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December 30, 2019

Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Ave SW
Washington, DC 20460-0001

Re: Docket Nos. EPA-HQ-OPPT-2019-0437 and EPA-HQ-OPPT-2019-0236, Toxic Substances Control Act (“TSCA”) Risk Evaluations for Methylene Chloride and N-methylpyrrolidone (“NMP”)

Dear Administrator Wheeler:

Earthjustice and the Occupational Safety & Health Law Project submit these comments on the U.S. Environmental Protection Agency’s (“EPA’s”) draft risk evaluations for methylene chloride and N-methylpyrrolidone (“NMP”) on behalf of the American Federation of Labor and Congress of Industrial Organizations (“AFL-CIO”); International Union, United Automobile, Aerospace, and Agricultural Implement Workers of America (“UAW”); North America’s Building Trades Unions (“NABTU”); and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (“United Steelworkers”). These unions and labor organizations represent millions of workers across a range of industries, many of whom regularly work with and are exposed to methylene chloride and NMP.

Methylene chloride and NMP are widely used and highly toxic solvents. Methylene chloride gives off fumes that anesthetize the central nervous system and turn to carbon monoxide in the lungs, killing workers in as few as 10 minutes at high doses.¹ NMP, which has been used as a replacement for methylene chloride, is a powerful reproductive and developmental toxin; animal studies have found that “[fetal] resorptions and mortality can occur following a single exposure during a sensitive developmental stage.”² According to EPA, millions of workers are exposed to unsafe levels of methylene chloride and NMP each year.³

While EPA’s draft risk evaluations find that certain uses of methylene chloride and NMP pose unreasonable risks, EPA understates those chemicals’ risks and thus violates TSCA’s mandate to protect workers. In both risk evaluations, EPA miscalculates the severity of worker risks by misconstruing Occupational Safety and Health Administration (“OSHA”) requirements

¹ See Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7468 (Jan. 19, 2017).

² EPA, EPA-740-R1-8009, Draft Risk Evaluation for N-Methylpyrrolidone (“Draft NMP Risk Evaluation”) at 193 (Oct. 2019).

³ EPA, EPA-740-R1-8010, Draft Risk Evaluation for Methylene Chloride (“Draft Methylene Chloride Risk Evaluation”) at 113 (Oct. 2019); Draft NMP Risk Evaluation at 72-73.

related to the use of respirators and other personal protective equipment (“PPE”); erroneously assumes that workers will be provided, will properly use, and will be protected by PPE in circumstances where OSHA does not require it; and understates the hazards posed by methylene chloride and NMP. As a result, workers will continue to be exposed to unreasonable risks.

As set forth below, EPA must immediately finalize its proposed ban on methylene chloride’s and NMP’s paint stripping uses and must revise its draft risk evaluations to ensure those chemicals’ other uses are adequately assessed so that their risks will be properly managed under TSCA.

I. TSCA REQUIRES EPA TO PROTECT WORKERS

TSCA requires EPA to conduct risk evaluations to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use.”⁴ The “conditions of use” are “the circumstances . . . under which [the] chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”⁵ Congress directed EPA to make an unreasonable risk determination for the chemical substance a whole, taking into account all of its uses. EPA violates that requirement in both risk evaluations, proposing use-by-use determinations of unreasonable risk that fail to consider the risks to workers who are exposed from multiple conditions of use (e.g., workers who use consumer products containing methylene chloride or NMP at home).

When Congress amended TSCA in 2016, it added a requirement that risk evaluations analyze risks to “potentially exposed or susceptible subpopulation[s]” who, “due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance.”⁶ The statute specifically defines potentially exposed or susceptible subpopulations to include “workers,”⁷ reflecting Congress’ intent that EPA evaluate and address occupational risks under TSCA.

Despite this mandate, EPA’s risk evaluation methodology accepts greater risks to workers than to consumers and other members of the general public. When measuring cancer risks to the public, EPA considers one increased incidence of cancer in every 10,000 to 1,000,000 people as evidence of unreasonable risk.⁸ For workers, however, EPA uses only the lowest end of the range, characterizing increased cancer risks for up 1 in 10,000 workers as reasonable and not warranting regulation.⁹ We believe there is no valid reason for EPA to accept such high risks to workers.

To justify this disparity, EPA cites a National Institute of Occupational Safety and Health (“NIOSH”) guidance document that recommends the use of a 1 in 10,000 cancer threshold when

⁴ 15 U.S.C. § 2605(b)(4)(A).

⁵ *Id.* § 2602(4).

⁶ *Id.* §§ 2605(b)(4)(A), 2602(12).

⁷ *Id.* § 2602(12).

⁸ Draft Methylene Chloride Risk Evaluation at 426.

⁹ *Id.*

determining risk management limits (“RMLs”) for carcinogens.¹⁰ NIOSH, however, is not required to set RMLs at levels that avoid unreasonable risk to potentially exposed and susceptible subpopulations. Moreover, as NIOSH has explained, “[a]n excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk ... [F]or most carcinogens, there is no known safe level of exposure ... [and] NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous ...”¹¹ EPA also cites *AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980) (the “Benzene decision”) to support a less protective risk threshold for workers.¹² The *Benzene* decision, however, interprets section 3(8) of the Occupational Safety & Health Act.¹³ It has no bearing on EPA’s duty to identify and manage unreasonable risks under TSCA. Consistent with NIOSH recommendations, EPA should reduce exposure to occupational carcinogens such as methylene chloride “as much as possible,”¹⁴ the extent of which should be decided during risk management and not during risk evaluation.

II. EPA ERRONEOUSLY AND UNLAWFULLY ASSUMES THE USE OF PPE

EPA’s risk evaluations confirm that many occupational uses of methylene chloride and NMP present unreasonable risk, with worker exposures substantially above the levels that are predicted to cause cancer and other adverse health effects.¹⁵ In measuring worker risks, however, EPA relies on several flawed assumptions that understate total exposure and thus downplay the extent of methylene chloride and NMP risks. In particular, EPA assumes that workers exposed to methylene chloride will wear respirators (full-mask, supplied air or self-contained breathing apparatus) with an average protection factor (“APF”) up to 25 and chemical resistant gloves with a protection factor up to 20.¹⁶ For NMP, EPA assumes that workers will wear chemical-resistant gloves with a protectiveness factor up to 20.¹⁷ As described below, these assumptions are legally and factually baseless.

A. EPA’s Misconstrues OSHA Requirements

- i. EPA improperly assumes the use of respirators at levels below the methylene chloride PEL

Methylene chloride is the first chemical that EPA is evaluating under the 2016 amendments to TSCA for which OSHA has promulgated a comprehensive occupational safety

¹⁰ *Id.*

¹¹ Christine Whittaker et al., NIOSH, Current Intelligence Bull. 68, NIOSH Chemical Carcinogen Policy 20 (July 2017), <https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf>.

¹² Draft Methylene Chloride Risk Evaluation at 426 n.23.

¹³ 29 U.S.C. § 653(8).

¹⁴ Whittaker et al., note 11 *supra*.

¹⁵ *See, e.g.*, Draft Methylene Chloride Risk Evaluation at 430-75; Draft NMP Risk Evaluation at 303-26.

¹⁶ Draft Methylene Chloride Risk Evaluation at 108-09, 430-31.

¹⁷ Draft NMP Risk Evaluation at 21.

and health standard under section 6(b)(5) of the OSH Act.¹⁸ In setting the methylene chloride standard, OSHA quantified methylene chloride's risks to workers and set an 8-hour time-weighted average ("TWA") permissible exposure limit of 25 parts-per-million ("ppm") and a short-term exposure limit of 125 ppm.¹⁹ Under the methylene chloride standard, employers must measure workplace concentrations "which occur[] or would occur if the employee were not using respiratory protection."²⁰ If exposures without the use of respirators exceed the PEL, employers must first "institute and maintain the effectiveness of engineering controls and work practices to reduce employee exposure to or below the PELs."²¹ If "engineering controls and work practices ... are not sufficient to reduce employee exposure to or below the [PEL]," employers may "supplement them by the use of respiratory protection."²² Additional use of respirators to achieve methylene chloride exposure below the PEL are not required.²³

Both OSHA and EPA acknowledge that the OSHA PEL – 25 ppm over an eight-hour time-weighted average ("TWA") – leaves workers exposed to unreasonable risks. OSHA calculated a cancer risk of 3.62 deaths per 1,000 workers exposed to the PEL over a working lifetime, a level of risk several times above that which EPA deems acceptable.²⁴ EPA also identified unreasonable risk from chronic exposure to 4.8 ppm of methylene chloride, more than five times lower than the OSHA PEL.²⁵ Since OSHA does not require workers to be provided or to use PPE when exposures fall below the PEL, it stands to reason that even if PPE is provided and the PEL is attained, workers will still be left exposed to unreasonable risk. But that is not what EPA concluded.

Instead, EPA assumes that employers will voluntarily provide and that workers will consistently and properly use respirators to reduce methylene chloride exposures far below the level required by OSHA. For instance, the high-end exposure concentration for workers who process methylene chloride as a reactant is several times lower than the OSHA PEL.²⁶ While those exposures present unreasonable risk based on the margins of exposure calculated by EPA, EPA avoids an unreasonable risk determination by assuming that workers will be provided and will use APF 25 respirators.²⁷ Similarly, for other conditions of use EPA assumes that workers who are exposed to methylene chloride concentrations below the PEL will voluntarily use respirators, even though OSHA does not require such respirator use. There is simply no evidence that employers voluntarily implement expensive respirator protection programs, which are costly to establish and maintain, in order to achieve exposure levels below those required by OSHA.

¹⁸ 29 U.S.C. § 655(b)(5); 29 C.F.R. § 1910.1052.

¹⁹ 29 C.F.R. § 1910.1052(c)(1), (c)(2).

²⁰ 29 C.F.R. § 1910.1052(b) (defining "employee exposure").

²¹ *Id.* § 1910.1052(f)(1).

²² *Id.*

²³ See *Sec'y of Labor, U.S. Dep't of Labor v. Seward Ship's Drydock, Inc.*, 2019 WL 4284345, at *7 (citing 29 C.F.R. § 1910.1000(e).) See also OSHA, Final Rule: Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494, 1581 (Jan. 10, 1997).

²⁴ 62 Fed. Reg. at 1562.

²⁵ Draft Methylene Chloride Risk Evaluation at 283.

²⁶ *Id.* at 108, 116.

²⁷ *Id.* at 307.

- ii. OSHA regulations do not require employers to comply with Safety Data Sheet (“SDS”) recommendations

As it has in prior risk evaluations, EPA continues to rely on OSHA’s Hazard Communication Standard to support its “expect[ation]” that workers will be provided “appropriate PPE consistent with the applicable SDSs in a manner adequate to protect them.”²⁸ However, the Hazard Communication Standard merely requires the provision of SDSs, not PPE, and OSHA has made clear that employers are under no obligation to follow the recommendations in an SDS.

The information and recommendations included in SDSs are based on manufacturers’ judgment. As a result, they are often vague and inconsistent. One SDS for NMP states that workers should “[u]se personal protective equipment as required,” without any indication of when such equipment is required and without any specific mention of protective gloves, which EPA assumes will be provided.²⁹ Another SDS states “handle with gloves,”³⁰ but does not specify what type of gloves should be worn, even though EPA acknowledges that “some glove types do not provide adequate protection.”³¹ According to EPA, multiple SDSs recommend the use of natural rubber or nitrile gloves,³² despite the California Department of Public Health’s warning that “NMP will go right through less durable gloves such as those made of natural rubber, nitrile, or polyethylene.”³³ None of those SDSs provide employers with the specific information on exposure levels necessary to protect workers from the unreasonable risks EPA has identified in its draft risk evaluation. More broadly, a comprehensive survey of SDSs identified “a number of common themes . . . regarding inaccuracies, incompleteness, [and] incomprehensibility” and cautioned that “there are serious problems with the use of []SDSs as hazard communication tools.”³⁴

Further, even when manufacturers do recommend protective exposure limits and specific types of PPE, neither the Occupational Safety and Health Act (“OSH Act”) nor OSHA regulations impose a duty on employers to implement those recommendations. OSHA cannot cite an employer for failing to follow manufacturer recommendations in an SDS. The preamble to OSHA’s Hazard Communication Standard expressly states that “while the . . . final standard

²⁸ Draft NMP Risk Evaluation at 335.

²⁹ ThermoFisher Sci., Safety Data Sheet: NMP (last revised Jan. 17, 2018), <https://www.fishersci.com/store/msds?partNumber=O36884&productDescription=1-METHYL-2-PYRROLIDINONE+P+4L&vendorId=VN00033897&countryCode=US&language=en>.

³⁰ Sigma-Aldrich, Safety Data Sheet: NMP (last revised Jul. 13, 2018)), <https://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=1437202&brand=USP&PageToGoToURL=https%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fsearch%3Finterface%3DAI%26term%3DN-methyl-2-pyrrolidone%26N%3D0%26focus%3Dproduct%26lang%3Den%26region%3DUS>.

³¹ Draft NMP Risk Evaluation at 20.

³² *Id.* at 375.

³³ Cal. Dep’t of Pub. Health, Health Hazard Advisory: NMP (June 2014), <https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/HESIS/CDPH%20Document%20Library/nmp.pdf>.

³⁴ Nicol, A. M. et al., *Accuracy, Comprehensibility, and Use of Material Safety Data Sheets: A Review*. *Am. J. of Indus. Med.*, 51(11), 861-876 (2008).

require[s] the provision of information on recommended control measures, including respiratory protection, personal protective equipment, and engineering controls, *there is no requirement for employers to implement the recommended controls.*”³⁵ In the absence of such a requirement, there is no basis for EPA’s assumption that the Hazard Communication Standard will result in the uniform use of appropriate PPE.

B. EPA’s PPE assumptions violate TSCA

i. EPA’s PPE assumptions are not consistent with the “best available science”

EPA’s assumption of PPE use also violates TSCA’s requirement to “use scientific ... methods, protocols, [and] methodologies ... in a manner consistent with the best available science.”³⁶ The best available science for occupational risk assessment requires the measurement of worker exposures and risks without PPE. This methodology has been incorporated into every OSHA standard promulgated since 1970, including the methylene chloride standard.³⁷ These non-PPE measurements permit OSHA and other regulatory agencies to determine whether risks can be eliminated through the use of engineering controls and hazard elimination before the consideration of PPE, consistent with the well-established occupational hierarchy of controls.³⁸

The hierarchy of controls has been endorsed by the National Institute of Occupational Safety and Health (“NIOSH”), the American Society of Safety Engineers, the American Industrial Hygiene Association, the American Conference of Governmental Industrial Hygienists, the American Public Health Association, the American Federation of Labor and Congress of Industrial Organizations and many others. OSHA has incorporated the hierarchy of controls into all of its health standards, and EPA has endorsed this risk management approach.³⁹ As explained by NIOSH, “[t]he hierarchy of controls normally leads to the implementation of inherently safer systems” because chemical regulation and substitution are “more effective and protective” than PPE.⁴⁰

³⁵ Hazard Communication, 77 Fed. Reg. 17,574, 17,693 (Mar. 26, 2012) (emphasis added).

³⁶ 15 U.S.C. § 2625(h).

³⁷ See, e.g., 29 C.F.R. § 1910.1053(b); 29 C.F.R. § 1910.1052(b).

³⁸ See NIOSH, Hierarchy of Controls (Jan. 13, 2015), <https://www.cdc.gov/niosh/topics/hierarchy/default.html>.

³⁹ See, e.g., 81 Fed. Reg. at 16,779–83 (silica preamble) (explaining OSHA’s longstanding policy of rejecting reliance on respirators to protect employees from health hazards); 29 C.F.R. § 1926.55 (to prevent employee exposure to inhalation, ingestion, skin absorption or contact with substances above safe levels, “engineering controls must first be implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or other protective measures shall be used”); *Id.* § 1910.134(a)(1) (the prevention of occupational disease due to “shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used”); Significant New Use Rules on Certain Chemical Substances, 78 Fed. Reg. 38,210, 38,214 (June 26, 2013) (expressing EPA’s “agree[ment] that a hierarchy of controls should be applied and that personal protective equipment is the last resort to prevent exposures.”).

⁴⁰ See Nat’l Inst. for Occupational Safety & Health, Ctr. for Disease Control & Prevention, *Hierarchy of Controls* (last updated Jan. 13, 2015), <https://www.cdc.gov/niosh/topics/hierarchy/>.

While the draft risk evaluation pays lip service to the hierarchy of controls—stating that “PPE is the last line of defense against exposure in an industrial hygienist’s hierarchy of controls”⁴¹—EPA’s assumption of PPE use prior to the consideration of other risk management tools is fundamentally at odds with this approach. Given the broad acceptance of this methodology when conducting occupational risk assessment, EPA’s deviation from the hierarchy of controls violates the obligation to use the best available science in TSCA risk evaluations.

ii. EPA’s PPE assumptions conflate risk evaluation and risk management

By assuming extensive use of PPE at the risk evaluation stage, EPA also conflates risk evaluation with risk management. TSCA requires EPA to complete a risk evaluation and to make a determination of unreasonable risk before it considers how such risks may be managed.⁴² PPE is a risk management tool, albeit a poor one that may be used only when preferable options are not available. As such, PPE may only be considered, if at all, during the risk management stage when it can be weighed against more effective means of risk reduction.

Methylene chloride is an excellent example of why TSCA separates risk evaluation from risk management. Because traditional air-purifying respirators are not effective against methylene chloride, OSHA requires – and EPA assumes – that only full-face supplied air systems or self-contained breathing apparatuses will be provided.⁴³ As OSHA has recognized, however, the costs associated with such respirators are significant:

Atmosphere-supplying respirators are a relatively expensive type of respiratory equipment, requiring the employer not only to purchase the respirators themselves but also to install an air compressor and associated ductwork or rent cylinders containing breathing air. In the case of methylene chloride, the situation is complicated by the predominance of relatively small companies among the employers whose employees are currently exposed above the 8-hour TWA PEL.⁴⁴

For those reasons and others, OSHA found that “engineering controls are the most effective method of protecting employees” from methylene chloride.⁴⁵ However, because EPA assumes extensive respirator use to avoid unreasonable risk determinations—as it has for workers who manufacture methylene chloride, process it as a reactant, and use methylene chloride in laboratory settings—EPA will never proceed to the risk management stage where it can consider whether other, more cost-effective control options exist.⁴⁶ Even where EPA finds unreasonable risk with the use of PPE, EPA’s PPE assumptions result in the understatement of that risk. Because EPA need only regulate methylene chloride under TSCA “to the extent necessary” to eliminate the risks that EPA finds to be unreasonable,⁴⁷ the inclusion of PPE in EPA’s risk evaluations means that any subsequent TSCA regulations will not protect workers who are not provided or cannot use respirators, leaving those workers facing unreasonable risk.

⁴¹ Draft NMP Risk Evaluation at 373; Draft Methylene Chloride Risk Evaluation at 595.

⁴² See 15 U.S.C. § 2605(a).

⁴³ Draft Methylene Chloride Risk Evaluation at 108.

⁴⁴ OSHA, Methylene Chloride; Final Rule, 63 Fed. Reg. 50,712-01, 50,718 (Sept. 22, 1998).

⁴⁵ Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494, 1582 (Jan. 10, 1997).

⁴⁶ Draft Methylene Chloride Risk Evaluation at 430-33, 463-65.

⁴⁷ 15 U.S.C. § 2605(a)(1).

In short, EPA's assumption of PPE use in its risk evaluation preempts the required consideration of alternate regulatory tools during the risk management stage, in violation of TSCA.

- C. EPA's assumptions of PPE use has no support in the record
 - i. EPA improperly assumes the use of supplied air respirators by workers exposed to methylene chloride

EPA's risk evaluations must be supported by "substantial evidence" in the administrative record.⁴⁸ Not only do EPA's unsupported assumptions of PPE use fall far short of that standard, but in many instances they are directly contrary to EPA's prior findings and analyses.

Methylene chloride is produced or used by millions of workers across a range of different sectors.⁴⁹ Some exposed workers work for large companies with established environmental health and safety programs, whereas others work for small businesses, are independent contractors, or are public sector employees who are not subject to OSH Act requirements. Even within a given condition of use (e.g., the commercial use of lubricants and greases containing methylene chloride), there often are a wide range of employers and workplaces. However, EPA arbitrarily assumes that all workers in many conditions of use will be provided and will use PPE, without any supporting evidence.

The scope of EPA's PPE assumptions are opaque, since EPA's unreasonable risk determinations fail to specify precisely which conditions of use workers are presumed to wear PPE. For some conditions of use, EPA states that it "does not expect routine use of respiratory PPE *sufficient to mitigate risk*," but nonetheless discounts the extent of unreasonable risks based on the "expected use of PPE" or states elsewhere in the risk evaluation that PPE use is "considered plausible."⁵⁰ EPA also fails to explain how it determined whether workers exposed from a given condition of use were expected to use PPE. EPA must clarify the scope of and basis for any PPE assumptions in its final risk evaluation, and cease relying on any assumptions that are not supported by substantial evidence.

EPA fails to provide any data supporting its PPE assumptions. To the contrary, in its draft methylene chloride risk evaluation EPA states that "no data were found about the overall prevalence of the use of respirators to reduce [methylene chloride] exposures and it was not possible to estimate the numbers of workers who have reduced exposures due to the use of respirators."⁵¹ TSCA does not permit EPA to rely on unsupported assumptions in its risk evaluations.

EPA's PPE assumptions are also contrary to EPA's prior findings concerning methylene chloride. In support of a proposed ban on methylene chloride paint strippers, EPA found that respirators and other PPE are inadequate to comply with TSCA's worker protection mandate, in

⁴⁸ 15 U.S.C. § 2618(c).

⁴⁹ Draft Methylene Chloride Risk Evaluation at 45-51 (listing methylene chloride's conditions of use).

⁵⁰ See, e.g., Draft Methylene Chloride Risk Evaluation at 449-51; *id.* at 316, 321.

⁵¹ Draft Methylene Chloride Risk Evaluation at 690.

part because “not all workers may be able to wear respirators.”⁵² In particular, EPA explained that “[i]ndividuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease ... may be physically unable to wear a respirator.”⁵³ Workers’ facial hair, including beards and sideburns, can also interfere with the seal of a respirator, rendering it ineffective.⁵⁴ Other workers forgo respirators because they “may also present communication problems, vision problems, worker fatigue, and reduced work efficiency.”⁵⁵ These same concerns apply to other conditions of use as well, including those for which EPA has assumed universal use of supplied air respirators.

OSHA and NIOSH have similarly found that respirators can cause discomfort, skin irritation, heat stress, communication difficulties, and vision limitations, and that they often create other hazards for workers, such as trips, falls, and “struck by” hazards.⁵⁶ The increased heat hazard associated with respirator use is a significant limitation of the draft risk evaluation, given that many users of methylene chloride are likely to work outside or in non-air conditioned spaces. Moreover, with warming conditions globally due to climate change, it is “reasonably foreseen” that PPE which imposes additional heat stress will be even less frequently used. For multiple reasons, OSHA has found “*only a nominal possibility that respirators will be properly worn at all times.*”⁵⁷ Indeed, OSHA inspection data show that the respirator standard is the fourth most often cited violation, indicating a high level of non-compliance even in situations where respirators are required.⁵⁸

TSCA requires EPA to evaluate chemicals based on “the circumstances ... under which [the] chemical substance is intended, known, *or reasonably foreseen* to be manufactured, processed, distributed in commerce, used, or disposed of.”⁵⁹ EPA has not asserted, much less established, that it is reasonably foreseen that all affected workers in any condition of use will consistently be provided and will correctly use supplied air respirators. Therefore, EPA must evaluate the risks of methylene chloride use under the foreseen (and known) circumstances where such respirators are *not* worn.

ii. EPA improperly assumes the use of impervious gloves

For both methylene chloride and NMP, EPA assumes that exposed workers will be provided and will use protective gloves.⁶⁰ However, EPA admits that it “does not know the likelihood that workers wear gloves of the proper type and have training on the proper usage of gloves” since “[n]o information on employee training was found” and “data on the prevalence of

⁵² Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7481 (Jan. 19, 2017).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.* (citing Respiratory Protection, 63 Fed. Reg. 1152 (Jan. 8, 1998)).

⁵⁶ *See e.g.*, Occupational Exposure to Respirable Crystalline Silica, 81 Fed. Reg. 16,286, 16,779–83 (Mar. 25, 2016).

⁵⁷ Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite, 51 Fed. Reg. 22,612, 22,693 (June 20, 1986) (emphasis added).

⁵⁸ OSHA, Top 10 Most Frequently Cited Standards for Fiscal Year 2018, https://www.osha.gov/Top_Ten_Standards.html.

⁵⁹ 15 U.S.C. § 2602(4).

⁶⁰ Draft NMP Risk Evaluation at 303-26. The sole exception is the use of NMP in wood preservatives. *Id.* at 326.

glove use is not available ...”⁶¹ In the absence of data, EPA “assumed glove usage is likely based on professional judgment.”⁶² EPA does not state what the judgment was based upon.

Even if gloves were worn by certain workers, EPA has little to no information about the types of gloves worn, a critical omission given that not all gloves are protective against NMP or methylene chloride.⁶³ EPA lists the range of gloves recommended in SDSs for NMP; however, as explained above, SDS recommendations are not binding on employers.⁶⁴ Moreover, the SDSs recommend a wide range of glove materials, some of which (*i.e.*, polyvinyl chloride and Teflon) have not been tested for effectiveness against NMP and others of which (*i.e.*, latex) are known to be relatively ineffective.⁶⁵ Without data on which gloves are provided to which employees, EPA has no basis for assuming specific glove protection factors in its draft risk evaluation.

With respect to methylene chloride, EPA states that “data about the frequency of effective glove use – that is, the proper use of effective gloves – is very limited in industrial settings.”⁶⁶ EPA also acknowledged that nitrile gloves provide “poor” protection and are “NOT recommended” for use with methylene chloride.⁶⁷ However, multiple SDSs for methylene chloride nonetheless recommend the use of nitrile gloves.⁶⁸ A table containing methylene chloride and NMP’s permeation and breakthrough times for different glove materials is attached to these comments as **Exhibit A**.

Improper glove use can lead to increased worker exposures due to “contamination of the interior of the glove” (if workers are not properly training in glove use and replacement) or by “acting as a reservoir” for contaminants (if the gloves are not impermeable).⁶⁹ Notably, “EPA has not found information that would indicate specific activity training (e.g., procedure for glove removal and disposal) for tasks where dermal exposure can be expected to occur in a majority of sites ...”⁷⁰ EPA must therefore consider the foreseeable exposure scenarios in which employees are not provided protective gloves, or, worse, are provided inadequate gloves or are not adequately trained and thus face even greater dermal exposures due to glove contamination and the occlusion of methylene chloride and NMP close to the skin.

III. EPA FAILS TO CONSIDER REASONABLY AVAILABLE EXPOSURE DATA.

⁶¹ *Id.* at 68; Draft Methylene Chloride Risk Evaluation at 110 (“[D]ata about the frequency of effective glove use – that is, the proper use of effective gloves – is very limited in industrial settings.”)

⁶² Draft NMP Risk Evaluation at 76.

⁶³ *Id.* at 162, 373.

⁶⁴ See Point II.A.ii *supra*.

⁶⁵ Draft NMP Risk Evaluation at 162, 183, 375.

⁶⁶ Draft Methylene Chloride Risk Evaluation at 110.

⁶⁷ *Id.* at 596.

⁶⁸ *Id.* at 600.

⁶⁹ See TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2019-02, EPA-HQ-OPPT-2019-0237-0064 at 55 (2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0237-0064>.

⁷⁰ See Draft NMP Risk Evaluation at 69; Draft Methylene Chloride Risk Evaluation at 111.

EPA is in possession of a wealth of information on occupational exposures to methylene chloride, and the Agency has ready access to even more exposure data. However, for multiple conditions of use, EPA determined that methylene chloride presents no unreasonable risk without considering the vast majority of that data. In so doing, EPA violated its statutory obligation to consider “reasonably available information” when evaluating chemical risks.⁷¹

For the manufacturing of methylene chloride and the processing of methylene chloride as a reactant, EPA relied exclusively on exposure data from three facilities provided by the Halogenated Solvents Industry Alliance (“HSIA”).⁷² HSIA did not provide any information about the conditions under which these samples were taken or the sampling protocols and methodology.⁷³ Nonetheless, EPA relied on the HSIA data without questioning its reliability or representativeness. This is especially concerning because HSIA represents companies with a strong financial interest in EPA making risk determinations that will allow methylene chloride to continue to be used widely.

When evaluating those conditions of use, EPA did not consider exposure data provided by Adam Finkel, the former Director of Health Standards Programs at OSHA. Through a FOIA request, Dr. Finkel obtained information on 12,152 air samples that OSHA collected on methylene chloride, and he provided all of that data to EPA in comments on the problem formulation document for the draft methylene chloride risk evaluation.⁷⁴ However, EPA references only 15 of those samples (less than 0.2%) in its draft risk evaluation, solely for the spot cleaning and fabric finishing conditions of use. Similar data is available from OSHA. OSHA’s Chemical Exposure Health Data tool yielded 11,272 air samples for methylene chloride, dated as recently as June 2019.⁷⁵ EPA does not explain why it ignored these available data sources.

EPA also made no apparent effort to secure additional data from OSHA or from the companies that manufacture and use methylene chloride. OSHA’s methylene chloride rule requires employers to establish and keep an accurate record of all workplace monitoring data, including, for all employers with more than 20 employees, “the date of measurement for each sample taken,” “the operation involving exposure to [methylene chloride which is being monitored],” “[s]ampling and analytical methods used and evidence of their accuracy;” the “[n]umber, duration, and results of samples taken;” and the “[n]ame, job classification and exposure of all of the employees represented by monitoring, indicating which employees were actually monitored.”⁷⁶ If employers do not turn over such data upon EPA’s request, EPA has the authority to order its production under TSCA section 8 or to subpoena such records under TSCA section 11.⁷⁷

⁷¹ 15 U.S.C. § 2625(k).

⁷² Draft Methylene Chloride Risk Evaluation at 114, 115.

⁷³ Comment by Halogenated Solvents Indus. Alliance on Problem Formulation of the Risk Evaluation for Methylene Chloride, Docket No. EPA-HQ-OPPT-2016-0742 (Aug. 16, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0742-0103>.

⁷⁴ See Comment by Dr. Adam M. Finkel, Docket No. EPA-HQ-OPPT-2016-0231-0536 (May 19, 2017).

⁷⁵ OSHA, Chemical Exposure Health Data, <https://www.osha.gov/opengov/healthsamples.html>.

⁷⁶ *Id.* § 1910.1052(m)(2)(ii).

⁷⁷ 15 U.S.C. §§ 2607(a), 2610(c).

EPA's information on NMP exposures is similarly deficient. For instance, in the draft NMP risk evaluation, EPA proposes a finding that an estimated 4 million workers exposed to NMP from soldering face no unreasonable risks.⁷⁸ Yet EPA acknowledges that it does not have any "inhalation monitoring data specifically related to the use of NMP-based soldering products."⁷⁹ In its risk evaluation, EPA assumes that "most NMP may be destroyed in the soldering process, mitigating the potential for significant inhalation exposures," yet it does not have the data needed to quantify or support that assumption.⁸⁰ The absence of workplace monitoring data is particularly significant for NMP, since NMP in indoor air is not only inhaled by workers but also absorbed as vapor through the skin.⁸¹ However, for multiple conditions of use, EPA identified little to no exposure data, and relied on modeled values that were not validated with workplace monitoring data.

TSCA requires EPA to conduct risk evaluations based on "reasonably available" information,⁸² a term that EPA defines to include not only "information that EPA possesses" but also information that EPA "can reasonably generate, obtain, and synthesize for use in risk evaluations."⁸³ For both methylene chloride and NMP, EPA either had possession of or had the ability to obtain far more data than EPA used to declare conditions of use free from unreasonable risk. EPA must exercise its information gathering authority to collect and consider additional data on those uses.

IV. EPA FAILS TO CONSIDER REASONABLY FORESEEN OCCUPATIONAL EXPOSURE SCENARIOS

A. EPA fails to consider the risks posed by combined dermal and inhalation exposures to methylene chloride

In its draft risk evaluations, EPA acknowledges that workers are likely to be exposed to methylene chloride and NMP from multiple routes and pathways. However, EPA fails to evaluate the risks posed by those combined exposures, and thus understates the risks facing exposed workers.

With respect to methylene chloride, EPA states that "[i]nhalation and dermal exposures are assumed to occur simultaneously for workers and consumers."⁸⁴ However, EPA does not consider the risks to workers who have both dermal and inhalation exposure; instead, it separately calculates the risks from each exposure route in isolation. EPA states that it "chose not to employ simple additivity of exposure [routes] at this time ... because of the uncertainties

⁷⁸ Draft NMP Risk Evaluation at 73.

⁷⁹ EPA, Draft Risk Evaluation for N-Methylpyrrolidone, Supplemental Information on Occupational Exposure Assessment 182 (Oct. 2019), https://www.epa.gov/sites/production/files/2019-11/documents/13_nmp_occupational_exposure_assessment.pdf.

⁸⁰ Draft NMP Risk Evaluation at 108.

⁸¹ *Id.* at 25.

⁸² 15 U.S.C. § 2625(k).

⁸³ 40 C.F.R. § 702.33.

⁸⁴ Draft Methylene Chloride Risk Evaluation at 304.

present in the current exposure estimation procedures.”⁸⁵ These alleged uncertainties do not provide a basis for ignoring realistic exposure scenarios; to the contrary, all of EPA’s risk evaluations acknowledge and address numerous uncertainties relating to toxicity, exposure, and risk calculations. EPA combines exposure routes in the draft NMP risk evaluation, and it often does so when calculating pesticide risks. It can, and must, do so for methylene chloride as well.

In addition, people may be exposed to methylene chloride from multiple conditions of use. Workers who manufacture or work with methylene chloride may also be exposed at home by their or their family members’ use of methylene chloride containing products. As EPA acknowledges, “[s]ome products [containing methylene chloride] are used in both commercial and consumer applications such as adhesives and sealants.”⁸⁶ TSCA requires EPA to evaluate risks to those who, “due to ... greater exposure, may be at greater risk than the general population of adverse health effects from” methylene chloride, including those sub-populations who are exposed from multiple conditions of use.⁸⁷

For NMP, EPA considers total exposures within a condition of use but not across conditions of use. In particular, EPA calculates the combined risks posed by dermal and inhalation exposures, but “does not consider the potential for aggregate exposures from multiple conditions of use,” including the risks to workers who also use products containing NMP at home.⁸⁸ EPA does not justify this failure to consider foreseeable combinations of exposures, an omission that EPA admits “could result in an underestimate of risk.”⁸⁹

In its report on the 1,4-dioxane risk evaluation, EPA’s Science Advisory Committee on Chemicals wrote that “EPA should evaluate combined exposures through several pathways ...”⁹⁰ To comport with the “best available science” for risk evaluation methodology, EPA should evaluate the foreseeable combination of exposures from multiple routes and pathways for methylene chloride and NMP as well.

B. EPA ignores evidence of work shifts longer than eight hours.

In calculating methylene chloride’s risks to workers, EPA assumes an exposure duration of eight hours per day.⁹¹ The data provided by HSIA, however, references twelve-hour shifts by workers who manufacture methylene chloride.⁹² EPA should clarify whether its 8-hour TWA values for manufacturing account for the longer work shifts indicated by HSIA, and, if not,

⁸⁵ *Id.*

⁸⁶ *Id.* at 52.

⁸⁷ 15 U.S.C. § 2602(12).

⁸⁸ Draft NMP Risk Evaluation at 283.

⁸⁹ *Id.*

⁹⁰ TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2019-02, EPA-HQ-OPPT-2019-0237-0064 at 77 (2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0237-0064>.

⁹¹ Draft Methylene Chloride Risk Evaluation at 106-107.

⁹² Comment by Halogenated Solvents Indus. Alliance on Problem Formulation of the Risk Evaluation for Methylene Chloride, Docket No. EPA-HQ-OPPT-2016-0742 (Aug. 16, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0742-0103>.

should revise its calculations to reflect those workers' increased exposures, as well as those for any other workers who work shifts longer than eight hours.

C. EPA erroneously assumes a single dermal exposure per day.

In its dermal exposure assessment for methylene chloride, EPA assumes a single exposure event per day.⁹³ EPA acknowledges that this assumption “likely underestimates exposure as workers often come into repeat contact with the chemical throughout their work day.”⁹⁴ In other words, EPA acknowledges that it is reasonably foreseen that workers will have multiple daily exposures to methylene chloride, and that those repeated exposures would present greater risks, but has nonetheless chosen not to consider those risks in the draft risk evaluation. This is an admitted violation of TSCA.

D. EPA fails to adequately consider exposures from spills and accidents

EPA does not evaluate occupational exposures from spills and other accidental releases of methylene chloride or NMP. Such exposures are not only reasonably foreseen, but virtually inevitable in an industrial workplace. The NMP risk evaluation references an incident in which a pregnant worker “cleaned up an NMP spill that dissolved her latex gloves during week 16 of the pregnancy” and “was ill for the next four days and experienced malaise, headache, nausea and vomiting.”⁹⁵ During the comment period on the draft risk evaluations, an explosion at a refinery in Port Neches, TX released NMP into the air, threatening workers and the surrounding community where many of the workers likely live.⁹⁶ Methylene chloride can also present severe health effects if spilled or accidentally released.

There are thousands of spills and accidental chemical releases each year, making such exposures a reasonably foreseen occupational hazard.⁹⁷ Moreover, accidental releases are considered to be “reasonably ... expected” under the Clean Water Act,⁹⁸ the National Environmental Policy Act,⁹⁹ and other environmental laws. OSHA’s methylene chloride standard specifically recognizes the likelihood that leaks and spills will occur and subject employees to increased risk.¹⁰⁰ Under TSCA, as well, EPA must evaluate the risks posed by reasonably foreseen spills and other occupational releases of methylene chloride and NMP.

⁹³ Draft Methylene Chloride Risk Evaluation at 165.

⁹⁴ *Id.*

⁹⁵ Draft NMP Risk Evaluation at 183.

⁹⁶ Jacob Dick, *Vapor cloud cited in TPC explosion by Chemical Safety Board*, Beaumont Enter., Dec. 5, 2019, <https://www.beaumontenterprise.com/news/article/Vapor-cloud-cited-in-TPC-explosion-by-Chemical-14885208.php> (“Two of the tanks that stored NMP were believed to have ruptured at the time of the initial explosion that was centered around the butadiene processor.”).

⁹⁷ See ATSDR, National Toxic Substance Incidents Program (NTSIP) Biennial Report 2013-2014, https://www.atsdr.cdc.gov/ntsip/docs/NTSIP_2013-14_final_report_508.pdf.

⁹⁸ 33 U.S.C. § 1321(j)(1); *Pepperell Assoc.'s v. EPA*, 246 F.3d 15 (1st Cir. 2001).

⁹⁹ See *N.Y. v. Nuclear Regulatory Comm'n*, 681 F.3d 471, 479 (D.C. Cir. 2012) (finding that the Nuclear Regulatory Commission’s NEPA analysis was “not supported by substantial evidence on the record because the Commission failed to properly examine the risk of leaks in a forward-looking fashion and failed to examine the potential consequences of pool fires.”).

¹⁰⁰ 29 C.F.R. § 1910.120, App. C; 29 CFR § 1910.1052(f)(3)(ii).

E. EPA fails to properly account for risks to so-called “occupational non-users”

EPA lacks data measuring exposures by workers who do not regularly handle or work with the chemical but who work in or near areas where the chemical is handled, including the cleaning workers, skilled trade workers, supervisors, and managers who EPA misleadingly characterizes as Occupational Non-Users, or ONUs. The range of workers that EPA defines as ONUs is too large to support a single classification. Supervisors have very different exposure patterns than skilled trade workers, yet both of them are assumed to face similar risks under EPA’s overbroad ONU categorization.¹⁰¹

While EPA assumes that ONUs will be exposed to lower contaminant concentrations than direct users of methylene chloride and NMP, EPA has no factual basis for these ONU worker assumptions. For most uses, EPA simply uses the central tendency (50th percentile) of worker inhalation exposures to calculate ONU risks, as opposed to collecting ONU-specific data or using the higher end exposure estimates as EPA does for other workers. This assumption alone, which has no support in the record, resulted in multiple determinations of no unreasonable risk for ONUs.

EPA also assumes that ONUs will have no dermal exposures to methylene chloride or NMP, despite EPA’s acknowledgement that “[ONUs] may have direct contact with NMP-based liquid products due to incidental exposure at shared work areas with workers who directly work with NMP.”¹⁰² Both methylene chloride and NMP pose acute risks, with the potential for death or other severe health effects based on short-term exposures to high concentrations. Particularly over a short period (e.g., response to a spill or equipment maintenance), ONU exposures may be as great as or greater than those of other workers, and ONUs are even less likely to be provided PPE. EPA’s failure to collect ONU-specific data and its reliance on central tendency exposure estimates thus understates the risks to ONUs.

Moreover, even where EPA’s risk calculations indicate unacceptable risks to ONUs, EPA often fails to make the required unreasonable risk determination. For instance, EPA calculated ONU margins of exposure of 0.55 (high end scenario) and 8.54 (central tendency scenario) for chronic exposures from the repackaging of methylene chloride, compared to a benchmark MOE of 10.¹⁰³ Therefore, even under the central tendency scenario, ONUs face unreasonable risks of chronic liver effects. Instead of regulating those risks, however, EPA states that “[i]n consideration of the uncertainties in the exposures for ONUs for this [condition of use], EPA has determined the non-cancer risks presented by chronic inhalation are not unreasonable.”¹⁰⁴ The “uncertainties” identified by EPA are that “ONU inhalation exposures are expected to be lower than inhalation exposures for workers directly handling the chemical substance” and that “[u]se of pre-PEL data may overestimate some exposures in some occupational exposure scenarios.”¹⁰⁵

¹⁰¹ Draft NMP Risk Evaluation at 66; Draft Methylene Chloride Risk Evaluation at 117.

¹⁰² EPA, Draft Risk Evaluation for N-Methylpyrrolidone: Supplemental Information on Occupational Exposure Assessment at 130, (Oct. 2019), https://www.epa.gov/sites/production/files/2019-11/documents/13_nmp_occupational_exposure_assessment.pdf.

¹⁰³ Draft Methylene Chloride Risk Evaluation at 311.

¹⁰⁴ *Id.* at 436.

¹⁰⁵ *Id.*

EPA has already accounted for the first of those uncertainties by (improperly) using central-tendency exposure estimates to calculate ONU risks; if EPA actually treated ONUs similarly to other workers and used the high-end exposure scenario, the risks presented by this condition of use would be nearly 20 times lower than the benchmark MOE. As for the second uncertainty, EPA has evaluated exposure data taken before and after OSHA lowered the methylene chloride PEL in 1997 and concluded that “exposure data from before the PEL (over 20 years old) are adequate for EPA’s risk evaluation purposes.”¹⁰⁶ Having made the decision to rely upon that older data, EPA cannot discount the risk calculations that flow from that choice.

For plastic manufacturing, EPA calculated ONU margins of exposure of 8.3 from acute exposure to methylene chloride, lower than the benchmark MOE of 10.¹⁰⁷ EPA states that “[w]hile the point estimate for the chronic non-cancer inhalation scenario estimate for ONUs indicates risk, in consideration of the uncertainties in the exposures for ONUs for this [condition of use] and the single data point for ONU exposure, EPA has determined these risks are not unreasonable.”¹⁰⁸ As noted above, for many conditions of use EPA has no ONU-specific data, and instead calculates ONU risks based on workers’ central tendency exposures. Here, doing so would have resulted in an MOE of 5.4 – approximately half the benchmark MOE.¹⁰⁹ Therefore, EPA’s typical approach *and* the ONU-specific data both support a finding of unreasonable risk.

E. EPA improperly assumes that all dermal exposures cease at the end of the work shift

In calculating NMP’s dermal risks, EPA assumes that any NMP on the skin is “removed by cleaning at the end of the work period.”¹¹⁰ But EPA offers no evidence that all workers actually do clean their hands and other exposed body parts following each shift, nor that facilities are available for them to do so. In the absence of such cleaning, dermal exposure durations – and associated risks – will be greater than those estimated by EPA. EPA also ignores the fact that clothing can absorb NMP liquids and/or vapors. As many workers return home in the same clothes they were wearing at work, this absorption creates that potential for additional exposures that EPA has not addressed in either of its draft risk evaluations.

V. EPA UNDERSTATES METHYLENE CHLORIDE’S AND NMP’S TOXICITY

A. EPA fails to address risks to potentially exposed and susceptible sub-populations

When evaluating the risks from methylene chloride and NMP, EPA treats all workers as if they are equally susceptible. But, as EPA’s own risk evaluations acknowledge, that is not the case. Under TSCA, EPA must account for and protect not only exposed workers, but those subpopulations of workers—such as pregnant workers, workers with preexisting conditions,

¹⁰⁶ *Id.* at 108.

¹⁰⁷ *Id.* at 336.

¹⁰⁸ *Id.* at 467.

¹⁰⁹ *Id.* at 336.

¹¹⁰ Draft NMP Risk Evaluation at 67.

smokers, etc.—who are most susceptible to a chemical’s risks. The draft methylene chloride and NMP risk evaluations fail to do so.

In its draft methylene chloride risk evaluation, EPA states that “certain human subpopulations may be more susceptible to exposure to methylene chloride than others,” including smokers and people with preexisting cardiovascular disease.¹¹¹ However, EPA does not estimate smoking rates within the worker populations exposed to methylene chloride or separately adjust its risk calculations to account for these susceptibilities. Instead, EPA states that “to account for variation in sensitivity within human populations intraspecies [uncertainty factors] were applied for non-cancer effects.”¹¹² In fact, EPA reduced the intraspecies uncertainty factor for chronic, non-cancer risks from 10 to 3, without any evidence that the reduced uncertainty factor is adequate to account for the increased susceptibilities of certain subpopulations.¹¹³

Certain populations are also genetically predisposed to methylene chloride’s carcinogenic effects. In particular, people with the GSTT1 +/+ genotype – who comprise approximately 1/3 of the U.S. population, and thus also represent a significant proportion of the workforce – “are expected to be more susceptible to cancer endpoints.”¹¹⁴ When calculating methylene chloride’s cancer risks, however, EPA relies on “the full distribution of GSTT genotypes in the human population,” as opposed to the most susceptible subpopulation.¹¹⁵ This is a marked shift from EPA’s 2014 risk assessment of methylene chloride paint strippers and 2011 IRIS assessment, both which relied on the “the most sensitive (GSTT1+/+) genotype (**i.e., the group that would be expected to be most sensitive to the carcinogenic effects of DCM**)” to calculate cancer risk.¹¹⁶ As a result of this and other modeling changes, the inhalation unit risk (“IUR”) used in the draft methylene chloride risk evaluation (i.e., the excess lifetime cancer risk estimated to result from continuous exposure to methylene chloride at a concentration of 1 µg/m³ in air) is more than seven times lower than the IUR from the 2014 risk assessment. This change violates TSCA and understates methylene chloride’s risk to workers with the GSTT1 +/+ genotype.

For NMP, EPA states that pregnant women, women of reproductive age, people with lower metabolic capacity, or people with impaired liver function face heightened risks.¹¹⁷ However, EPA does not evaluate the risks facing these specific subpopulations, but instead relies on a default intraspecies uncertainty factor to account for all of them. Under TSCA, EPA must calculate risks for these potentially exposed or susceptible subpopulations, or at a minimum demonstrate that its chosen uncertainty factor is sufficient to account for all such populations.

¹¹¹ Draft Methylene Chloride Risk Evaluation at 386.

¹¹² *Id.* at 387.

¹¹³ *Id.* at 274.

¹¹⁴ *Id.* at 386.

¹¹⁵ *Id.* at 659.

¹¹⁶ EPA, EPA 740-R1-4003, TSCA Work Plan Chemical Risk Assessment, Methylene Chloride: Paint Stripping Use at 273 (Aug. 2014).

¹¹⁷ Draft NMP Risk Evaluation at 282.

B. EPA understates methylene chloride's cancer risk

The cancer risks in EPA's draft risk evaluation and 2014 methylene chloride risk assessment are also far lower than those calculated in OSHA's 1997 methylene chloride rulemaking. OSHA estimated a working-lifetime excess cancer risk of 3.62×10^{-3} at the 25 ppm PEL, which corresponds to an IUR of 1.45×10^{-4} per ppm given the linear dose-response endorsed in the draft risk evaluation.¹¹⁸ This IUR is substantially higher than the IUR calculated by EPA, despite the fact that both OSHA and EPA base their cancer risk calculations on the same NTP bioassay. EPA fails to acknowledge or explain this discrepancy. To ensure adequate protections for exposed workers, EPA should use the higher OSHA-derived IUR.

C. EPA disregards important health effects

For multiple human health endpoints, EPA acknowledged potential harm but failed to quantify risks due to alleged uncertainties or data gaps. As a result, the draft risk evaluations do not provide a complete evaluation of either methylene chloride or NMP's risks.

For instance, in its methylene chloride risk evaluation, EPA "did not carry immune system effects forward for dose-response" analysis "due to a limited database" of immunotoxicity studies.¹¹⁹ The evidence that EPA does have, however, indicates that methylene chloride is immunotoxic. An epidemiological study identified an association between methylene chloride exposure and Sjogren's syndrome,¹²⁰ and animal studies detected other immune system effects.¹²¹ EPA acknowledges "suggestive but inconclusive evidence of methylene chloride's association with immune-related outcomes," but concludes that the data are too "sparse" to support further analysis.¹²² This undermines the very purpose of a TSCA risk evaluation, which must comprehensively evaluate the risks posed by a chemical in order to ensure that all unreasonable risks are addressed at the risk management stage. If EPA needs additional data to evaluate immunotoxicity, it can use its TSCA authority to gather that information, or at the very least apply an additional uncertainty factor to account for database deficiencies. Instead, EPA has chosen to simply ignore the evidence of methylene chloride's immunotoxicity.

Similarly, while epidemiological and animal studies identified reproductive and developmental effects from methylene chloride exposure – including heart defects in children, reduced fertility, and spontaneous abortions – EPA dismisses those studies as too limited or inconclusive to warrant further analysis.¹²³ For NMP, EPA professes a "lack of complete information on potentially sensitive reproductive and developmental endpoints."¹²⁴ While "there is evidence of neurodevelopmental effects following gestational exposure to a relatively high dose of NMP," EPA does not determine a No Adverse Effects Level ("NOAEL") or carry that

¹¹⁸ Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494, 1555 (Jan. 10, 1997).

¹¹⁹ Draft Methylene Chloride Risk Evaluation at 380.

¹²⁰ *Id.* at 234.

¹²¹ *Id.* at 236–37.

¹²² *Id.* at 260–61.

¹²³ *Id.* at 263.

¹²⁴ Draft NMP Risk Evaluation at 278.

endpoint forward for dose response analysis.¹²⁵ In a risk evaluation, a decision not to further analyze an endpoint has the same effect as a finding of no unreasonable risk. EPA's risk management rules for methylene chloride and NMP will not address immune system, developmental, or reproductive effects because EPA has neglected its responsibility to evaluate whether and at what levels those risks are unreasonable. This, too, violates TSCA.

IV. CONCLUSION

EPA has known of methylene chloride's and NMP's unreasonable risks for years before the release of the draft risk evaluations. EPA's risk evaluation documents more than a dozen worker deaths from the use of methylene chloride paint strippers alone. Additional fatality reports from OSHA and the Massachusetts Department of Public Health are attached to these comments as **Exhibit B**.

In 2014 and 2015, EPA issued risk assessments analyzing the use of methylene chloride and NMP for paint and coating removal. Both of those assessments found unreasonable risks, and in January 2017 EPA proposed a ban on commercial and consumer uses of methylene chloride and NMP paint strippers. Since then, EPA has taken no further action with respect to NMP, and it has finalized a ban only on consumer uses of methylene chloride paint strippers, leaving tens of thousands of workers at risk.

Given the dangers posed by both of those chemicals, there is no justification for further delay. Methylene chloride continues to kill workers, and each exposure to NMP can cause lasting reproductive and development harm. EPA should finalize bans on all paint stripping uses of methylene chloride and NMP that EPA assessed in 2014 and 2015, revise the draft risk evaluations to address the issues raised in these comments, and promptly take action to eliminate all of methylene chloride and NMP's unreasonable risks.

Thank you for your consideration.

s/ Randy Rabinowitz

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¹²⁵ *Id.*

On behalf of:

American Federation of Labor and Congress of Industrial Organizations

International Union, United Automobile, Aerospace, and Agricultural Implement Workers
of America

North America's Building Trades Unions

United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and
Service Workers International Union