as packaging material in shipping. In its June 2014 report on alternatives to HBCD, EPA's Design for the Environment Program

[56] 88 Fed. Reg. at 28330 (emphasis added).

assessed the human health and ecotoxicity hazard for EI 3000 to be low, due to the polymer's very large size, lack of low-molecular-weight components, and lack of reactive functional groups. Others (BC-52 and BC-58) help protect plastics used in a wide variety of products in the automotive, electrical, and electronics industries against burning.

LANXESS's manufacturing processes were designed to use DCM as a solvent in the reaction steps. DCM is the only solvent known to satisfy all of the following process requirements: readily dissolves the reactants; does not react with or otherwise interfere with the reactants; is not flammable; and has a low boiling point, which, among other things, facilities the separation of co-solvents by distillation and the recovery of solvents. Solvents other than DCM may react to form impurities, have similar hazards, have too high a boiling point, are flammable, or present a combination of these defects. DCM also is the only solvent known to satisfy the following additional requirements: yields suitable products (*i.e.,* ones that meet customers' specifications, work in customers' applications, and lack problematic impurities; meet applicable environmental permitting requirements; and allow LANXESS to comply with process safety management requirements, handle process wastes, and deliver products in a reasonable time with reasonable capital equipment costs).

In LANXESS's manufacturing processes, there is no technically and economically feasible alternative to DCM that also benefits human health or the environment as compared to DCM – and no such alternative may exist. EPA's alternatives assessment for DCM bears no apparent relationship to how or why LANXESS uses DCM in its manufacturing processes. For this reason, EPA's alternatives assessment identifies no obvious or plausible alternatives to DCM in LANXESS's processes.

Simply to conduct the research necessary to identify a potential replacement for DCM in LANXESS's manufacturing processes would take an estimated 3-5 years and cost an estimated $14-20 million, all without any guarantee of identifying an acceptable replacement. Should LANXESS be fortunate enough to find an acceptable replacement, it would take an additional, estimated 4-5 years and $40-45 million to design, build, test, and resource a new manufacturing process for EI 3000, and it would take LANXESS an additional, estimated 3-5 years and $40-45 million to design, build, test, and resource a new manufacturing process for BC-52 and BC-58 – up to ten years and $90 million in total, if efforts to replace DCM in the separate manufacturing processes for EI 3000 and BC 52/BC 58 proceed in parallel and are

successful. Spending all of this time and money, however, would achieve no new or additional benefit to, or protection of, human health or the environment as compared to LANXESS's continuing safely to use DCM in its manufacturing processes.

Furthermore, by eliminating a processing aid vital to manufacturing flame retardants needed for public safety, a U.S. ban of DCM as a manufacturing processing aid likely would devastate global supply chains while achieving no improvement in human safety and no benefit to the environment. While alternatives to these brominated flame retardants exist, they may not be available for all applications that would need alternatives, in sufficient volumes, or both. The difficulty of switching to alternatives would be magnified where the LANXESS products are specified by industry, military, or other government standards. Yet LANXESS can comply with a WCPP for DCM as easily as any other industrial use of DCM that EPA is not proposing to ban.

None of this discussion will be found in the Economic Analysis. For processing aids, "EPA did not find it practicable to consider whether there are alternative processes that directly replace methylene chloride with an alternative chemical or represent larger changes in multiple process steps in the production of a given chemical, due to the complexity of the analysis."[57]

2. Flawed Alternatives Analysis Example – Furniture Refinishing

EPA's analysis does recognize several important uses where alternatives are not available. Foremost among these is furniture refinishing, Here EPA found "in the unique case of furniture refinishing (within the commercial paint and coating removal condition of use), alternatives to products containing methylene chloride may not be economically viable and may cause damage to the substrate, and thus the prohibition of this use could impact the sector significantly. . . . EPA estimates that as many as 5,000 furniture refinishers still use methylene chloride, a majority of which are small businesses. . . . The impact of a prohibition of methylene chloride for furniture refinishing could result in the closure of an unknown number of the 5,000 potentially affected furniture re-finishing firms using methylene chloride in the baseline."[58] EPA

[57] Economic Analysis at 5-7. Complex though it may be, this is an analysis that TSCA § 6(c) does not authorize EPA to forego when proposing to ban a use.

[58] 88 Fed. Reg. at 28287.

then claims that a complete shut-down is "extreme and unlikely," even as it sketches out the head-on collision its proposed rule poses for the industry.

EPA's analysis is flawed and incomplete, and where it acknowledges shortcomings in the data, it inserts rosy and unfounded assumptions that result in a distorted view of the economic impact. EPA admits that it does not know the "extent to which each [furniture refinishing] firm relies on the use of methylene chloride," but relies on the "fact that firms in the furniture refinishing sector also perform activities that do not involve paint and coating removal," as a mitigating factor.[59] EPA admits that the furniture refinishing industry has no viable replacements for DCM-containing products—used in the basic task of paint stripping—and that the industry represents $1.8 billion in economic activity with razor thin 3.8% margins for firms which "are generally small firms with one to five employee." EPA thus admits ignorance on foundational questions needed to evaluate the economic impact of the proposed rule -- who will the rule impact and how much will it impact them?[60]

Not to worry -- EPA says -- for particularly valuable projects "firms could incur the increased cost of paint and coating removal without the use of methylene chloride."[61] Presumably, for the less valuable projects, the refinishers are expected to take a loss or simply not perform the work. This is not an analysis of the problem so much as it is an acknowledgement that furniture refinishers, with tight margins and small, unsophisticated market participants, will have to make do or go under. And how many will? EPA does not know; it "does not have the detailed financial data to estimate how this rule would affect the probability of increased rates of firm closure in this sector as a result of prohibiting the use of methylene chloride in paint and coating removal."[62]

Rather than express any curiosity over how this nearly $2 billion sector may be impacted by the proposed rule, EPA simply assumes the costs will be manageable, even while acknowledging the factors strongly indicating material impacts on market participants: thin

[59] Economic Analysis at 7-47, 7-48.

[60] The Economic Analysis is also silent as to the cultural significance of eliminating furniture refinishing. Generations of antique dealers have relied on DCM for their trade: what will they do if its use is banned? We also understand that major restoration projects for historic buildings and art depend upon the continued availability od DCM.

[61] *Id.*, at 7-48.

[62] *Id.*, at 7-49.

margins, smaller and unsophisticated market participants, the centrality of the regulated product to business operations, and the absence of alternatives. The most EPA can bring itself to say is that the impacts will *probably* be something less than total collapse of the furniture refinishing industry. Meanwhile, EPA assumes vast benefits from reduced incidence of liver and lung cancers. Yet it ignores the best available science in deriving these benefits, as noted above. Workers have been exposed to DCM for decades, but rather than focus on liver disease/cancer in worker cohorts, EPA relies on effects such as vacuolization seen in rodents but not in humans.[63]

EPA likewise selectively quotes from the sources it does cite to paint a slanted picture in support of the rule. For example, EPA cites a study by Hoang *et al.* (2021) for the notion that "between 2000 and 2020, there were a total of 21 reported methylene chloride-related deaths associated with commercial bathtub refinishing."[64] In fact, Hoang *et al.* say that there were 13 "occupational methylene chloride–related deaths of bathtub refinishers occurring between 2000 and 2011" but critically "[i]n all cases, the refinishers worked in poorly ventilated bathrooms, with inadequate or no PPE." They go on to note that every single death they evaluated involved no PPE or PPE that did not meet NIOSH standards. Despite the fact that EPA's own cited studies emphasize that the DCM-related deaths result from absent or inadequate PPE, EPA simply concludes that, for nearly every condition of use, a complete prohibition is appropriate.

In sum, TSCA § 6(c) provides that "in selecting among . . . restrictions," EPA "shall factor in, to the extent practicable," considerations such as "the effects of the chemical . . . on the environment," "the benefits of the chemical substance or mixture for various uses," and "the reasonably ascertainable economic consequences" of the rule. The assessment of economic consequences must include the "costs and benefits" and the "cost effectiveness" of the "proposed and final regulatory action" as well as of at least one alternative. EPA must publish a statement discussing those factors. If a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute." Having

[63] The shortcomings of the assessment of liver toxicity are discussed in detail in § II(A) above.

[64] *Id.*, at 8-3.

failed to conduct a meaningful alternatives analysis, a wholesale ban on DCM in these use sectors is unauthorized.[65]

IV. DISTRIBUTION IN COMMERCE

EPA should confirm the no unreasonable risk determination and order under TSCA § 6(i)(l) for distribution of DCM in commerce.[66] Because distribution in commerce does not pose an unreasonable risk, risk management regulation is not necessary to prevent such unreasonable risk. Additionally, the proposed rule requires a WCPP to prevent unreasonable risk in any upstream or downstream use following distribution in commerce, therefore negating any need to regulate distribution in commerce to address upstream or downstream activities.[67] EPA should clarify that distribution in commerce in compliance with regulations for transportation of DCM does not pose an unreasonable risk so that additional regulation is not necessary.

EPA could clarify the applicability of the regulation of distribution to the COUs allowed under the rule by inserting the following new § 751.110 (based upon the Risk Evaluation Condition of Use description in Section 5.2.1.7, p. 468):

> Distribution in Commerce. For the purpose of use conditions listed in 40 CFR § 751.109 or use conditions not otherwise prohibited in this subpart, distribution in commerce of methylene chloride, the transportation associated with the moving of methylene chloride in commerce, is an allowed use condition. Loading and

[65] Much of the foregoing discussion is acknowledged in the preamble: "Unquantified costs exist, including determining the best substitute for the firm's specific needs and how a different product may impact a firm's existing workflow (*e.g.,* does a different adhesive take longer to dry) and how a firm may work through the hierarchy of controls to comply with a WCPP. Although some costs cannot be quantified, they are not necessarily less important than the quantified costs. The most notable unquantified cost is change in labor and wait times within applications for which methylene chloride use is more efficient than substitute methods or alternative chemicals for achieving desired results. Additionally, in the unique case of furniture refinishing (within the commercial paint and coating removal condition of use), alternatives to products containing methylene chloride may not be economically viable and may cause damage to the substrate, and thus the prohibition of this use could impact the sector significantly." 88 Fed. Reg. at 28286.

[66] Risk Evaluation at 518. For some reason, distribution is missing from the list of allowable conditions of use in the proposed rule. As noted, it was deemed to present "no unreasonable risk" in the 2020 Risk Evaluation. Although the response to comments on the draft Revised Risk Determination states: "[b]ased on the limited emissions from the transportation of chemicals, EPA has determined that distribution in commerce of methylene chloride does not drive the unreasonable risk determination for methylene chloride," it was not included in the Revised Risk Determination under the whole chemical approach: "Distribution: EPA is not making a condition of use-specific risk determination for this condition of use."

[67] Of course, this is not to concede that either the upstream or downstream uses pose an unreasonable risk, or that EPA has the authority to regulate upstream activities which do not pose an unreasonable risk.

unloading activities are not included in the Distribution in Commerce use condition.

V. WCPPS SHOULD REQUIRE COMPLIANCE WITH OSHA LIMITS, NOT THE ECEL/STEL

EPA proposes that ten current uses of DCM would be allowed to continue subject to WCPP requirements to be implemented by employers (referred to by EPA as "owners or operators"). WCPPs would apply to the following conditions of use identified in the proposed rule:

- domestic manufacturing
- processing for incorporation into a formulation, mixture, or reaction product
- industrial and commercial use as a laboratory chemical
- disposal
- import
- processing in repackaging
- industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft by Federal agencies and their contractors
- processing as a reactant
- processing in recycling
- 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 specialty batteries for such applications by Federal agencies and their contractors

The WCPPs to be implemented would have to achieve far lower exposure limits than those adopted by OSHA. Specifically, EPA is proposing the following limits:

	(Reduction from OSHA Limit)
8-Hour Time-Weighted Average (TWA) 2 ppm ECEL	(-92%)
15-Minute Short-Term Exposure Limit (STEL) 16 ppm	(-87%)

As noted above, chronic liver toxicity is the basis of the ECEL, and acute neurotoxicity is the basis of the STEL. These limits would be complemented by a proposed ECEL Action Level of 1 ppm over an 8-hour TWA. The Action Level is a definitive cut-off point below which certain compliance activities, such as periodic monitoring, would not be required.

For implementing a WCPP, EPA proposes a 180-day compliance period after the final rule is published, with several caveats and conditions subject to more generous limitations. After the 180-day implementation period, users would have an additional 90 days (270 total) to ensure that they meet ECEL and STEL limits by operation of their WCPP. The exposure control plan must be fully implemented by 360 days after publication of the final rule. Despite the ~90% reduction from the OSHA PEL/STEL, EPA believes this timeframe is achievable because the requirements "are consistent with the timeframes in OSHA's 1997 standard for methylene chloride," although the WCPPs would include correspondingly more onerous PPE, monitoring, and implementation requirements. EPA acknowledges that a WCPP is in addition to, and not a substitute for, OSHA requirements. Having two regulators responsible for the same workplace obviously will raise serious compliance issues for employers which now find themselves subject to both sets of regulations.

HSIA urges EPA to adopt the OSHA limits as its ECEL/STEL. If it were to do so, HSIA could support the proposed approach to these ten uses.

A. Having determined that compliance with WCPPs eliminates unreasonable risk, there is no justification for a time limit on such compliant uses

EPA considers "Industrial and commercial use in paint and coating removers from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators" for a WCPP as its primary alternative action, but proposes as its regulatory action a prohibition with a 10-year time-limited exemption and interim WCPP. For the reasons stated below, we do not believe such a prohibition is warranted and urge EPA to allow this sector to continue operating subject to a WCPP.

EPA's proposal to exempt uses of DCM for paint and coating removal that are essential for critical infrastructure provides a 10-year exemption for commercial aviation and commercial aerospace applications from the proposed prohibition on the use of DCM in commercial paint and coating removal. EPA's rationale for the exemption follows:

> "To effectively prevent significant disruptions to critical infrastructure including commercial aviation and aerospace, EPA would make this exemption available to three different groups of commercial entities. In each case, the exemption would be available only for the use of methylene chloride to remove paint and coatings from safety-critical, corrosion-sensitive components of aircraft or aerospace vehicles. The first group would consist of those facilities that primarily maintain and repair aircraft used by air carriers and commercial operators. More

specifically, maintenance and repair facilities operated by air carriers and commercial operators certificated under 14 CFR part 119 would be eligible for the exemption, as would be repair stations certificated under 14 CFR part 145, if their primary business is performing maintenance, preventive maintenance, rebuilding, or alteration of aircraft operated by air carriers and commercial operators certificated under 14 CFR part 119. The second group would consist of manufacturers of aircraft intended for, or capable of being used by, air carriers and commercial operators certificated under 14 CFR part 119. The third group would consist of any person manufacturing or repairing spacecraft, space vehicles, or payloads or similar hardware that is intended for, or used in, commercial space transportation operations subject to 14 CFR chapter III.

"The conditions for the proposed exemption would be: (1) The use of methylene chloride for commercial paint or coating removal by certificated air carriers, commercial operators, or repair stations, or by manufacturers of aircraft or aerospace vehicles or hardware, would be limited to the safety-critical, corrosion-sensitive components on aircraft and aerospace vehicles; (2) The use of methylene chloride for paint or coating removal would be required to be performed on the premises of the certificated air carrier or commercial operator or repair station, or of the manufacturer of aircraft or aerospace vehicles or hardware; and (3) The certificated air carrier, commercial operator, repair station, or manufacturer of aircraft or aerospace vehicles and hardware manufacturer would have to comply with the WCPP discussed in Unit IV.A.1.

"EPA wishes to make clear that the exemption for the commercial aerospace and aviation industry would only be available for the purpose of paint and coating removal from components of aircraft and spacecraft that are corrosion-sensitive and safety critical components, such as landing gear, gear boxes, turbine engine parts, and other aircraft and spacecraft and components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials. In addition, these components would have to be of the type that not only require their paint or coatings to be removed for inspection and maintenance but also would be so negatively affected by the use of paint and coating removal chemicals or methods other than methylene chloride that the safety of the system could be compromised. General paint and coating removal on aircraft and spacecraft would not be authorized under this exemption. . . .

"EPA requests comments on all aspects of the proposed TSCA section 6(g) exemption from the proposed prohibition on use of methylene chloride in commercial paint and coating removal for paint and coating removal essential for critical infrastructure by certificated commercial air carriers, commercial operators, or repair stations, or by manufacturers of aircraft or aerospace vehicles and hardware, noting that the proposed exemptions would be limited to the safety-

> critical, corrosion-sensitive components on aircraft and aerospace vehicles, including safety-critical components."[68]

What is missing from this discussion is the reason that a 10-year time limitation is needed; there is only a reference to TSCA § 6(g).[69] In any event, EPA provides no justification for treating air carriers or commercial operators differently from Federal agencies and their contractors with regard to "paint and coating removal from components of aircraft and spacecraft that are corrosion-sensitive and safety critical components, such as landing gear, gear boxes, turbine engine parts, and other aircraft and spacecraft and components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials." The DCM use is exactly the same no matter whether it is done by industry or federal agencies and their contractors; in fact many contractors work for both government and the private sector. TSCA does not distinguish, either in § 6(g) or otherwise, between government and private operators. Either is perfectly capable of developing a WCPP, and once such a WCPP is implemented the unreasonable risk asserted by EPA is eliminated.

Indeed, some of the foregoing is acknowledged by EPA:

> "[W]hile EPA expects that some of these facilities could successfully follow the requirements of the WCPP, based on qualitative information provided by stakeholders, this expectation is not sufficiently supported by monitoring data in the 2020 Risk Evaluation for Methylene Chloride. As a result, there is significant uncertainty whether the requirements of the WCPP could be implemented successfully in this sector for this particular use on a consistent and reliable basis, in part due to the diversity of facilities in this sector. EPA understands that generally large commercial aviation facilities could have industrial hygiene expertise, sophisticated engineering and administrative controls, and experience with rigorous safety requirements and methods for ensuring continuous strong safety records (Ref. 31). However, EPA is concerned about the ability of smaller aircraft repair shops to implement the WCPP over the long term, particularly for this condition of use. While EPA recognizes that the proposed TSCA section 6(g) exemption for commercial aircraft paint and coating removal could also cover these smaller aircraft repair shops, the exemption is time-limited and ultimately

[68] 88 Fed. Reg. at 28311.

[69] Regarding the § 6(g) essential use exemption generally, it is important to note that various chlorinated solvents are produced as coproducts in the same production process. Unintended consequences in the production and availability of critical building block chemicals will occur if sufficient time is not provided to evaluate any necessary changes to IH procedures, monitoring protocols, or manufacturing processes across a manufacturing unit. DCM obviously has critical uses, but production of commodity chemicals such as DCM may be curtailed if the only markets are a handful of essential uses. A minimum baseload volume is necessary to achieve economically acceptable operating rates. Elimination of the majority of current COUs, as proposed, may well result in closure of chlorocarbon production facilities with significant economic impact that is not addressed in the Economic Analysis.

would result in these small shops using alternatives to methylene chloride. While Federal agencies and contractors should be regulated under the WCPP, the Agency is proposing that commercial use of methylene chloride for a similar type of paint and coating removal be regulated with a time-limited, conditional exemption under TSCA section 6(g), due to notable differences in the two sectors. Specifically, exposure information assessed by EPA resulted in key differences in risk estimates for paint and coating removal by civilian aviation and DOD (see discussion in this Unit and Unit V.A.1.). Additionally, as described in Unit V.A.1., Federal and Federal contractor facilities are subject to multiple levels of oversight as a result of the governmental and public nature of their activities, while many civilian aviation facilities are not likely to experience the same level of scrutiny. EPA emphasizes that in the absence of information, it must still ensure that unreasonable risks are addressed. Because EPA has found inadequate information to otherwise determine whether the unreasonable risk would be addressed when using methylene chloride under a WCPP for commercial use of methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and aerospace vehicles for commercial aviation and aerospace, EPA has determined that the proposed exemption under TSCA section 6(g) allowing for time-limited, conditional use of methylene chloride for this critical use is the appropriate approach.

"EPA recognizes that in some situations, certain facilities may do both Federal contractor and commercial aviation work and may use methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components on military, Federal, or commercial aviation. EPA requests comment on whether such co-located activities in a facility should be subject to the WCPP, rather than the exemption under TSCA section 6(g). Additionally, EPA seeks additional information and requests comment on whether it is possible to distinguish between commercial aviation facilities that would be able to meet the WCPP and those that would not, including what criteria should be used for such distinctions (*e.g.*, size of facility, volume or type of work performed, record of exposure reduction practices). EPA also requests comment on the extent to which specific commercial aviation and aerospace uses or types of facilities could fully comply with the WCPP to address identified unreasonable risk."[70]

Once again, as in the case of the 34 commercial uses EPA proposes to eliminate outright discussed in Section III, the foregoing discussion represents a profound misunderstanding of the statutory directive, encapsulated by the sentence: "EPA emphasizes that in the absence of information, it must still ensure that unreasonable risks are addressed." Nowhere does TSCA so provide. Rather, TSCA § 6(a) directs EPA to regulate "to the extent necessary so that the chemical substance or mixture no longer presents such risk." A facility in compliance with its

[70] 88 Fed. Reg. at 28310-28311.

WCPP has acted, by EPA's definition, to "ensure that unreasonable risks are addressed." The statute does not ask or empower EPA to gather any further information (although EPA of course maintains its enforcement mechanisms). Here, indeed, EPA acknowledges that "certain facilities may do both Federal contractor and commercial aviation work and may use methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components on military, Federal, or commercial aviation" and "requests comment on whether such co-located activities in a facility should be subject to the WCPP, rather than the exemption under TSCA section 6(g)." The answer, both legally and practically, is yes. It would be absurd for EPA to split a single facility and regulate parts of it differently based on whether they are stripping a plane for the government or the private sector. And again, as in the case of the prohibited uses above, EPA mistakes its mandate to include establishing criteria to make "such distinctions (*e.g.*, size of facility, volume or type of work performed, record of exposure reduction practices)," betraying its bias against small business in the face of the TSCA § 6(c)(2) requirement that it consider "the likely effect of the rule on . . . small business." Once it establishes the regulatory requirements, EPA has no further authorization "to distinguish between commercial aviation facilities that would be able to meet the WCPP and those that would not."

VI. THE PROHIBITION ON SALES BY RETAILERS, IF NOT CHANGED, WILL DESTROY THE SUPPLY CHAIN FOR SMALL COMMERCIAL USERS

> "EPA is proposing to prohibit retailers from distributing in commerce methylene chloride and all methylene chloride-containing products, in order to prevent products intended for industrial and commercial use under the WCPP outlined in Unit IV.A.1 from being purchased by consumers. A retailer is any person or business entity that distributes or makes available products to consumers, including through e-commerce internet sales or distribution. If a person or business entity distributes or makes available any product to at least one consumer, then it is considered a retailer (40 CFR 751.103). For a distributor not to be considered a retailer, the distributor must distribute or make available products solely to commercial or industrial end-users or businesses. Prohibiting manufacturers (including importers), processors, and distributors from distributing methylene chloride, or any products containing methylene chloride, to retailers would prevent retailers from making these products available to consumers, which would help address that part of the unreasonable risk driven by consumer use of methylene chloride (Ref. 37). EPA promulgated a similar prohibition for retailers in the 2019 final rule addressing unreasonable risk from consumer use of methylene chloride in Paint and Coating Removal (84 FR 11420, March 27, 2019), and has not received negative feedback from retailers regarding sales losses. EPA has continued to receive feedback from stakeholders, including

> small businesses, on particular strategies they suggest could be used to ensure that distribution only occurs to commercial entities, such as requiring a business number (Ref. 6). To that end, EPA would like comment on whether distributors that are not retailers should be required to use tax IDs or other verification methods prior to selling methylene chloride or products containing methylene chloride to ensure consumers are not purchasing methylene chloride or industrial or commercial products containing methylene chloride.
>
> "Additionally, during litigation on the 2019 final rule petitioners argued that EPA's definition of ''retailer'' was so broad as to cover all commercial entities, creating supply chain issues for commercial users seeking to attain and use the chemical for commercial activities (*Lab. Council for Latin Am. Advancement* v. *United States Env't Prot. Agency*, 12 F.4th 234 (2d Cir. 2021)). EPA has not found this to be the case; small businesses that are non-retail distributors exist and even participated as small entity representatives consulted as part of the SBAR process for this rulemaking. Nonetheless, EPA is soliciting comment on whether similar supply chain issues for uses that are permitted under the WCPP are anticipated."[71]

HSIA does not support elimination of consumer use of DCM. Our concern here, however, is the ongoing ability of small businesses to purchase the DCM-based products they need in order to continue to provide services efficiently. It is true, as referenced in the quote above, that the definition of "retailer" is so broad that it eliminates virtually all supply outside of one or two "non-retail distributors. . . that participated as small entity representatives consulted as part of the SBAR process." These companies provide a valuable service by making DCM available in bulk to large commercial users. They are able legally to do so because they do not sell to the public. It should be obvious, however, that one or two bulk distributors cannot serve a geographically dispersed nation of tens of thousands of small businesses desiring to purchase small containers for allowed uses. In the absence of availability at hardware and home improvement stores, these small businesses will be unable to access a supply. In this as in other ways, the definition of retailer in the proposed rule discriminates unlawfully against small businesses.

The solution is not that "distributors that are not retailers should be required to use tax IDs or other verification methods prior to selling methylene chloride or products containing methylene chloride," as identified by EPA. This would solve a problem that exists only in EPA's imagination: there is no evidence of any consumer attempting to purchase from a bulk

[71] 88 Fed. Reg. at 28308.

seller. The solution is for EPA to eliminate the incredibly broad definition of "retailer," while leaving in place the prohibition on selling to consumers. Thus, sales of DCM-based products for consumer use will be unlawful, and formulators and distributors would have to provide notice of that prohibition down the distribution chain. Sales could be restricted to individuals with commercial accounts or those who can show tax IDs or other verification methods to establish that they are businesses. This would also be administratively straight-forward, requiring only the elimination of the prohibition on distributing to retailers and limiting the prohibition on retailers from distributing DCM-containing products "for any use" to distributing to "consumers." A definition of "consumer" could also be provided to replace that of "retailers." Laws is all states prevent sales by retailers of alcohol or tobacco products to minors, and limit sale of drugs to customers who have a prescription. Clearly a limitation on sales of DCM-based products to commercial users could be effective.

VII. EPA HAS NOT MET THE REQUIREMENTS OF TSCA § 9

TSCA § 9, as originally enacted and as updated by the Lautenberg Act, requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes." Worker health and safety falls under the jurisdiction of the federal OSHA, and use of DCM is already more than adequately regulated under the OSH Act. This comprehensive regulatory framework provides adequate protections with respect to the same potential adverse impacts and potential exposure pathways targeted by the current EPA initiative. Taking steps that may lead to the removal of products from the marketplace because workers or consumers failed to comply with these existing requirements is not consistent with TSCA either as initially enacted or as revised.

A. From its inception, TSCA has been intended to fill gaps in regulation, not to supplant existing regulatory frameworks

TSCA § 9, as amended, provides:

> "(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation

identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

> (A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and (ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and
>
> (B) to respond to the Administrator with respect to the matters described in subparagraph (A).

"Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

> "(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—
>
> (A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or
>
> (B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities, the Administrator may not take any action under section 6(a) or 7 with respect to such risk."

> "(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—(1) The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.
>
> "(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the actions to be taken under this title and an action to be taken under such other law to protect against such risk."

It was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another act is sufficient to regulate a particular risk."[72] With specific reference to the workplace, the legislative history states:

> The Committee recognizes that the requirements prescribed by the Administrator under this section may provide protection for employees in the workplace. For example, by prohibiting the manufacture of a substance, risks to employees involved in the manufacturing of the substance would be eliminated. However, *the Committee wishes to emphasize that none of the authorities included in section 6(a) should be construed as authorizing the Administrator to issue workplace standards directly regulating such matters as the airborne concentrations of a substance to which employees may be exposed* or the manner in which an employee is permitted to handle a substance.
>
> *There is no authority in the bill for the Administrator to issue rules respecting personal protective equipment for employees*, work practices in hazardous operations, or procedures for emergency situations. *Such direct regulation of*

[72] 122 Cong. Rec. H11344 (Sept. 28, 1976).

> *the workplace falls under the jurisdiction of the Occupational Safety and Health Act of 1970 not under this bill.*[73]

This Congressional statement at the time TSCA was enacted clearly expresses the limitations on EPA's authority, and more recent legislative history also leaves no doubt. The House Energy and Commerce Committee Report on the Lautenberg Act states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while section 5 makes no amendment to TSCA section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[74] Indeed, TSCA § 9 was strengthened by the Lautenberg Act, as evidenced by two colloquies on the floor of the House of Representatives with specific reference to methylene chloride. First:

> "Mr. SHIMKUS. Mr. Speaker, I yield 2 minutes to the gentlewoman from Tennessee (Mrs. *Blackburn*), the vice chair of the full committee.
>
> Mrs. BLACKBURN. Mr. Speaker, I do rise in support of the amendments to H.R. 2576, and I congratulate Chairman *Shimkus* on the wonderful job he has done. Mr. Speaker, I yield to the gentleman from Illinois (Mr. *Shimkus*) for the purpose of a brief colloquy to clarify one important element of the legislation.
>
> Mr. Chairman, it is my understanding that this bill reemphasizes Congress' intent to avoid duplicative regulation through the TSCA law. It does so by carrying over two important EPA constraints in section 9 of the existing law while adding a new, important provision that would be found as new section, 9(b)(2).
>
> It is my understanding that, as a unified whole, this language, old and new, limits the EPA's ability to promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA.
>
> Would the chairman please confirm my understanding of section 9?
>
> Mr. SHIMKUS. Will the gentlewoman yield?

[73] H. Rep. No. 1341, 94th Cong., 2d Sess. 34 (1976) (emphasis added), reprinted in House Committee on Interstate and Foreign Commerce, Legislative History of the Toxic Substances Control Act, at 441 (1976).

[74] H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28.

Mrs. BLACKBURN. I yield to the gentleman from Illinois.

Mr. SHIMKUS. The gentlewoman is correct in her understanding.

Mrs. BLACKBURN. I thank the chairman. The changes you have worked hard to preserve in this negotiated bill are important. As the EPA's early-stage efforts to regulate methylene chloride and TCE under TSCA statute section 6 illustrate, they are also timely.

EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New section 9(b)(2) will force the Agency to do just that.

I thank the chairman for his good work."[75]

Second:

"Mr. PITTENGER. Mr. Speaker, I thank the chairman for this very sensible legislation. I appreciate his efforts in leading a bipartisan effort to reform U.S. chemical safety law that is decades in the making.

I particularly thank him for securing amendments to section 9 of the TSCA law that remain in the negotiated text. These amendments reemphasize and strengthen Congress' intent that TSCA serve as an authority of last resort for the regulation of a chemical when another authority under EPA's jurisdiction, or another Federal agency, already regulates the chemical and the risk identified by EPA.

As a unified whole, TSCA now makes clear that EPA may not promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when:

Number one, the agency either already regulates that chemical through a different statute under its own control, like the Clean Air Act, and that authority sufficiently protects against a risk of injury to human health or the environment; or

Number two, a different agency already regulates that chemical in a manner that also sufficiently protects against the risk already identified by EPA.

Mr. Speaker, in light of yet another regulatory overreach in the rulemaking at EPA, the new amendments to section 9 of TSCA are a welcome reform with the intent that it will help restrain the agency's unnecessary activities. These are commonsense, but important, protections given what EPA is likely to pursue."[76]

[75] 162 Cong. Rec. H3028 (May 24, 2016).

[76] *Id.*

B. The instant proposal fails to take into account existing regulation of DCM, as required by TSCA § 9

As noted above, OSHA has regulated occupational exposure to DCM for many years. OSHA should be given an opportunity to consider whether a lower workplace standard would be appropriate.[77] Otherwise, if EPA were to go forward with regulation under TSCA, there would be a potential for conflicting and overlapping regulation. OSHA's existing limits would remain in place, regardless of EPA's action, and OSHA's enforcement of its own standards is mandatory (subject to prosecutorial discretion). OSHA may not, however, enforce an EPA regulation under the general duty clause of the OSH Act, even if the EPA regulation were more stringent, as long as an OSHA standard on the same substance is in effect.

It is also significant that, as noted above, EPA is not authorized to establish ambient concentration limits under TSCA § 6.[78] Acting on its own, EPA thus cannot limit employee exposure directly, but could only do so indirectly, *e.g.*, by controlling the amount of substance used in a product or prohibiting a particular use of the substance under § 6. Such more burdensome regulation can be avoided if EPA cooperates with OSHA under TSCA § 9 and OSHA sets limits, allowing each employer subject to the limits to achieve the necessary reduction in exposure in the most cost-effective manner. Indeed, TSCA § 6(c)(2) requires EPA carefully to consider the cost-effectiveness of a proposed regulatory action against at least one alternative, and Executive Order 13563 requires agencies to achieve their objectives by using the least costly regulatory alternative.[79] Here, the most cost-effective alternatives have not been chosen.

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[77] EPA applied TSCA § 9 in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the Occupational Safety and Health Act, and referring the matter for action by OSHA. 50 Fed. Reg. 27674 (July 5, 1985). And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that "Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them." Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2. *See also* TSCA § 2(c): "INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided to take under this Act."

[78] H. Rep. No. 1341, 94th Cong., 2d Sess. 34 (1976), *reprinted in* House Committee on Interstate and Foreign Commerce, *Legislative History of the Toxic Substances Control Act*, at 441 (1976).

[79] Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821-3823 (January 21, 2011). In pertinent part, E.O. 13563 states:

In light of the foregoing, considerations of avoiding unnecessary duplication and utilizing established expertise weigh in favor of invoking the Administrator's referral authority under TSCA § 9(a) even if EPA were to proceed under TSCA. If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[80] Yet there is no evidence that EPA has submitted to OSHA "a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk." The non-existent report obviously did not "include a detailed statement of the information on which it is based" and was not "published in the Federal Register," as required.

Had the required report been issued, in the case of OSHA it presumably would have identified how OSHA's authority over the workplace was insufficient to address the risks posed by DCM. A letter from the Assistant Secretary of Labor for Occupational Safety and Health (undated but apparently issued on April 4, 2016) identifying limits on OSHA's authority to regulate hazardous substances such as DCM was issued in connection with a previous rulemaking, but it does not come close to meeting the requirements of TSCA for EPA action in this case. The April 2016 letter identifies no such gap specific to use of DCM in any particular

"This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."

[80] As noted above, § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

workplace, rather it simply recites how OSHA's authority does not extend to self-employed workers, military personnel, and consumer uses. But those are limitations that were imposed by Congress and have existed since the Occupational Safety and Health Act was enacted. Those limitations apply to every use of every toxic substance. Congress cannot have meant, in enacting "gap-filling" legislation, to open the door to EPA assuming all authority over the use of hazardous substances in the workplace.

Finally, EPA has not taken into account its own extensive regulation of DCM uses under the Clean Air Act, as required under TSCA § 9(b). For example, EPA has adopted a number of emission standards that limit emissions of DCM, which is a Hazardous Air Pollutant (HAP) listed in Clean Air Act (CAA) § 112. These include, notably, National Emission Standards for Organic Hazardous Air Pollutants for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources ("the NESHAP").[81] Under CAA § 112, these standards must ensure an "ample margin of safety to protect public health." Thus, if the risk of concern was significant, EPA would have to adopt more protective standards under the Clean Air Act.

The applicable requirements of the NESHAP are as follows:

> "(a) Each paint stripping operation that is an affected area source must implement management practices to minimize the evaporative emissions of MeCl [DCM]. The management practices must address, at a minimum, the practices in paragraphs (a)(1) through (5) of this section, as applicable, for your operations.
>
> (1) Evaluate each application to ensure there is a need for paint stripping (e.g., evaluate whether it is possible to re-coat the piece without removing the existing coating).
>
> (2) Evaluate each application where a paint stripper containing MeCl is used to ensure that there is no alternative paint stripping technology that can be used.
>
> (3) Reduce exposure of all paint strippers containing MeCl to the air.
>
> (4) Optimize application conditions when using paint strippers containing MeCl to reduce MeCl evaporation (e.g., if the stripper must be heated, make sure that the temperature is kept as low as possible to reduce evaporation).
>
> (5) Practice proper storage and disposal of paint strippers containing MeCl (e.g., store stripper in closed, airtight containers).
>
> "(b) Each paint stripping operation that has annual usage of more than one ton of MeCl must develop and implement a written MeCl minimization plan to

[81] 40 C.F.R. Part 63, Subpart HHHHHH.

> minimize the use and emissions of MeCl. The MeCl minimization plan must address, at a minimum, the management practices specified in paragraphs (a)(1) through (5) of this section, as applicable, for your operations. Each operation must post a placard or sign outlining the MeCl minimization plan in each area where paint stripping operations subject to this subpart occur. Paint stripping operations with annual usage of more than one ton of MeCl, must comply with the management practices in paragraphs (a)(1) through (5) of this section, as applicable, but are not required to develop and implement a written MeCl minimization plan.
>
> "(c) Each paint stripping operation must maintain copies of annual usage of paint strippers containing MeCl on site at all times.
>
> "(d) Each paint stripping operation with annual usage of more than one ton of MeCl must maintain a copy of their current MeCl minimization plan on site at all times."82

The NESHAP referenced above applies to all area sources engaged in paint stripping using DCM-containing paint strippers, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating operations, except those excluded in 40 C.F.R. § 63.11169(d). This includes virtually the entire universe of small paint stripping operations, as an "area source is defined in the Clean Air Act (CAA) section 112(a) as any stationary source of HAP that is not a major source, and a major source is defined as any stationary source or group of stationary sources located within a contiguous area and under common control that emits, or has the potential to emit, considering controls, in the aggregate, 10 tons per year (tpy) or more of any single HAP or 25 tpy or more of any combination of HAP."[83] Thus, regulations that were adopted during a process that properly took into account small business considerations and that by definition provide an "ample margin of safety to protect public health" are already in effect for many of the use sectors where EPA now proposes to eliminate DCM use.

The existence of a comprehensive regulatory framework for paint strippers under the Clean Air Act has two important implications for any consideration of TSCA § 6 rulemaking for the same sector. First, it means that regulation under TSCA § 6 is precluded under TSCA § 9(b) unless EPA can make a determination "that it is in the public interest to protect against such risk by actions taken under this Act," where sponsors of the Lautenberg Act have stated the view that EPA's "own existing regulatory framework already appropriately addresses risk to human

[82] 40 C.F.R. § 63.11173.
[83] 73 Fed. Reg. 1738 (Jan. 9, 2008).

health."[84] Second, it is remarkable that EPA has not drawn on use and exposure information from these regulated uses to inform the instant proposal. Analyses conducted by the EPA Air Office and data collected under the various NESHAPs applicable to DCM would provide information that is missing from the meager Alternatives Analysis in the record.

VIII. THE ELEMENTS ADDED IN THE REVISED RISK DETERMINATION ARE INCONSISTENT WITH TSCA

EPA published a draft Revised Risk Determination for DCM in 2022,[85] in which it announced its intent to implement two changes to the approach taken in the 2020 Risk Evaluation: (i) EPA stated it would make a revised risk determination of unreasonable risk for DCM as a whole chemical, instead of making risk determinations for each of DCM's conditions of use; and (ii) EPA stated it would no longer assume that all workers wear personal protective equipment (PPE) when conducting risk evaluations. HSIA commented that the proposed whole chemical approach and decision no longer to assume the use of PPE are inconsistent with the requirements of TSCA and EPA's implementing regulations, are not within the scope of EPA's discretion, and fail to provide the public with an accurate picture of the risks presented by a chemical substance under the substance's actual conditions of use. HSIA urged EPA to withdraw its proposed revision to the DCM risk determination, to continue to make condition-of-use specific risk determinations for DCM and other chemical substances, and to continue to include reasonable assumptions regarding the use of PPE for each condition of use.[86]

Those comments are all relevant and in the docket. In light of EPA's justification of its unreasonable risk findings by unrealistic exposure scenarios, it warrants repeating that TSCA § 3(4) defines the term "conditions of use" as "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." The structure of the definition makes clear that "circumstances" includes aspects of the context in which a chemical substance is manufactured, imported, processed, distributed in commerce, used, or disposed of, including whether workers wear PPE. EPA's proposal no longer to assume the use of PPE is

[84] 162 Cong. Rec. H3028 (May 24, 2016).

[85] 87 Fed. Reg. 39824 (July 5, 2022).

[86] EPA-HQ-OPPT-2016-0742-0131.

contrary to TSCA because it effectively eliminates "circumstances" from the definition of conditions of use. The use of PPE is a circumstance that "is intended, known, or reasonably foreseen." PPE use therefore belongs as a component of the conditions of use that EPA must consider in its risk evaluations.

As noted above, in the 2020 Risk Evaluation "EPA generally assume[d] compliance with OSHA requirements for protection of workers."[87] EPA explained that "existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE," and that reasonable evidence supported the assumption that workers were complying with OSHA's requirements. EPA also acknowledged that it could not presume, "in the absence of supporting information," a lack of compliance with OSHA's existing regulatory programs. Nevertheless, EPA based its decisions on unreasonable risk to workers on "high-end exposure estimates, in order to account for the uncertainties related to whether or not workers are using PPE." Even with these estimates, the Risk Evaluation found no unreasonable risk from either domestic manufacture or feedstock use.[88] EPA's Revised Risk Determination does not explain why the prior findings that OSHA requirements will result in appropriate PPE use are no longer supported. Without supporting record evidence or analysis, EPA's decision no longer to assume the use of PPE is clearly inconsistent with TSCA requirements. EPA has also not explained why some conditions of use that did not require PPE for the no unreasonable risk determination still require a WCPP for compliance.

IX. COMPLIANCE ISSUES/NEED FOR EXTENDED COMPLIANCE DEADLINES

Monitoring methodologies, laboratory availability, monitoring protocols and control development, training and implementation all require time to implement a new ECEL, particularly one considerably lower and more conservative than other DCM limits currently in effect for the workplace. EPA should extend the time in § 751.109 to implement the WCPPs required under the regulations.

[87] *See* Risk Evaluation, EPA-HQ-OPPT-2019-0437-0107, at 38.

[88] *Id*. at 517-518.

A. Time is needed for monitoring methodology validation and lab availability

The proposed requirement of Good Laboratory Practices (GLP) is inconsistent with current workplace monitoring that is conducted to Industrial Hygiene Laboratory Accreditation Program (IHLAP) standards, which most IH labs follow. DCM samples could not be analyzed at IHLAP labs and would need to be sent to EPA or the handful of commercial labs that follow GLP. This could cause a backlog at the available GLP labs, resulting in samples not being analyzed before their hold time expires.

Further, one of the methods recommended in the ECEL documentation is NIOSH 3900, an area sampling method that uses a canister. This is not a method that can be used for personal breathing zone sampling. NIOSH 2549 is capable of meeting the detection limit for the 15-minute STEL (16 ppm), but the method has not been validated for short sample collection times (less than 60 minutes). It is unclear if there is a validated method that could meet the STEL sampling requirement.

EPA's expectation of GLP testing for workplaces is also inconsistent with EPA's TSCA § 5(e) order template, which states: "Compliance with TSCA GLP[s], however, is not required under this New Chemical Exposure Limit Section where the analytical method is verified by a laboratory accredited by either: the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP") or another comparable program approved in advance in writing by EPA." A similar provision should be considered in the instant rulemaking.

B. 12 months is needed for personal monitoring assessment, implementation and training

To allow proper implementation of the steps and time taken to assess or reassess an IH program for a new ECEL/STEL, at a minimum EPA should revise § 751.109(d)(2)(i) to allow 12 months for the initial exposure monitoring requirement.

EPA should extend the timeframe for conducting initial monitoring to 12 months from promulgation as suggested in the primary alternative. Each facility will need to determine whether a corporate exposure assessment strategy will need to be reassessed for the new ECEL/STEL evaluation.

A typical exposure assessment/reassessment strategy would include identifying and involving stakeholders in the re-evaluation, such as operations management, process engineers,

PSM engineers and HESS personnel. An exposure assessment/reassessment strategy may include confirming and/or reassessing the following exposure assessment goals and written plans for the ECEL/STEL evaluation:

a. Methods for systematic information gathering;

b. Confirming similar exposure groups (SEG) for the new ECEL/STEL;

c. Identify decision statistics and number of random samples that will be used to determine whether the exposure profile for a SEG is acceptable, unacceptable, or uncertain;

d. Identify exposure thresholds and appropriate exposure monitoring methods to meet thresholds; and

e. Training to ensure the proper execution of an exposure assessment strategy.

To proceed with an exposure reassessment against a new ECEL/STEL, each representative air sample that will be evaluated will be subject to a Qualitative Exposure Assessment to help determine the expected exposure category before attempting to perform exposure monitoring.

The Qualitative Exposure Assessment includes identifying the following:

a. All tasks

b. The frequency/duration of each task

c. Estimate of quantity of stressor per task

d. Exposure controls in place for each task exposure

Once the Qualitative Exposure Assessment is complete, the Quantitative Exposure Assessment (personal exposure monitoring) takes place. This step includes:

a. Collecting the appropriate number of random samples (full-shift and tasks)

b. Performing statistical analysis on sample set, as appropriate

c. Comparing to exposure level

d. Decisions related to exposure profile

In addition to the reassessment strategy and implementation steps listed above, monitoring at the proposed action level of 1 ppm likely will require laboratory analysis (rather than direct measurement) that will delay the availability of results and make meeting a 6-month time frame challenging.

C. Adequate time is needed to evaluate monitoring data, plan for, and implement a performance-based WCPP

24-36 months is needed by facilities to evaluate and implement a WCPP. An appropriate compliance deadline for evaluating the hierarchy of controls will allow entities adequately to plan for and implement the controls, which will thus help to ensure that adequate protection is provided for workers.

As described above, requiring that initial monitoring be completed within 6 months of the effective date of the rule provides insufficient time to assess/reassess an IH strategy and conduct monitoring for a new ECEL/STEL. Likewise, additional time is required to allow owner/operators to document their efforts to implement the NIOSH hierarchy of controls – elimination, substitution, engineering controls, and administrative controls – to reduce exposures to the ECEL, STEL, or lowest level achievable.

The proposal would require a detailed description of efforts to implement the control hierarchy. Respirator use would be permitted to supplement the exposure controls, but only "after all other feasible controls"[89] are determined to be insufficient to achieve the ECEL/STEL. The discussion of the exposure control plan suggests a rigid consideration of each of the steps in the control hierarchy, requiring that each step in the hierarchy be fully considered until moving to the next step. EPA should give greater flexibility to facilities when applying the hierarchy of controls. In addition, we recommend that the time required to develop the plan be extended to 1 to 2 years from the completion of initial exposure monitoring, for a total of 24-36 months from the effective date, to provide adequate time to evaluate and implement appropriate compliance approaches that are the least burdensome and most effective for workers.

While the proposal lays out the requirements for the use of respiratory protection as a supplement to the control hierarchy, the information is not consistent with the standard approach to respiratory protection. Respirators are predominantly used to control exposures during short-term tasks (*e.g.*, maintenance operations) where concentrations may be elevated, but EPA's requirements are described in the context of the full-shift ECEL.[90] It is not clear how the Agency anticipates that facilities will be able to implement the requirements for respiratory protection as proposed. In reality, short-term excursions at or near the STEL can be accommodated without

[89] 88 Fed. Reg. at 28304.

[90] *Id*. at 28305.

leading to an exceedance of the ECEL for the full shift. It is not necessary to require that respirators provide protection down to the ECEL, only that the level of protection afforded ensure that the STEL is not exceeded and that the exposure during the use of the respirator not contribute to an exceedance of the ECEL for the full shift. In some cases, compliance may be achieved with a lower level of protection than proposed by the Agency; in others, a higher level of protection may be required. Since companies have been complying with OSHA's PEL and STEL requirements for DCM for many years, the proposed specifications for respiratory protection may not be necessary and could result in confusion. EPA should carefully review the specifications to determine whether it can defer to standard IH practices related to respirator use.

To allow adequate time to plan for and implement the controls, which will thus help to ensure that adequate protection is provided for workers, EPA should allow 24-36 months after the effective date for full implementation of the exposure control plan in proposed § 751.109(e). Adequate time would also allow for full implementation of any necessary engineering, administrative or other controls for compliance with the new ECEL/STEL.