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Environmental Defense Fund Comments on

Methylene Chloride and N-Methylpyrrolidone;

Regulation of Certain Uses Under TSCA Section 6(a)

EPA-HQ-OPPT-2016-0231

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Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on its proposed section 6 rule under the Toxic Substances Control Act (TSCA) to regulate methylene chloride (DCM) and N-Methylpyrrolidone (NMP).

The rule would: 1) prohibit manufacture, processing, and distribution in commerce of DCM for consumer and most types of commercial paint and coating removal, with a ten-year time-limited exemption for specific uses critical to national security; 2) prohibit the use of DCM in these commercial uses; 3) require any paint and coating removal products containing methylene chloride to be packaged for distribution in commerce in containers with volumes no less than 55 gallons; 4) require manufacturers, processors, and distributors, except for retailers of DCM for any use, to provide downstream notification of these prohibitions throughout the supply chain; and 5) require associated recordkeeping.

The proposed rule invites comment on two options to restrict NMP.

Option 1 would: 1) prohibit manufacture, processing, and distribution in commerce of NMP for consumer and all commercial paint and coating removal, with a ten-year time-limited exemption for specific uses critical to national security; 2) prohibit the use of NMP in these commercial uses; 3) require any paint and coating removal products containing NMP to be packaged for distribution in commerce in containers with a volume no less than 5 gallons; 4) require manufacturers, processors, and distributors, except for retailers of NMP for any use, to provide downstream notification of these prohibitions throughout the supply chain; and 5) require associated recordkeeping.

Option 2 would: 1) Prohibit the manufacture, processing, and distribution in commerce of paint and coating removal products containing more than 35% NMP by weight except for products used for critical national security uses; 2) require product formulators to test gloves for the product formulations being processed and distributed in commerce to identify specialized gloves that provide protection for users and keep records relevant to these tests; 3) require product formulators to label products with information for consumers about the risks presented by the products and how to reduce these risks during use, including identifying which specialized gloves provide protection against the specific formulation; 4) require product formulators to provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication, and

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to keep records; 5) prohibit the commercial use of paint and coating removal products that contain more than 35% by weight of NMP, except for critical national security uses; and 6) require commercial users to establish worker protection programs for dermal and respiratory protection, including hazard communication and training, and to require their employees to wear specialized gloves, impervious clothing that covers most of the body, and a respirator with an assigned protection fact (APF) of 10 or compliance with an alternative air exposure limit.

We respectfully submit these comments in strong support of EPA's proposed restrictions on DCM and proposed option 1 restrictions on NMP. We strongly believe that approaches short of a full prohibition on these uses of DCM and NMP would be insufficient to mitigate the clearly unreasonable risks identified by EPA.

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I. Summary

EDF strongly supports EPA's proposed actions under Section 6 of TSCA to address the clear, unreasonable risks to human health posed by the use of DCM and NMP for paint and coating removal.

DCM is a highly volatile, high production volume chemical (261 million pounds reported produced or imported in the U.S. in 2011) with well-documented risks. DCM exerts numerous acute and chronic health effects for both cancer and non-cancer endpoints, which have been documented in human, animal, and mechanistic studies. DCM has strong links to multiple types of cancer, including brain cancer, liver cancer, certain lung cancers, non-Hodgkin's lymphoma, and multiple myeloma. The U.S. EPA Integrated Risk Information System (IRIS) determined that DCM is "likely to be carcinogenic in humans" based on a mutagenic mode of action[1] and the U.S. National Toxicology Program under the Department of Health and Human Services, in its 14th Report on Carcinogens, determined that DCM is "reasonably anticipated to be a human carcinogen."[2]

DCM is also highly acutely neurotoxic. It has been linked to over 50 worker deaths reported nationwide since the mid-1980s.[3] More than 40 of these deaths have been attributed to use of DCM-based paint and coating removers, many involving use in confined spaces to refurbish bathtubs (p. 7468). EPA's 2014 DCM work plan risk assessment[4] discusses 15 such reported worker deaths, noting that they were associated with 10 different DCM-containing paint stripper products. Additional non-cancer effects well-documented in the scientific literature include liver toxicity, kidney toxicity, reproductive toxicity, and neurological impacts.

EPA's risk assessment and supplemental technical reports[5] amply demonstrate that DCM's use as a paint and coating remover presents unreasonable risks of multiple cancer and non-cancer effects to workers,

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[1] US EPA, Integrated Risk Information System (IRIS), "Toxicological Review of Dichloromethane." November 2011. EPA/635/R-10/003F. Available: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0070tr.pdf.

[2] NTP (National Toxicology Program). "Trichloroethylene" from *Report on Carcinogens, Fourteenth Edition*. Available: https://ntp.niehs.nih.gov/ntp/roc/content/listed_substances_508.pdf.

[3] Hopkins, JS. The Center for Public Integrity, "Common solvent keeps killing workers, consumers." September 21, 2015. Available: https://www.publicintegrity.org/2015/09/21/17991/common-solvent-keeps-killing-workers-consumers.

[4] US EPA, Office of Chemical Safety and Pollution Prevention. "TSCA Work Plan Chemical Risk Assessment. Methylene Chloride: Paint Stripping Use." August 2014. EPA Document #740-R1-4003. Available: https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

[5] US EPA, Office of Chemical Safety and Pollution Prevention. "Supplemental Consumer Exposure and Risk Estimation Technical report for Methylene Chloride in Paint and Coating Removal." November 2016.See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0254.

US EPA, Office of Chemical Safety and Pollution Prevention. "Respirator and Glove Specifications for Workers Exposure to Methylene Chloride in Paint and Coating Removal." November 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0255.

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occupational and residential bystanders, and consumers. DCM exposures resulting from these uses are well above the benchmark risk levels for both non-cancer and cancer effects, often by orders of magnitude.

NMP is a common DCM replacement, and is sometimes marketed as a safer and greener alternative.[6] Yet NMP also presents well-documented health risks, including developmental impacts (e.g., fetal death, decreased infant birth weight, delayed ossification), neurotoxicity, immunotoxicity, liver and kidney toxicity, and reproductive effects. NMP has been classified as a substance of very high concern (SVHC) under the EU's REACH regulation, due to its categorization as a reproduction category 1B toxicant.[7] NMP is also a high production volume chemical (185 million pounds reported produced or imported in the U.S. in 2011).

EPA demonstrated in its 2015 NMP risk assessment[8] and supplemental technical reports[9] that use of NMP-containing paint and coating removers poses unacceptably high risks of adverse developmental toxicity (fetal effects) associated with acute and chronic exposures in both female workers and consumers of childbearing age. EPA found that such exposures in excess of four hours per day present risks that cannot be mitigated through use of protective gear such as gloves and respirators.

US EPA, Office of Chemical Safety and Pollution Prevention. "Recommendation for an Existing Chemical Exposure Concentration Limit (ECEL) for Occupational Use of Methylene Chloride and Workplace Air Monitoring Methods for Methylene Chloride." November 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0253.

[6] US, EPA presentation, "Proposed Regulation under TSCA section 6(a) of Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal (RIN 2070-AK07)." Small Business Administration Environmental Roundtable, April 7, 2017.

[7] ECHA (European Chemicals Agency). "Agreement of the Member State Committee on the Identification of1-methyl-2-pyrrolidone as a Substance of Very High Concern." May 2011. Available: https://echa.europa.eu/documents/10162/d863ae05-8bd5-4cb6-a017-2a19974b9ad1.

[8] US EPA, Office of Chemical Safety and Pollution Prevention. "TSCA Work Plan Chemical Risk Assessment. N-Methylpyrrolidone: Paint Stripping Use." March 2015. EPA Document #740-R1-5002. Available: https://www.epa.gov/sites/production/files/2015-11/documents/nmp_ra_3_23_15_final.pdf.

[9] US EPA, Office of Chemical Safety and Pollution Prevention. "Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal." November 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0199.

US EPA, Office of Chemical Safety and Pollution Prevention. "Recommendation for an Existing Chemical Exposure Limit (ECEL) for Occupational Use of NMP and Workplace Air Monitoring Methods for NMP." January 2017. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0238.

US EPA, Office of Chemical Safety and Pollution Prevention. "Respirator and Glove Specifications for Workers and Consumers Exposure to NMP in Paint and Coating Removal and Estimated Fractions of Worker Population Vulnerable to the Acute Health Effect." January 2017. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0200.

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EPA's determinations that the uses of DCM and NMP subject to this rule present unreasonable risks are strongly scientifically supported. Further, EPA has amply demonstrated that the specific TSCA section 6 risk management actions EPA has proposed for DCM are necessary to meet the Agency's statutory mandate to impose requirements "to the extent necessary" such that DCM no longer presents these unreasonable risks (TSCA section 6(a)).

With respect to NMP, EPA has amply demonstrated that the specific TSCA section 6 risk management actions presented in option 1 would meet the agency's statutory mandate to mitigate unreasonable risk; however, the agency does not provide sufficient evidence to conclude that option 2, which relies on a combination of reformulation, labeling, and worker protection programs, would mitigate exposure "to the extent necessary" such that NMP no longer presents unreasonable risks (TSCA section 6(a)). Furthermore, EPA's economic analysis demonstrates that it would cost industry far *more* (on the order of $100 million) to implement such concentration, labeling, and worker protection program requirements than to comply with a simple prohibition.

DCM and NMP may be substituted for each other in paint and coating removal products, and, thus, addressing them simultaneously in a single section 6 rulemaking will help to avoid regrettable substitution – where one risky chemical is replaced with another. Importantly, safer chemical paint and coating removal alternatives are available.

We urge the Agency to finalize the proposed rule by implementing a ban on the use of DCM and NMP in paint and coating removal, and to do so as expeditiously as possible in order to safeguard human health.

II. EPA's assessments of DCM and NMP's hazards and risks underpinning the proposed TSCA section 6 rule are scientifically rigorous

EPA's DCM and NMP risk assessments and supplemental technical reports make clear that both chemicals, under the conditions of use subject to this proposed rule, present unreasonable risks of injury to the health of workers, bystanders, and/or consumers. These documents reflect the input from numerous and extensive peer reviews, use the best available science, and apply a weight- of-the-scientific-evidence approach.

A. The DCM and NMP assessments have received extensive peer review

The DCM and NMP risk assessments, as well as the underlying information, have undergone multiple, extensive peer reviews, as briefly described here and further documented in Appendix A.

1. DCM

The DCM risk assessment and technical reports draw heavily from the earlier 2011 IRIS Toxicological Review of DCM ("IRIS assessment"). As described in the IRIS assessment, "[t]his document has been provided for review to EPA scientists, interagency reviewers from other federal agencies and White

House offices, and the public, and peer reviewed by independent scientists external to EPA."[10] The IRIS assessment applied a systematic review approach to the identification, consideration, and integration of the scientific literature bearing on the health effects of DCM.

In addition to the 2011 IRIS assessment, EPA relied on the following peer-reviewed reports for hazard and dose-response information:

- Interim Acute Exposure Guideline Levels (AEGL) for methylene chloride[11]

- Spacecraft Maximum Allowable Concentrations (SMAC) for Selected Airborne Contaminants: Methylene chloride (Volume 2) published by the U.S. National Academies[12]

- Acute Reference Exposure Level (REL) and Toxicity Summary for Methylene Chloride published by the Office of Environmental Health Hazard Assessment[13]

The 2014 DCM risk assessment itself underwent a contractor-managed peer review that entailed three convenings of an expert panel during the fall of 2013, culminating in a peer review report.[14] In addition, opportunities for public comment were provided upon issuance of the draft risk assessment (Jan – March 2013)[15] and in conjunction with each of the three expert panel meetings.[16] EPA took into serious consideration input from the peer review as well as public comments, as evidenced in its "Summary of

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[10] US EPA, Integrated Risk Information System (IRIS). "Toxicological Review of Dichloromethane." November 2011. EPA/635/R-10/003F. Available: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0070tr.pdf.

[11] NAC (National Advisory Committee). "Interim Acute Exposure Guideline Levels (AEGL) for Methylene Chloride." December 2008. Washington, DC. Available: https://www.epa.gov/aegl/methylene-chloride-results-aegl-program.

[12] NRC (National Research Council). "Spacecraft Maximum Allowable Concentration for Selected Airborne Contaminants: Methylene Chloride." Volume 2 (1996). National Academy Press, Washington, DC. Available: http://www.nap.edu/catalog.php?record_id=5170.

[13] OEHHA (Office of Environmental Health Hazard Assessment). "Acute Reference Exposure Level (REL) and Toxicity Summary for Methylene Chloride." 2008. State of California Environmental Protection Agency, Sacramento, CA.

[14] US, EPA peer review panel. "OPPT Methylene Chloride (DCM) Draft Risk Assessment Final Comments of Nine-Member Peer Review Panel." December 2013. Available: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/oppt-methylene-chloride-dcm-draft-risk-assessment-final.

[15] US, EPA. "Posting EPA-HQ-OPPT-2012-0725 to Regulations.gov for Public Access." January 2013. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0001.

[16] 78 Fed Reg. 52525. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0036.

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External Peer Review and Public Comments and Disposition," in which the agency responded to 55 specific areas of comment it received.[17]

2. NMP

While an IRIS assessment has not been conducted for NMP, EPA's NMP risk assessment also involved a critical consideration of the scientific literature that, among other evidence, included a number of authoritative, peer-reviewed reports such as:

- The Dutch National Institute for Public Health and the Environment (RIVM) Proposal for a Restriction of NMP[18]
- Organization for Economic Co-operation and Development (OECD) SIDS Initial Assessment Report[19]
- WHO Concise International Chemical Assessment Document (CICAD) for NMP[20]
- Cal OEHHA Maximum Allowable Dose Levels (MADL) for NMP[21]

The NMP risk assessment itself was peer-reviewed through the same contractor-managed peer review process used for DCM, culminating in a peer review report.[22] In addition, opportunities for public comment were provided upon issuance of the draft risk assessment (Jan – March 2013)[23] and in conjunction with each of the three expert panel meetings.[24] EPA took into serious

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[17] US EPA. "Summary of External Peer Review and Public Comments and Disposition." August, 2014. Available: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/response-comments-dcm-work-plan-risk-assessment.

[18] RIVM (National Institute for Public Health and the Environment (RIVM)). 2013. Annex XV Restriction Report: Proposal for a Restriction, N-Methylpyrrolidone (NMP). Version 2. RIVM, Bureau REACH, The Netherlands.

[19] OECD (Organization for Economic Co-operation and Development). 2007. SIDS Initial Assessment Report. 1-Methyl-2-Pyrrolidone.

[20] WHO (World Health Organization). 2001. Concise International Chemical Assessment Document (CICAD) 35, N-Methyl-2-Pyrrolidone. Geneva, Switzerland. www.who.int/entity/ipcs/publications/cicad/en/cicad35.pdf.

[21] OEHHA (Office of Environmental Health Hazard Assessment). 2003. Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for N-Methypyrrolidone for Dermal and Inhalation Exposures. Reproductive and Cancer Hazard Assessment Section.

[22] US, EPA peer review panel. "OPPT N-Methylpyrrolidone (NMP) Draft Risk Assessment Final Comments of Nine Member Peer Review Panel." December 2013. Available: https://www.epa.gov/sites/production/files/2015-09/documents/nmp_consolidated_peer_review_comments_december_31_2013.pdf.

[23] US, EPA. "Posting EPA-HQ-OPPT-2012-0725 to Regulations.gov for Public Access." January 2013. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0001.

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consideration input from the peer review as well as public comments, as evidenced in its "Summary of External Peer Review and Public Comments and Disposition," in which the Agency responded to 90 specific areas of comment it received.[25]

B. The DCM and NMP assessments use the best available science and a weight-of-the scientific-evidence approach

1. Work plan risk assessments

i. DCM

The DCM risk assessment identified numerous unreasonable risks to human health (cancer and non-cancer) resulting from both acute and chronic inhalation exposures to workers and occupational bystanders as well as acute non-cancer risks to consumers and residential bystanders. The Supplemental Consumer Exposure and Risk Technical Report for DCM also identified acute risks to consumers for eight additional inhalation exposure scenarios for both consumers and residential bystanders.

EPA's 2014 DCM risk assessment relied on multiple peer-reviewed sources to characterize cancer as well as non-cancer acute and chronic hazards. The assessment drew heavily from the extensively peer-reviewed 2011 IRIS assessment (see Appendix A), specifically for characterizing cancer and repeat exposure non-cancer hazards. The DCM IRIS assessment employed a systematic approach to identify studies for inclusion and to evaluate the quality of such studies so as to incorporate the best available science, and applied a weight-of-the-scientific-evidence approach to determine and characterize DCM human health hazards. For non-cancer acute hazard characterization, EPA relied on dose-response information from the three additional peer reviewed reports listed in subsection II.A.1 above.

Multiple study types were used in the identification and characterization of DCM hazards and corresponding dose-response relationships, including human, animal, mechanistic, and toxicokinetic studies. EPA's hazard identification and dose-response methodologies are clearly and extensively documented and explained in the IRIS assessment as well as in section 3.3.1 and Appendix I of the 2014 risk assessment. Through these rigorous assessments, EPA identified multiple adverse cancer and non-cancer effects that present unreasonable risks to human health for the uses subject to the current proposed rule. Non-cancer effects include neurotoxicity resulting from either direct narcosis or the formation of carbon monoxide following acute exposure, as well as hepatic effects from chronic exposure. Additionally, chronic DCM exposure is associated with cancer, most notably lung and liver cancers.

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[24] 78 Fed Reg. 52525. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0036.

[25] US, EPA. "Summary of External Peer Review and Public Comments and Disposition." Available: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/summary-external-peer-review-and-public-comments-and.

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ii. NMP

The 2015 NMP risk assessment found unreasonable acute and chronic risk of developmental toxicity to female workers of childbearing age and evidence of acute risk to female consumers of childbearing age, the latter of which was further supported by the Supplemental Consumer Exposure Technical Report for NMP in Paint and Coating Removal.

Multiple study types were used in the identification and characterization of NMP hazards and corresponding dose-response relationships, including animal, mechanistic, and toxicokinetic studies as well as a human case report. These include the following:

- EPA obtained toxicological information from the four peer-reviewed assessments of NMP listed in subsection II.A.2. above. EPA found the assessments to be "reasonably robust, as they were peer reviewed and generally consistent in their conclusions." EPA identified key fetal toxicity endpoints from these peer-reviewed reports.
- For these endpoints, EPA collected additional publicly available data, and then selected a subset of studies described as "the most robust, sensitive and consistent fetal effects compared to other studies."
- EPA adapted and validated a PBPK model based on a published, peer-reviewed model to calculate internal doses of NMP and estimate aggregate exposures across multiple exposure routes, and used benchmark dose (BMD) modeling to generate a point of departure (POD).

EPA's literature collection (including study quality analysis), hazard identification, and dose-response methodologies are clearly documented and explained in section 3 as well as Appendices F-I of the 2015 risk assessment.

Based on these rigorous assessments, EPA found unreasonable risk of adverse developmental outcomes to women of childbearing age from acute (fetal mortality) and chronic (decreased fetal body weight) NMP exposure for the uses subject to the current proposed rule. Additional non-cancer effects resulting from either acute or chronic exposure to NMP identified by EPA include irritation and sensitization, systemic effects such as liver and kidney toxicity, reproductive toxicity, and neurotoxicity.

2. Supplemental assessments

Following the publication of the 2014 DCM and 2015 NMP risk assessments, EPA developed three supplemental technical reports for each chemical in order to: 1) refine specific aspects of the risk assessments for consumer exposure scenarios, 2) develop a recommendation for an Existing Chemical Exposure Concentration Limit (ECEL) for occupational use and workplace air monitoring, and 3) assess the efficacy of available gloves and respirator options and calculate the extent of risk associated with various risk reduction options.

The exposure scenarios examined in the supplemental reports are fully within scope of the final DCM and NMP risk assessments and utilize the methods and models applied in those assessments (i.e., the Multi-Chamber Concentration and Exposure Model [MCCEM] used in the DCM and NMP assessments, and the physiologically-based pharmacokinetic [PBPK] modeling methodology used in the NMP

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assessment). While those methods and models have themselves already been peer-reviewed, EPA has indicated it is also subjecting each of the supplemental technical reports to peer review before promulgating the final rule.

With respect to the DCM supplemental reports, EPA notes in its proposed rule:

> Following the methylene chloride risk assessment, EPA conducted supplemental analyses to inform risk management. These analyses are consistent with the scope of the methylene chloride risk assessment and were based on the peer-reviewed methodology used in the methylene chloride risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced methylene chloride content in paint removers, addition of local exhaust ventilation (LEV), use of personal protective equipment (PPE), additional consumer exposure scenarios, and methods of monitoring to determine workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 19, 20, and 21). Prior to promulgation of the final rule, EPA will peer review the "Respirator and Glove Specifications for Workers Exposed to Methylene Chloride in Paint and Coating Removal," "Supplemental Consumer Exposure and Risk Estimation Technical Report for Methylene Chloride in Paint and Coating Removal", and "Recommendation for an Existing Chemical Exposure Concentration Limit (ECEL) for Occupational Use of Methylene Chloride and Workplace Air Monitoring Methods for Methylene Chloride" (Refs. 19, 20, 21). (p. 7472)

With respect to the NMP supplemental reports, EPA notes in its proposed rule:

> Following the NMP risk assessment, EPA conducted supplemental analyses to inform risk management and to expand on the consumer exposure scenarios. These analyses are consistent with the scope of the NMP risk assessment and were based on the peer-reviewed methodology used in the NMP risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced NMP content in paint removers, addition of local exhaust ventilation (LEV), use of personally protective equipment (PPE), and methods of monitoring to ascertain workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 37, 75, and 76). Prior to promulgation of the final rule, EPA will peer review the "Recommendation for an Existing Chemical Exposure Limit (ECEL) for Occupational Use of NMP and Workplace Air Monitoring Methods for NMP," "Respirator and Glove Specifications for Workers and Consumers Exposed to N-methylpyrrolidone (NMP) in Paint and Coating Removal and Estimated Fractions of Worker Population Vulnerable to the Acute Health Effect," and "Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal" (Refs. 37, 75, and 76). (pp. 7500-7501)

The extensive peer reviews of the agency's 2011 IRIS toxicological review of DCM, the 2014 and 2015 risk assessments for DCM and NMP and the methods and models used in the supplementary analyses, as well as the many opportunities for public comment on these assessments of each chemical, have ensured robust consideration of the major scientific issues bearing on the health risks of DCM and NMP as well as the use of the best available science in the determination of these risks.

C. DCM and NMP present unreasonable risks for multiple endpoints

1. DCM

EPA has found that DCM presents unreasonable risks for multiple cancer and non-cancer chronic effects for the conditions of use subject to the proposed rule. DCM exposures from paint and coating removal result in risks that are well above acceptable risk levels for non-cancer effects, typically by orders of magnitude. Cancer risk estimates similarly are orders of magnitude higher than the standard cancer risk benchmarks.

These results are well-documented in the risk assessment and the Supplemental Consumer Exposure and Risk Technical Report for DCM, and are highlighted clearly in the proposed rule, as reflected in these excerpts:

- "For cancer effects, EPA estimated that workers and occupational bystanders exposed to methylene chloride in paint and coating removal have an increase in cancer risk that ranged from **10 times to almost 1,000 times** greater than a cancer benchmark of 1 in 1,000,000, depending on the specific way paint or coating removal was conducted with methylene chloride." (p. 7471)
- "Cancer risks [in commercial furniture refinishing] ranged from **2 in 10,000 to 8 in 10,000, with a maximum of 5 in 1,000** (workplaces using immersion methods)." (p. 7494)
- "MOEs [Margin of Exposure] for consumer acute risks from exposures of one hour or less ranged from **1.6 to 0.2**; this equates to estimated exposures that are between **six and 50 times greater** than those that are expected to produce no risks of concern." (p. 7478)
- "MOEs for acute [occupational] risks ranged from an average of **0.11** (automotive refinishing) **to 0.037** (graffiti removal), **with a lowest end of 0.0063** (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels between **100 times to greater than 1,000** times more than those that are of concern." (p. 7478)
- "For residential bystanders, EPA identified risks of concern for all scenarios, even assuming that any bystander in the house was not in the room where the paint and coating removal occurred. Depending on the parameters of the scenario, MOEs for acute risks ranged from **2.9 to 0.5, or between three and 20 times greater** than those that are expected to produce no risks of concern" (p. 7478)
- "In most workplaces engaged in commercial furniture refinishing, **MOEs for chronic exposure ranged from a central tendency of 0.60 to 0.3**." (benchmark MOE = 10, p. 7494)

It should be noted that the DCM risk assessment excluded dermal exposures, due to lack of sufficient data; hence, it underestimated overall exposure, and thus risk. As described in the 2013 peer review comments[26] on the draft DCM risk assessment: "Another major point is the exclusion of dermal exposure in spite of the assumption that gloves will not be worn. Greater justification is needed to exclude a DCM pathway when the use obviously involves extensive dermal contact." While this is clearly a shortcoming of the risk assessment, because the identified risks so far exceed safe levels, further refinement is not needed to determine that the risks are unreasonable and that a ban is warranted. In "closer-call" cases, better characterization of the exposure from all routes of exposure will be critical.

2. NMP

EPA has found that NMP presents unreasonable risks for acute non-cancer effects (fetal death) and chronic non-cancer effects (decreased birth weight) for the conditions of use subject to the proposed rule. Specifically, acute and chronic NMP exposures from paint and coating removal result in risks that are above acceptable risk levels for female workers of childbearing age and acute risk to female consumers of childbearing age. Further, exposures of women of childbearing age beyond four hours per day present risks that cannot be mitigated from use of protective gear such as gloves and respirators.

These results are well-documented in the risk assessment and supplemental technical report on consumer exposure and risk, and are highlighted clearly in the proposed rule, as reflected in these excerpts (benchmark MOE=30):

- "For commercial users, the occupational scenarios in which acute risks were identified included four hours of paint removal in one day with no gloves, with or without a respirator, indoors or outdoors, assuming mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (**MOEs range from 12 to 15**); and four hours of paint removal in one day with or without a respirator and gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (**MOEs range from 0.7 to 11.8**)" (p. 7505)
- "Risk of decreased birth weight was identified for commercial users of NMP for paint and coating removal in several scenarios, including four hours of paint removal during each day in a work week without gloves, with or without a respirator, indoors or outdoors, assuming the mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (**MOEs range from 5.4 to 6.1**); and eight hours of paint removal during each day in a work week, with or without a respirator or gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (**MOEs range from 0.1 to 3.2**)" p. 7505)
- "To identify what, if any, risks may be present for consumers in different scenarios, EPA conducted additional analyses consistent with the risk assessment to provide an expanded understanding of consumer exposures (Ref. 76). Additionally, it appears that consumers could engage in patterns of use comparable to worker exposures that present risk; for example, any consumers engaging in paint and coating removal with NMP for longer than four hours in one day could be subject to the acute occupational risks identified." (p. 7505)

[26] US, EPA peer review panel. "OPPT Methylene Chloride (DCM) Draft Risk Assessment Final Comments of Nine-Member Peer Review Panel." December 2013. Available: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/oppt-methylene-chloride-dcm-draft-risk-assessment-final.

The expanded consumer exposure modeling described above identified acute risk for developmental effects in 14 consumer exposure scenarios with **MOEs as low as 5.6.**[27] Seven of these scenarios could not be mitigated with the use of gloves.

Exposures to DCM and NMP resulting from paint and coating removal uses are widespread. EPA estimates that 32,600 workers annually are exposed to DCM during paint and coating removal activities. The agency goes on to explain in the proposed rule that "EPA estimates that a large percentage of users of paint and coating removal products containing methylene chloride are consumers, rather than occupational users. EPA estimates that approximately 1.3 million consumers annually use paint removal products containing methylene chloride."

With regard to NMP, EPA states that "[t]here are increased risks for these reproductive effects for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal," and further estimates that "732,000 consumers annually use paint removal products containing NMP." EPA noted during a Small Business Administration (SBA) presentation on April 7, 2017[28] that it is seeing an increase in NMP use in the consumer market as companies transition out of DCM.

D. DCM and NMP present unreasonable risks to potentially exposed or susceptible subpopulations

Under TSCA, EPA must consider risks to "potentially exposed or susceptible subpopulations," which include "infants, children, pregnant women, workers or the elderly," (TSCA 3(2)(12)) when it examines a chemical's risks.

With regards to DCM, EPA concludes that exposure from the targeted conditions of use is likely to present acute risks to children as bystanders, even if they are not physically in the area in which the work is conducted.

The use of NMP as paint stripper poses particularly significant risks to pregnant women due to its developmental toxicity. The proposed rule indicates that:

> EPA has concerns for effects on the developing fetus from acute and chronic worker and consumer maternal exposures to NMP. The risk estimates focus on the most susceptible life stages, which for NMP are women of childbearing age and their developing fetus. However, because women may not know that they are pregnant (Refs. 80 and 81) and short-term

[27] US EPA, Office of Chemical Safety and Pollution Prevention. "Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal." November 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0199.

[28] EPA presentation, "Proposed Regulation under TSCA section 6(a) of Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal (RIN 2070-AK07)." Small Business Administration Environmental Roundtable, April 7, 2017.

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> exposure to NMP may adversely impact fetal development during a single day or single week of exposure, the life stages of concern for risk assessment include all women of childbearing age (i.e., women between the ages of 16 and 49 years) and the developing fetus. (p. 7503)

Workers are also a relevant potentially exposed or susceptible subpopulation, given the large number of workers potentially exposed from the use of DCM and NMP in occupational settings. In addition, environmental justice concerns exist with regards to both DCM and NMP as a result of disproportionately high representation of Hispanics and foreign-born workers in the construction trades. As noted in the proposed rule, 35% of construction workers are Hispanic, while only 16% of the U.S. adult national population is Hispanic, and, 28% of construction workers are foreign-born, compared to 17% of workers in all industries in the U.S. population overall. Consequently, these two subpopulations are in all likelihood more highly exposed to both DCM and NMP in construction settings, which heavily engage in paint and coating removal, relative to other segments of the population, and as such are at higher risk for any of the wide range of potential health impacts resulting from both of these chemicals. Given that foreign-born workers often have limited English proficiency, this has important implications for risk management strategies that rely on oral or written communication, such as labels and worker training. The most equitable solution is to universally prohibit DCM and NMP in such products, as will be discussed in more detail below.

* * * *

In sum, EPA has identified unreasonable risks in both occupational and consumer settings for a range of non-cancer and cancer effects from the use of DCM in paint strippers, as well as non-cancer effects from the use of NMP in paint strippers. Most exposure scenarios for DCM and many exposure scenarios for NMP were clearly above risk benchmarks for these effects, and result in unreasonable risks to potentially exposed or susceptible subpopulations, including workers, pregnant women, as well as certain racial, ethnic, and foreign-born groups disproportionately represented in the construction trades.

EPA must act immediately to protect against these significant human health risks by banning these uses of DCM and NMP.

III. EPA's proposed ban of DCM, and its proposed ban of NMP under option 1, are appropriate and necessary to address the identified unreasonable risks

A. Only regulation under TSCA can effectively address the identified unreasonable risks

1. Existing DCM and NMP regulations do not address the unreasonable risks identified

As elaborated upon in EPA's proposed rule, existing federal regulations for DCM and NMP do not address the specific serious health risks EPA is seeking to address in the proposed TSCA section 6 rules.

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DCM is designated as a hazardous air pollutant (HAP) under the Clean Air Act, and in 2008, EPA promulgated a National Emission Standards for Hazardous Air Pollutants (NESHAP) for paint stripping, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating. Some in industry have pointed to this regulation as justification for why a TSCA section 6 rule is unnecessary. However, the NESHAPs were developed to regulate emissions to the environment and from only certain types of paint and coating removal operations, and do not address worker or consumer exposures.[29] Therefore, they are insufficient to mitigate the risks identified by EPA from both occupational and consumer use of DCM-based paint and coating removal products.

The U.S. Occupational Safety and Health Administration's (OSHA) has set a permissible exposure limit (PEL) of 25 ppm (8-hour time-weighted average) for workplaces. OSHA's PEL was last updated in 1997 – 20 years ago. The proposed rule concludes that OSHA's PEL is higher than the levels at which EPA identified unreasonable risk (p. 7470). Furthermore, OSHA itself has indicated[30] that the PEL would be insufficient to protect workers from the risks identified by EPA.[31]

DCM is also listed as a hazardous waste under Resource Conservation and Recovery Act (RCRA), which addresses disposal of DCM. In addition, 11 states and the District of Columbia have banned DCM for graffiti use.[32]

No existing federal or state regulations adequately address the risks from DCM EPA is proposing to mitigate through the current proposed rule. The NESHAP and RCRA requirements do not directly protect workers, and OSHA's PEL is inadequate to protect workers from the endpoints of concern. Furthermore, none of these regulations address consumer exposure – which is of major concern.

With respect to NMP, there are no existing federal regulations.

2. No referral under TSCA section 9(a) is warranted

EPA reasonably decided not to submit a report to another federal agency requesting that the agency address the risks presented by DCM and NMP. EPA may only submit a report pursuant to section 9(a)

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[29] US, EPA presentation, "Proposed Regulation under TSCA section 6(a) of Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal (RIN 2070-AK07)." Small Business Administration Environmental Roundtable, April 7, 2017.

[30] US Department of Labor- Occupational Safety and Health Administration (OSHA). Letter to James J. Jones from David Michaels, PhD, MPH. March 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0153.

[31] As a further indication of the inadequacy of OSHA's PEL, in the course of developing this proposed rule, EPA developed a recommendation for an ECEL as a more current benchmark for workplace exposures; this recommended value (1.3 ppm, 8-hour time weighted average), is significantly lower than OSHA's PEL.

[32] The success of the District of Columbia and 11 states (California, Connecticut, Delaware, Illinois, Indiana, Maine, Maryland, Michigan, New Jersey, New York, and Rhode Island) in banning DCM for graffiti removal indicates that there are viable alternatives for paint stripping.

upon making two requisite findings and complying with specified procedures.[33] Section 9(a) states that EPA must:

> determine[] 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.

The proposed rule supports that determination. Second, EPA must "determine[], *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."

EPA must make both determinations before relying on the section 9(a) process. In the proposed rule, EPA reasonably determined that the unreasonable risks presented by DCM and NMP would not be prevented or reduced to a "sufficient extent" by action taken under a Federal law administered by another agency. That determination was not only well within EPA's discretion, but on this factual record, a contrary conclusion would not be justified.

Factually, considering the letters that both the Consumer Product Safety Commission (CPSC)[34] and the Occupational Safety and Health Administration (OSHA)[35] provided to the record for this rulemaking, it would be irrational to refer the risks posed by DCM and NMP to those agencies. Neither agency disagreed that these chemicals presented the risks identified by EPA. Each agency acknowledged that, while each one could address some of the risks to some extent, neither agency has the authority to address the risks to a sufficient extent. CPSC can address some of the risks to consumers, but "CPSC lacks authority to address occupational hazards." Meanwhile, "OSHA's jurisdiction is limited to the workplace, and the agency does not have authority to address exposures outside that scope, such as purely consumer uses of hazardous chemicals." Additionally, OSHA "does not cover self-employed

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[33] Procedurally, section 9(a) requires that EPA "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." The report "shall include a detailed statement of the information on which it is based and shall be published in the Federal Register." The report also must request that such agency respond by a specified deadline. EPA's report must request that the agency first "determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law." EPA's report must also request that, "if the agency determines that such risk may be so prevented or reduced," the agency must "issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk." In turn, the responding agency must provide "a detailed statement of [its] findings and conclusions," published in the Federal Register.

[34] US Consumer Product Safety Commission (CPSC). Letter to James J. Jones from Patricia H. Adkins. June 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0154.

[35] US Department of Labor- Occupational Safety and Health Administration (OSHA). Letter to James J. Jones from David Michaels, PhD, MPH. March 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0153.

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workers, military personnel and uniquely military equipment, systems, and operations," whereas the proposed rule expressly addresses some risks to military personnel.[36] The proposed rule also covers self-employed workers; self-employed rates are high among construction workers,[37] and construction workers often engage in paint and coating removal. Thus, even combined, the agencies could not address the identified risks. Each agency also stated that its "current regulatory agenda" does not include taking further steps to address these chemicals and they did not anticipate such regulatory activity in the near future. While EPA has authority and is prepared to act to address the risks immediately, any action that the other agencies might be able to take could not be promptly initiated. Hence, action by EPA under TSCA would be both more efficient and effective than action by another agency under a different statute.

More broadly, OSHA has explained that almost all of its current PELs for chemical substances date back to 1971, and in the last 40 years, it has only adopted or modified approximately 30 additional PELs, even though thousands of chemicals are used in American workplaces.[38] OSHA has acknowledged that in many instances scientific evidence indicates that current PELs are not sufficiently protective, and OSHA detailed its unsuccessful attempts to update them over the last forty years. OSHA attributed its lack of action in this area, in part, to the legal requirements it must meet under the OSH Act, as interpreted by the courts. Any reasoned decision to refer the identified risks of DCM and NMP to OSHA would have to account for this 40-year history and explain why it would be reasonable to expect OSHA to act on these chemicals in a reasonable timeframe, as informed by the ninety-day deadline suggested by section 9(a)(2).

Legally, section 9(a) contemplates that EPA will issue "a" report when a single federal agency has authority under federal law to address the unreasonable risk. The language does not require EPA to issue multiple reports to multiple agencies in an attempt to cobble together a sufficient level of protection. Numerous different agencies issuing multiple rules using differing authorities to address the same chemical substance, depending on whether it appears in the consumer or occupational setting, and acting under different timeframes, would be inconsistent with TSCA's requirement that EPA coordinate to avoid "duplicative requirements" under section 9(d). The purpose and legislative history of TSCA indicate that Congress intended to allow EPA to comprehensively address chemicals when appropriate, and the amendments made to TSCA by the Lautenberg Act sought to increase EPA's authorities and mandates to better ensure that TSCA would be workable and effective. It would

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[36] 82 Fed. Reg. at 7489. The proposed rule reasonably provides a limited, ten-year exemption for critical corrosion-sensitive components of military aviation and vessels. The proposed rule otherwise would apply to protect military personnel. 82 Fed. Reg. at 7490, 7518.

[37] US Bureau of Labor Statistics. "Self-employment in the United States." March 2016. Available: https://www.bls.gov/spotlight/2016/self-employment-in-the-united-states/pdf/self-employment-in-the-united-states.pdf ("In 2015, unincorporated self-employment rates were highest for workers in construction and extraction occupations (14.8 percent)."); *see also* Center for Public Integrity. "Common solvent keeps killing workers, consumers." September 2015. Available: https://www.publicintegrity.org/2015/09/21/17991/common-solvent-keeps-killing-workers-consumers.

[38] 79 Fed. Reg. 61,384, 61,386 (Oct. 10, 2014).

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undermine these goals and purposes for EPA to take a piecemeal approach through section 9(a) referrals.

Additionally, as EPA explained in the proposed rule, a referral decision must be informed by both EPA's authorities and obligations under TSCA and the legal authority provided to the other federal agency. Section 9(a) only permits a referral if the risk will "be prevented or reduced to a sufficient extent" by the other federal agency. Reduction in risk must be "sufficient" as defined by TSCA, and the word "extent" cross-references the basic standard set forth in section 6(a). Section 6(a) provides that if EPA determines that a substance or mixture "presents an unreasonable risk of injury to health or the environment," EPA "shall" apply requirements to the "substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk." Thus, EPA may only refer a chemical upon a determination that the other agency can take action that will reduce the risk "to the extent necessary so that [it] no longer presents [an unreasonable risk of injury to health or the environment]." EPA reasonably considered the limits on OSHA's and the CPSC's authorities when assessing whether either agency could meet that standard. Here, EPA reasonably concluded that they would be unable to address the identified risks to a sufficient extent under their authorities. Of course, this determination depends on the specific factual and legal circumstances presented by each unreasonable risk determination, and a finding that the risks presented by DCM and NMP should not be referred does not dictate the outcome in other circumstances.

Finally, in these circumstances, any referral would appear to violate the directive in section 9(d) that the Administrator "consult and coordinate" with other agencies "for the purpose of achieving the maximum enforcement of" TSCA. Here, EPA has consulted and coordinated with OSHA and CPSC, and they have indicated that they have no intention of addressing the identified risks presented by DCM and NMP in the near future. A referral in these circumstances would ignore that prior consultation and fail to achieve the maximum enforcement of TSCA.

B. Prohibitions on the manufacture, processing, distribution, and use of DCM and NMP are needed to mitigate the identified unreasonable risks

TSCA requires that, where EPA determines there is unreasonable risk, the Agency must, by rule, apply one or more requirements "to the extent necessary so that the chemical substance no longer presents such risk" (section 6(a)).

In consideration of EPA's DCM and NMP risk assessments and supplemental analyses, and its subsequent, exhaustive review of potential risk management options,[39] the proposed rule's risk management approach for DCM and proposed option 1 for NMP are the only approaches that will effectively manage the unreasonable risks identified.

EDF strongly supports EPA's two-part approach to evaluating the effectiveness of various risk management options to address identified unreasonable risks: 1) a technical analysis to determine

[39] Technical analyses of risks associated with different risk management options are elaborated upon in EPA's supplemental technical reports and are described in detail in the proposed rule.

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whether risk management options could reach (or surpass) risk benchmarks and 2) consideration of how reliably those options would actually reach (or surpass) risk benchmarks.[40] The proposed rule states with respect to DCM:

> In considering whether a regulatory option would ensure the chemical no longer presents the unreasonable risk, the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks, as well as whether the option's protectiveness was influenced by concerns related to environmental justice, children's health, and potentially exposed or susceptible subpopulations identified as relevant to the Agency's risk evaluation. (p. 7473)

An analogous statement can be found on page 7501 for NMP.

Consideration of real-world effectiveness of a risk management option is key, as exposures resulting from DCM's and NMP's conditions of use subject to this proposed rule are occurring in the real-world, not in some hypothetical setting. With these considerations in mind, EDF strongly believes that prohibiting the manufacture, processing, distribution, and use of DCM and NMP in paint and coating removal is the only approach sufficient to mitigate the unreasonable risks to all of the relevant potentially exposed or susceptible subpopulations.

C. Risk management options short of a ban are inadequate and inappropriate to mitigate the identified unreasonable risks

Risk management options identified in TSCA section 6(a)(3) (minimum warning labels and instructions) and 6(a)(2) (concentration limits) will not address the health risks that result from DCM and NMP exposures under the conditions of use that are the subject of the proposed rule.

EDF has previously commented on the major limitations of relying on warning labels and use instructions to manage chemical risk. In 2016 EPA published a report, "The Effectiveness of Labeling on Hazardous Chemicals and Other Products,"[41] which applied a weight-of-the-scientific-evidence approach to a meta-analysis of nearly 50 studies examining the effectiveness of warnings and labels. Examples of limitations of warning labels and instructions documented in the report include: a lack of attention paid

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[40] EDF's support of the agency's two-part approach to evaluating the effectiveness of risk management options relates to the general *process* EPA has applied. For non-cancer endpoints, EPA has chosen to execute the first of these two steps by assessing whether the MOEs for various risk reduction options are below benchmark MOEs. As discussed in the conclusion section of these comments, going forward, EDF does not support EPA continuing always to characterize non-cancer chemical risks using MOEs, and urges the agency to move away from this as a general practice. Nonetheless, using the MOE approach, the non-cancer risks resulting from the uses of DCM and NMP addressed in this proposed rule are high and clearly unreasonable.

41 US EPA, Office of Chemical Safety and Pollution Prevention. "The Effectiveness of Labeling on Hazardous Chemicals and Other Products." Washington, DC 2016.

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by users to the presence of warning labels and instructions; inability to correctly comprehend warning labels and instructions; and non-compliance with warning labels and instructions owing to factors such as time and workload stress and social pressure.

For example, a study of 342 participants using household cleaning products found that less than 5% of the subjects were observed to look at the cautionary statement on the label.[42] Another study specifically assessing consumer use of DCM-based paint strippers concluded that users may not have extracted the necessary information from the labels, if they did in fact read them, given the ineffective work practices and precautionary measures reported.[43]

Furthermore, label comprehension tends to be correlated to the users' education and income, and is limited by language barriers and cultural differences in symbolic connotations, such as hazard colors. Additionally, a worker who refuses to use a paint and coating removal product or demand further protections based on information garnered from the label would likely put his or her job at risk. These limitations raise major environmental justice concerns, and are relevant to the Lautenberg Act's requirement to consider risks to potentially exposed or susceptible subpopulations.

The use of PPE is also insufficient to ensure health protection against the identified unreasonable risks. Reliance on PPE, as with labeling, pushes the burden onto chemical or product users, who may already belong to a marginalized population. For example, OSHA recently concluded that respirators are the "least satisfactory approach to exposure control," providing the following explanation:

> …to be effective, respirators must be individually selected, fitted and periodically refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides.
>
> Respirator effectiveness ultimately relies on the practices of individual workers who must wear them. … Furthermore, respirators can impose substantial physiological burdens on workers, including the burden imposed by the weight of the respirator; increased breathing resistance during operation; limitations on auditory, visual, and olfactory sensations; and isolation from the workplace environment.[44]

EPA affirmed its agreement with OSHA's conclusion in the proposed rule (p. 7481).

Furthermore, reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or

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[42] Kovacs, D. C., Small, M. J., Davidson, C. I., et al. (1997). "Behavioral factors affecting exposure potential for household cleaning products." Journal of Exposure Analysis and Environmental Epidemiology, 7(4): 505-520.

[43] Riley, D. M., Fishchhoff, B., Small, M. J., et al. (2001) "Evaluating the Effectiveness of Risk-Reduction Strategies for Consumer Chemical Products." Risk Analysis, 22(2): 357-369.

[44] U.S. Department of Labor- Occupational Safety and Health Administration (OSHA). Letter to James J. Jones from David Michaels, PhD, MPH. October 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0041.

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reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves through reliance on PPE and warnings. The HOC exemplifies the best available science for creating safe, healthful workplace environments.[45,46]

As one final note, while some commenters assert that reliance on risk management measures short of a ban would be sufficient to address the identified unreasonable risks, any such assertion would need to be supported by strong scientific evidence that meets the requirements of sections 26(h) and (i) of TSCA.

1. DCM

As noted in the proposed rule, any warning label language and instruction to protect against the unreasonable risks identified for DCM under conditions of use in the proposed rule would be so enormously complex as to be unrealistic:

> Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor, and effects to bystanders. Currently, though some paint removers containing methylene chloride are labeled with information about its fatal effects if used without ''adequate ventilation'' (Ref. 28) and this information appears on the product safety data sheet, deaths continue to occur. (p. 7474)

EPA determined that neither concentration limits on DCM in paint and coating removers nor imposing engineering controls (i.e., ventilation) in occupational settings would effectively address the unreasonable risks identified in the absence of PPE, as discussed in the proposed rule (p. 7479) and documented in the supplemental technical reports. In the furniture refinishing industry, EPA found unreasonable risks continued to be present even for occupational settings where local exhaust ventilation was assumed to be used as an engineering control and be 90% effective.

EPA also considered risk management through an occupational respiratory protection program, including air monitoring, medical monitoring, and respiratory protection, and appropriately chose not to pursue this route due to major limitations of such an approach. As is clearly laid out in the proposed rule:

> Although respirators, specifically SCBAs, could reduce exposures to levels that are protective of non-cancer and cancer risks, not all workers may be able to wear respirators. Individuals with

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[45] *See, for example*, U.S. EPA, Proposed Rule. "Significant New Uses of Chemical Substances: Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices." EPA-HQ-OPPT-2014-0650-0001. 2016. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0001; and references cited therein.

[46] Denison, R., "Comments on Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notice." EPA-HQ-OPPT-2014-0650-0052. Environmental Defense Fund. 2016. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052.

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> impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for tight fitting full-face piece respirators to provide the required protection. Individuals with facial hair, like beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). (p. 7481)

Finally, the costs associated with proper and effective respiratory protection can be significant. Accordingly, EPA indicates that:

> Given equipment costs and the costs of establishing a respiratory protection program, which involves training, respirator fit testing, and the establishment of a medical monitoring program, EPA anticipates that most companies would choose to switch to substitutes instead of adopting a program for this type of PPE to continue using methylene chloride for paint and coating removal because this type of PPE program is not cost-effective. (p. 7481)

2. NMP

Beyond the general limitations to labeling and PPE outlined above, there are a number of serious additional problems with EPA's proposed option 2 to manage risks from NMP's use as a paint and coating remover in commercial and consumer settings. EPA itself notes a number of concerns regarding this approach (p. 7509), with which EDF fully agrees.

i. Labeling has major real-world limitations

The proposed rule identifies a range of limitations to labeling as a risk management measure for NMP-based paint and coating removal products. With regards to the consumer setting, EPA raises a number of serious questions about the extent to which consumers can be expected to comply with labeling requirements.

As described in the proposed rule:

> If consumers using NMP formulations which did not exceed 35% of NMP were to consistently follow all the warnings on the label (specifically, if the consumer were to use a new pair of the formulation-specific gloves identified on the label each time the product is used; and were to adequately ventilate the workspace; and not spray apply the product; and if they were to wear clothing that covers exposed skin; and properly fit and use a respirator of APF 10, such as a NIOSH-certified air purifying elastomeric half-mask respirator equipped with N100, R100, or P100 filters) then the consumer exposures to NMP would be expected to result in MOEs that approach the benchmark MOE of 30 (Ref. 76).Under real-world conditions, EPA expects that not all consumers will adequately follow the label to reduce risk to a level above the Benchmark MOE. (pp. 7508-7509)

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In other words, a consumer would need to 1) read the label, 2) understand the label, 3) take proactive steps to acquire (if this is even possible) and properly wear the specified protective gear, including specialized gloves (a new pair each time the product is used) and the respirator indicated, and 4) comply with *all* of the specified measures. If a consumer failed to take even a single one of these many steps, he or she would face unreasonable risks. EDF believes the notion that consumers would be able to routinely comply with such complex requirements put forth by the proposed NMP label borders on the absurd.

EPA cannot regulate consumer behavior. To this end, EPA acknowledges in the proposed rule a number of factors that may hinder a consumer from complying with the label, with which EDF fully agrees:

> Even for those consumers who understand and follow the label, EPA expects some number will not follow the label instructions precisely or may be unable to readily locate the specialized gloves or the respirator indicated on the label (Ref. 28). Further, it is unlikely that consumers would have the fit of their respirator tested, which is important part of the proper use, and thus effectiveness, of a respirator, or that they would wear a new pair of specialized gloves for each use of the product containing NMP. EPA emphasizes that product labels are not equivalent to worker protection programs in which risks are reduced through, among other things, training programs, requirements that include proper testing and use of respirators, and requirements to use specialized gloves each time the product is used. (p. 7509)

EPA is specifically requesting comment on "whether the voluntary nature of consumer use and the information provided on the label that would allow consumers to avoid risk below the benchmark MOE if label directions were followed should be a factor in determining whether any remaining risk associated with this exposure scenario is unreasonable." (p. 7509)

EDF strongly believes that the information and analysis provided by EPA are more than enough to demonstrate that such measures are not sufficient.

On balance, the voluntary nature strongly counsels against EPA's finding these measures being sufficient. Because compliance is voluntary and not legally required, many consumers may not comply. Additionally, EPA cannot assume that consumers who fail to comply have rationally assessed that the risks of noncompliance are "reasonable." Consumers who fail to comply will rarely be fully-informed about the risks presented. As EPA's analysis has shown, many consumers will not read the labels, and many consumers may presume that the product must be reasonably safe to be available for sale. Additionally, some consumers would assume that a product would not be sold without the respirator and specialized gloves if those tools are necessary to avoid serious health risks.

For the reasons described above, labeling has very limited efficacy and EPA cannot assume high compliance unless it has definitive data, commensurate with the requirements of section 26(h) and (i), that demonstrate the great majority of consumers, including those who are members of relevant subpopulations, will routinely comply with the label instructions. Use of a labeled product should not be considered a form of consent to putting oneself at risk.

Based on the current record in the docket, a final rule that relies on labeling paint and coating removal products containing NMP would fail to comply with section 26(h) and (i) of TSCA requirements to use the best available science and base decisions on a weight-of-the-scientific-evidence approach. EPA has

not demonstrated that labeling would effectively reduce exposure to NMP. Rather, EPA provides ample evidence of the limitations of labeling and specifically requests comments to acquire data to the contrary.[47] If EPA were to decide to rely on such labeling in the final rule, it would need to demonstrate how that decision complies with the section 26(h) and (i) requirements.

ii. PPE and worker training programs have major real-world limitations

Beyond the general limitations of such an approach outlined above, we note the following points specific to the NMP option 2 proposal:

- EPA's risk mitigation strategy relies heavily on glove use to reduce dermal exposure to NMP. However, EPA has presented few data to support the efficacy of this approach. For example, the technical report on glove and respirators notes that "[t]he lack of measured data on dermal exposure parameters such as efficacy of glove use and surface areas of contact caused several parameter values to be based on assumptions." In both its risk assessment and supplemental analyses, EPA simply assumed 90% efficacy of gloves. Given a number of real-world limitations, this appears to be an extremely optimistic assumption that would result in overestimation of the protection afforded. For example, many of the types of gloves available to consumers are not sufficient to protect a user from NMP exposure (e.g., due to permeability). To address this concern, EPA is proposing that processors test their gloves and then label the products to identify formulation-specific gloves and to call for use of a new pair of gloves with each use of the product. As discussed earlier, EPA has not provided sufficient evidence that users will routinely 1) wear gloves, 2) wear the specified gloves, and 3) comply with the instructions to replace gloves with each use.

- Issues regarding worker marginalization are particularly pertinent to NMP exposure, given its devastating effects early in gestation. As noted in the proposed rule, female workers may not yet be aware that they are pregnant. Furthermore, they may not want to tell their employer about their pregnancy or vocalize their need for proper risk reduction measures required by the rule (e.g., training, respirator fitting, new gloves for each use) for fear of losing their jobs. Additionally, to be effective, trainings need to be provided in workers' native language, yet such a requirement is not included in the proposed rule.

- EPA proposes a monitoring program as an alternative to the respirator requirement. After an initial exposure monitoring, the proposed program requires limited or no periodic sampling, depending on the initial monitoring results. A robust monitoring program would require more frequent sampling. Further, such a monitoring program would be difficult to enforce. Finally, the monitoring program is based on EPA's derived ECEL of 20 mg/m^3; however, assuming gloves are worn and no respirator is used, the predicted MOE only just meets the "no risk" threshold of 30

[47] "EPA is also requesting comment on how labels may be constructed to effectively communicate risk and instructions on how to use the product, such as information on label content, placement of information, pictures, and font size and color; how to construct a label to effectively communicate and improve the user's understanding of risk and protective measures. EPA requests that this be supported by data demonstrating the effectiveness of a label approach, particularly as it pertains to susceptible sub-populations or individuals with limited English proficiency or low literacy in any language." p. 7509

(with 31). This does not leave room for error or even fluctuations in air concentrations between air sampling intervals for monitoring.

iii. Concentration limits are insufficient to protect health

The proposed 35% NMP concentration would not be not health protective.

EPA's supplemental document "Recommendation for an Existing Chemical Exposure Limit (ECEL) for Occupational Use of NMP and Workplace Air Monitoring Methods for NMP"[48] presents the MOEs resulting from use of product formulations at 35%, 50%, and 60% weight fractions of NMP, for both chronic (worker) and acute (worker and consumer) scenarios. As demonstrated in the associated Excel file (appendix C to the supplement), a number of scenarios using the 35% weight fraction would still result in unreasonable risks under both chronic and acute conditions. For chronic exposures, the MOE would be 2.6 (more than 10 times lower than the benchmark of 30) if no respirator or gloves are worn. Even if gloves are worn, the MOE is 31, which just barely meets the benchmark.

For acute scenarios, the MOE assuming no respirator or gloves are worn is 10 – representing a risk three times higher than the benchmark. While this may be unlikely in a worker setting, it is not hard to imagine a scenario in which a consumer does not wear protective gear (see earlier discussion). Furthermore, even if the correct gloves are worn and changed each time, the MOE is 30 – which just meets the benchmark.

These numbers assume an air concentration limit of 5 ppm for chronic scenarios and 45 ppm for acute scenarios, which cannot be assured of being met in worker settings without a robust monitoring program (EPA proposes a limited monitoring program as an *alternative* to a respirator program). There is absolutely no way to guarantee such air concentration limits will be met for consumer scenarios.

EPA explicitly recognizes that a 35% concentration limit is insufficient in the proposed rule: "EPA's analysis found that even with specialized gloves and a respirator, workers would be at risk of NMP exposure if they used products with more than 25 percent NMP." (p. 7505). The referenced analysis, presented in the Respirator and Gloves Specifications technical report,[49] specifically assessed what PPE and local exhaust ventilation (LEV) would be needed to manage risks of NMP-based paint and coating removal products of varying concentrations (5%-100%) for both acute and chronic worker exposure. The analysis found that products with as low as 5% weight fraction would require PPE or LEV to sufficiently reduce risk from chronic exposures in some scenarios. Acute exposure scenarios would require PPE or LEV at 25% weight fraction for many scenarios.

EDF strongly believes that EPA has not justified that a concentration limit of 35% would be sufficient to mitigate the unreasonable risk, especially for consumer exposures.

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[48] US EPA, Office of Chemical Safety and Pollution Prevention. "Recommendation for an Existing Chemical Exposure Limit (ECEL) for Occupational Use of NMP and Workplace Air Monitoring Methods for NMP." January 2017. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0238.

[49] US EPA, Office of Chemical Safety and Pollution Prevention. "Respirator and Glove Specifications for Workers and Consumers Exposure to NMP in Paint and Coating Removal and Estimated Fractions of Worker Population Vulnerable to the Acute Health Effect." January 2017. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0200.

ix. A ban is significantly less costly than the other option considered

As elaborated upon below, this risk management option is drastically more expensive for the regulated community – on the order of $100 million – than the cost to comply with a simple ban. Furthermore, this approach would place a greater burden on EPA (an additional estimated $900,000 annualized over 20 years, p.7467) to enforce complex labeling, concentration, respirator, and/or monitoring requirements.

D. The proposed limit on commercial distribution is needed

EDF fully supports EPA's proposal to require any distribution in commerce of DCM and NMP for paint and coating removal uses to be limited to distribution in containers with a volume of no less than 50 and 5 gallons, respectively. These requirements will help significantly to reduce the likelihood that consumers purchase these chemicals, and limit distribution to that intended for processing for non-prohibited uses.

E. Downstream notification is needed to inform the supply chain and ensure compliance with and facilitate enforcement of risk management measures

In addition to the prohibitions on the conditions of use of DCM and NMP for use in paint and coating removal, EPA is proposing to require that manufacturers, processors, and distributors, except for retailers of DCM and NMP for any use, provide downstream notification of these prohibitions throughout the supply chain. Such downstream notification creates an informed supply chain, helping to ensure that processors, distributors, and other customers and users are aware of and follow the restrictions, and also helping to prevent off-label purchase of commercial products by consumers. Downstream notification also streamlines and facilitates compliance and overall enforcement of the risk management actions. EPA should provide more specificity as to the acceptable forms of downstream notification in its final rule.

F. The Department of Defense exemption is not sufficiently justified

EDF acknowledges that certain needs of the Department of Defense (DOD) may be somewhat unique. However, the proposed rule's discussion of why EPA is providing a critical use exemption to DOD is relatively sparse; few references are provided and statements are presented with little or no documentation to support them. In contrast, the docket does contain several reports that suggest both chemical and non-chemical alternatives do exist for a number of military applications.[50]

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[50] *See, for example*:

- Naval Facilities Engineering Services Center (NFESC) (2001). "Benzyl Alcohol Paint Stripping." Joint Service Pollution Prevention Opportunity Handbook: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0065, which states:

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In EDF's view, DOD should be required to provide a more detailed and thorough demonstration that available alternatives are not sufficient at present for the specified uses EPA proposes to exempt, and why a 10-year exemption is warranted. Given the chemical and physical alternatives currently available, a full 10-year exemption may not be necessary. EPA in turn needs to fully explain and document why any exemptions it includes in the final rule meet both the requirements of section 6(g)(1) and the applicable requirements of section 26(h) and (i), and to provide a justification for the length of any exemptions it provides.

We acknowledge that there may be relevant information that cannot be shared with the public for national security reasons. If that is the case, EPA and DOD should utilize a means for securing a review of that information to ensure it is of sufficient quality and detail to support any requested exemptions, and should have the reviewer(s) so certify and make that certification available to the public.

It is also essential that EPA's final rule retain the conditions it has proposed for any exemptions it provides to DOD.

We are encouraged by some of the efforts EPA cites that have been taken by DOD to develop alternatives, and urge DOD to lead by example, by catalyzing innovative strategies to identify safer alternatives.

Our country asks a great deal of the men and women who serve in the military; we should do all we can to protect them from exposures to harmful chemicals. Unfortunately, there are too many examples where service members and their families have been put at risk from toxic chemical exposures that may have been prevented by more aggressive actions to identify and address those risks by both DOD and EPA. The decades-long exposure of military personnel and their families to contaminated water at

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> "Benzyl alcohol and benzyl alcohol blends have been identified as paint strippers that do not contain Hazardous Air Pollutants (HAPs) that can be substituted for methylene chloride paint strippers. Specifically, benzyl alcohol has been found to be effective on typical aircraft coatings (e.g, epoxy primer and polyurethane topcoat). Benzyl alcohol strippers also can be used in conjunction with conventional strippers to strip hard-to remove coatings."

- Chris Grethlein (2001). "Revolutionary New Paint Removal Process for Aircraft is Both Environmentally-Friendly and Cost Effective." Advanced Materials and Processes Technology 5(4): 16-17: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0094, which states:

> "These chemical systems contain extremely hazardous solvents, and the resulting waste stream (solvent and paint) must be disposed of in compliance with local and federal regulations. Mechanical paint removal systems utilize sanding, water jets, and plastic media to physically damage and remove the paint. In general, mechanical paint removal methods produce less hazardous waste but are more expensive and require more manpower and time to remove the coating. Mechanical removal systems can also damage thin aluminum skins as well as any composite structures."

Camp Lejeune in North Carolina is but one example.[51] Beyond the human toll of such incidents, the costs to our government have been enormous.[52]

G. The commercial furniture refinishing exclusion for DCM is inappropriate

EPA found clear unreasonable risk for the use of DCM and NMP in commercial furniture refinishing or "furniture stripping" (see section 1.c.i. above). However, EPA has excluded commercial furniture refinishing of DCM from the present rule, indicating it intends to issue a separate proposal for such use at a later date and then promulgate a single final rule covering both the uses covered in the current rule and commercial refinishing uses. EPA's rationale for such an approach is that it is continuing to gather information on the availability of alternatives to DCM for commercial furniture refinishing.

EPA's proposed approach is concerning for several reasons. First, there is already significant evidence that viable alternatives are available for commercial furniture refinishing. In the proposed rule itself, EPA notes that other countries, including Sweden and Denmark, have adopted non-chemical furniture refinishing methods such as heat guns, heat lamps, and microwave furnaces (p. 7497). Furthermore, a 2006 report prepared by Morris & Wolf for Cal/EPA's Department of Toxic Substances Control cited in the rule concluded: "The results of the tests indicate that alternative non-METH [DCM] strippers are available that can effectively strip items for consumer product applications ***and for large furniture stripping facilities*** that strip with equipment" (emphasis added) and that the most efficacious non-DCM-based stripping formulations contained benzyl alcohol as the active ingredient.[53]

The Small Business Advocacy Review (SBAR) report includes commentary from a number of commercial furniture refinishers that have used alternatives, including benzyl alcohol or immersion in acetone or an acetone-toluene-methanol blend. It appears that the main complaint from this community is dwell time, which EDF believes is an insufficient rationale for continuing the use of a highly toxic substance that presents unreasonable risks.[54]

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[51] *See for example,* U.S. Department of Veteran Affairs. "Public Health: Camp Lejeune Research Studies." Available: https://www.publichealth.va.gov/exposures/camp-lejeune/research.asp.

[52] *See, for example*, Yen, H. "U.S. to pay billions to Marines affected by contaminated drinking water. PBS Newshour. January 13, 2017. Available: http://www.pbs.org/newshour/rundown/u-s-pay-billions-marines-affected-contaminated-drinking-water/.

[53] Morris, M.; Wolf, K. Institute for Research and Technical Assistance. "Methylene Chloride Consumer Product Paint Strippers: Low-VOC, Low Toxicity Alternatives Prepared For: Cal-EPA's Department of Toxic Substances Control." May 2006. Available: http://www.irta.us/Methylene%20Chloride%20Consumer%20Product%20Paint%20Strippers%20REPORT%20ONLY.pdf.

[54] US, EPA, Office of Chemical Safety and Pollution Prevention. "Summary of Stakeholder Engagement on Methylene Chloride and N-Methylpyrrolidone in Paint and Coating Removal." August 2016. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0252.

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Furthermore, TSCA as amended by the Lautenberg Act does *not* require that viable alternatives are available in order for EPA to impose risk management measures. The law simply requires that EPA considers these factors:

> Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator *shall consider, to the extent practicable*, 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 when the proposed prohibition or other restriction takes effect. (emphasis added) (TSCA section 6(c)(2)(C))

EPA has amply fulfilled this requirement, including through an extensive SBAR review process. It is inappropriate for EPA to unduly delay action on an identified unreasonable risk for the sole purpose of further exploring alternatives.

For the reasons describe above, EDF believes that the agency should remove the commercial furniture refinishing exclusion when promulgating the final rule. However, if the agency should decide to continue along the proposed path, we strongly urge that it pursue a separate rule for commercial furniture refinishing and promptly finalize the current rule to ban the other uses of DCM and NMP. There is no reasonable rationale to delay the health protections that would be afforded from this action just so that the two rules could be finalized simultaneously.

* * * *

In sum, given the magnitude of the risks and the ineffectiveness and inadequacies of other risk management options, a ban of the conditions of use of DCM and NMP for these uses is necessary to achieve the statutory requirement that EPA impose restrictions on unreasonable risks identified from the use of DCM and NMP as paint strippers "to the extent necessary such that [the chemical] no longer presents such risk." (TSCA section 6(a))

IV. An RRP-like certification program would not be an effective or efficient method to manage the risks of DCM and NMP

As part of its development of the proposed rule, the SBAR panel suggested that the DCM and NMP rule be modelled after the agency's Lead-based Renovation, Repair, Painting Rule (RRP) to protect workers and bystanders. EDF strongly opposes this proposal. EPA's challenges in implementing the RRP rule serve as an excellent illustration of why a ban on DCM and NMP would be far simpler, more effective, and less costly.

Under the RRP, contractors and employees who disturb more than *de minimis* amounts of paint in target housing and child-occupied facilities built before 1978 must comply with detailed rules unless the

paint was verified not to meet the definition of lead-based paint. The supervisor must take a 1-day EPA-accredited training class, the employees must be trained, the renovation firm must be certified by EPA, and they must use lead-safe work practices. EPA can delegate its authority to states to implement the program.

The RRP rule was a major undertaking. The agency achieved its estimates of 212,000 firms seeking certification and 236,000 renovators taking a one-day training course. The vast majority of these firms were small businesses and many were simply individuals with a truck and no employees who arranged for individuals to help them on crews on an as-needed basis.

As the recent review of this program completed pursuant to Section 610 of the Regulatory Flexibility Act Section 610[55] revealed, concerns quickly arose that some states did not have sufficient certified firms and renovators. Only 14 states and one tribe accepted delegation of authority from EPA to implement the rule, leaving EPA's regional offices to ensure compliance for most of the nation.

Lacking sufficient staff and local presence in those states, EPA did what it could. In its fiscal year 2015, the agency conducted more than 700 inspections and completed 75 enforcement actions. But compliance was generally considered to be low and certified renovators complained that they were being undercut by competitors who were not certified or who were not using lead-safe work practices.

While no reliable estimate of compliance is available, the agency in its economic analysis[56] assumed that it could only get 75% compliance because of the very small businesses that would need to comply. Our understanding is that actual compliance is far from even EPA's modest 75% goal.

The compliance and cost burden of the RRP rule was addressed in a recent Washington Post article[57] discussing the current Administration's proposal to eliminate the program. The article notes: "Some operators in the home renovation industry have criticized the rule as too costly, noting that some customers simply opt to hire contractors who deliberately skirt the federal standards."

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[55] 73 Fed Reg. 21692. See docket: https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0126. In particular, see comments from the National Association of Home Builders at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0126-0011 and the Environmental Defense Fund at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0126-0007.

[56] US, EPA, Office of Chemical Safety and Pollution Prevention. "Economic Analysis for the TSCA Lead Renovation, Repair, and Painting Program Final Rule for Target Housing and Child-Occupied Facilities. March 2008. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2005-0049-0916.

[57] Mooney, C. and Eilperin, J. "Trump's EPA moves to dismantle programs that protect kids from lead paint." *Washington Post,* 5 April 2017. Accessed May 8, 2017. Available at: https://www.washingtonpost.com/news/energy-environment/wp/2017/04/05/trumps-epa-moves-to-defund-programs-that-protect-children-from-lead/?utm_term=.83d70c85af9d.

A DCM and NMP ban would be far less costly and more effective than an RRP-like approach. The RRP rule affected more than 37 million homes and child-occupied facilities. A DCM/NMP program would go beyond these facilities likely demanding many more certified firms and trained individuals. Ensuring compliance would be tougher as well.

A ban was not an option for the RRP rule because of the legacy of decades of use of lead-based paint. Such a training program is vital in the context of removing an existing hazard from homes such as lead-based paint, but it is illogical to develop such a resource-intensive program for use of a chemical that has viable alternatives. For DCM and NMP, we have a choice.

For these reasons, EDF maintains that the RRP rule is not a viable model for the final DCM and NMP rule.

V. EPA's proposed rule sufficiently considered all TSCA section 6(c)(2) requirements

Under TSCA section 6(c)(2)(A), EPA must consider several factors in the course of proposing or promulgating any risk management rule to the extent practicable and based on reasonably available information. EPA has sufficiently taken into consideration and documented in its proposed rule all reasonably available information with regard to these factors. Additionally, it has assessed and, to the extent practicable, factored these considerations into its decision to select the specific health-protective risk management actions it has proposed, as required under section 6(c)(2)(B).

A. EPA conducted a thorough cost-benefit analysis

A consideration of the costs and benefits associated with the proposed rule and alternative actions is one section 6(c)(2)(A) factor. EPA assessed the costs and benefits of "co-proposed option 1" (banning both DCM and NMP) and "co-proposed option 2" (banning DCM and managing NMP through lesser restrictions) as well as other regulatory options. The costs for the second co-proposed option are significantly higher – on the order of $100 million – than the costs for the first co-proposed option.[58]

It is critical to note that the estimated monetary benefits only account for a subset of health impacts of DCM and do not attribute any monetized benefits for reductions in NMP exposures.

Specifically, cancer and worker deaths were accounted for in the DCM benefits analysis, but all other non-cancer health effects were unable to be monetized due to constraints of current data and methodologies. Non-monetized effects of DCM exposure include hepatic effects, neurological impairment, immune effects, kidney effects, and gastrointestinal irritation. Furthermore, EPA only

[58] The net benefit (or cost) of the first co-proposed option ranges from $1,484,000 to ($27,624,000) (at a 3% discount rate) and $1,251,000 to ($27,688,000) (at a 7% discount rate) depending on the "willingness to pay value" utilized to monetize avoided non-fatal lung and liver cancers from DCM exposure. In comparison, the net cost for the second co-proposed option ranges from ($108,890,000) to ($101,287,000) (at a 3% discount rate) and ($109,997,000) to ($102,389,000) (at a 7% discount rate). The differences between these figures are on the order of $100,000,000.

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monetized fatalities that would be avoided from bathtub refinishing, excluding deaths in other industry sectors due to the inability to predict such worker deaths.[59,60]

In the case of NMP, EPA was unable to monetize any direct health benefits from preventing effects from exposure to NMP.[61] Neither fetal deaths nor low birth weight were monetized – despite the permanent or long-lasting impacts of these outcomes – due to constraints on current data and methodologies. The proposed rule, however, appropriately provides an in depth qualitative description of physical and mental impacts of fetal death and the life-long health consequences of low birth weight. For example:

- "The impacts of fetal death, including miscarriage or stillbirth, include emotional impacts on the woman experiencing the death of a fetus, and also present significant emotional impacts for partners and spouses." (p.7510)
- "Major depressive disorder has been identified in between 10% to 50% of women after a miscarriage, depending on the measures used." (p.7510)
- "[F]etal death can present health risks to the woman; in some cases, maternal death can result." (p. 7511)
- "[H]ealth impacts for infants with low birth weight include low oxygen levels at birth, inability to maintain body temperature; difficulty feeding and gaining weight; infection; breathing problems such as respiratory distress syndrome; neurologic problems, such as intraventricular hemorrhage (bleeding inside the brain); gastrointestinal problems such as necrotizing enterocolitis (a serious disease of the intestine), and a greater risk of Sudden Infant Death Syndrome (Ref. 102)" (p. 7511)
- "[C]ompared to their normal birth weight siblings, low birth weight children are less likely to be in excellent or very good health in childhood. They also score significantly lower on reading, passage comprehension, and math achievement tests. Low birth-weight children are roughly one-third more likely to drop out of high school relative to other children." (p. 7511)
- Decreased fetal weight and low birth weight are strongly associated with a number of adverse health effects in adults…Subsequent research in laboratory animals and in human epidemiological studies confirmed this pattern and extended the observations to include the relationship between delayed fetal growth, low birth weight and metabolic syndrome, which

[59] US, EPA, Office of Pollution, Prevention, and Toxics. "Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal (EPA Docket EPA-HQ-OPPT-2016-0231; RIN 2070-AK07." January 2017. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0270.

[60] US, EPA presentation, "Proposed Regulation under TSCA section 6(a) of Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal (RIN 2070-AK07)." Small Business Administration Environmental Roundtable, April 7, 2017.

[61] We note that hospital costs were considered for low birth weight and pregnancy loss fromNMP exposure. However, as noted at EPA's April 7th SBA roundtable presentation, these costs do not equate to the value of a lost fetus of low birth weight infant.

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> encompasses a host of adverse outcomes, such as hypertension, insulin resistance, obesity and type 2 diabetes mellitus." (p. 7511)

If EPA were able to monetize these health impacts, it would greatly affect the cost-benefit analysis conclusions. Careful consideration should be given to the qualitative analysis of the clearly substantial non-monetized health impacts when promulgating the final rule.

Moreover, indirect or ancillary benefits exist beyond the obvious and significant health benefits, for example, avoided spills or other environmental contamination and the clean-up costs associated with them. While these hidden benefits may be difficult for EPA to quantify, the agency should still describe them.

In finalizing the rule, EPA and Office of Information and Regulation Affairs (OIRA) under the Office of Management and Budget should give significant weight to these qualitative benefits, even if EPA cannot quantify them at this time.

B. EPA has adequately considered available alternatives

In addition to the 6(c)(2)(A) factors, under section 6(c)(2)(C), EPA must also consider whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available. Here again EPA has amply satisfied this requirement, identifying a number of available, preferable substitutes to the use of DCM and NMP in paint and coating removal. With regard to DCM the agency notes:

> Primary chemical substitutes for methylene chloride in paint and coating removal include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (collectively ATM); and caustic chemicals.... Overall, while the efficacies of the substitutes are comparable to the efficacy of methylene chloride, none of the substitute chemicals already available has the level of toxicity associated with methylene chloride. (p. 7886)

EPA states that the agency is aware of technically and economically feasible chemical alternatives for most paint and coating removal uses of DCM, with the exception of commercial furniture refinishing and specific coating removal uses it deemed critical for national security (i.e., DOD exemption).

In the context of NMP, EPA reviewed the same chemical alternatives and concluded that:

> when methylene chloride is excluded from consideration, the most likely chemical substitutes for NMP in paint and coating removal do not pose a risk of acute or chronic developmental effects, [and] generally have lower or similar exposure potential than NMP (p. 7514)

Similar to DCM, the agency notes that it is aware of a "cost effective, economically feasible chemical substitute or alternative method" for NMP in most situations, with the exception of critical corrosion-sensitive components of military aviation vessels.

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The agency also addresses non-chemical substitutes for paint and coating removal, including thermal removal, sanding, hydroblasting, abrasive blasting, and laser removal. EPA notes that other commercial sectors have adopted various soft media blasting methods for delicate substrates such (e.g., soda blasting on fiberglass vehicle parts (p. 9497). EDF encourages EPA to give further consider application of such approaches for commercial furniture refinishing.

In sum, EPA has adequately met all of the statutory requirements of section 6(c)(2).

VI. The agency is not under an obligation to seek out critical use exemptions, and must impose adequate exposure reduction conditions on any such exemption it grants

EPA's proposed rule references the authority to provide, by rule, time-limited critical use exemptions under TSCA section 6(g). Specifically EPA notes, as permitted by the law, that it will consider granting time-limited critical use exemptions for:

> a specific condition of use for which EPA can obtain documentation: that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; that compliance with the proposed rule would significantly disrupt the national economy, national security, or critical infrastructure. (p. 7490)

EPA is never required to grant an exemption under section 6(g) ("The Administrator *may* … grant an exemption…"), and EPA may only grant such a time-limited exemption when it meets the clear and specific parameters for granting such exemptions. To the extent EPA entertains including consideration of critical use exemptions in this final rule, EDF strongly agrees with the agency's proposal to define the parameters of a petition process for an exemption rulemaking in the current rule, and not to use the current rule as the vehicle to identify and grant critical use exemptions itself. Specifically, we agree with the Agency's description of the petition process:

> Under this process, entities who believe that their specific condition of use is a critical or essential use under TSCA section 6(g) would submit a petition for an exemption rulemaking with supporting documentation that they believe demonstrates that the use meets the statutory criteria. EPA would review the petition for completeness and, if the documentation warrants further action, respond to the petition by publishing a proposal in the Federal Register inviting comment on a proposed exemption. EPA would consider the comments received, along with any additional information reasonably available, and then take final action on the proposed exemption. (p. 7490)

The law imposes no obligation on the agency to seek out cases for such exemptions; rather, EPA proposes appropriately to place the responsibility on an interested party seeking an exemption to notify the agency of such interest through a petition. It is essential that EPA require a petition to include documentation sufficient for the agency to determine whether the requested exemption warrants

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further consideration through the initiation of a rule-making process. The petitioner must be required to demonstrate in specific terms why there are no technically and economically feasible alternatives for the particular vapor degreasing use for which it seeking an exemption. The petitioner must also establish that the use is "critical or essential" or otherwise meets the specific criteria of section 6(g)(1).

Additionally, to the extent a requested exemption is granted, pursuant to section 6(g)(4), EPA must specify and mandate compliance with exposure reduction controls and other conditions "necessary to protect health and the environment while achieving the purpose of the exemption."

In the present case, these must include conditions that reduce the exposures to consumers, workers, and occupational bystanders to the maximum extent practicable. Such exposure reduction measures should include: 1) concentration limits; 2) requirements for workplaces and labeling instructions for consumers calling for use of engineering controls (e.g., local exhaust ventilation); and 3) requirements for workplaces and labeling instructions for consumers calling for use of PPE. Additionally, as specified under section 6(g)(4), EPA should require workplace exposure monitoring and reporting requirements to ensure compliance with such conditions.

Finally, it bears emphasizing that EPA has identified a wide variety of technically and economically feasible alternatives to the use of DCM and NMP for paint and coating removal. These alternatives must be taken into account when the agency considers whether or not to permit a critical use exemption and in specifying the length of time for which a critical use exemption will be granted.

VII. EPA has full authority, and should move expeditiously, to finalize a ban and other requirements on DCM and NMP in paint and coating removal

The Lautenberg Act established clear authority and an expectation for EPA to finalize this and the other section 6 risk management rules it has recently proposed, which are based on risk assessments EPA completed prior to passage of the Lautenberg Act. Yet some in industry are now suggesting that EPA should instead abandon these rules altogether and reconsider these already fully assessed high-risk uses in the risk evaluations EPA initiated on December 19, 2016, which are intended to address *other* uses of these chemicals. We strongly disagree with the legality of, and intent of, delaying finalization of the actions in this proposed rule.

The Lautenberg Act clearly intended for EPA to move forward to address risks it identified in assessments completed prior to enactment.

Section 26(l)(4) states (emphases added):

> (4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has *published a completed risk assessment prior to the date of enactment* of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator *may publish proposed and final rules under section 6(a)* that are consistent with the scope of the completed

> risk assessment for the chemical substance and consistent with other applicable requirements of section 6.

Section 26(p)(3) states (emphasis added):

> (3) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES, PROCEDURES, AND GUIDANCE. – *Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule* under this Act solely because the action was completed prior to the development of a policy, procedure, or guidance pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

These provisions of the law make abundantly clear that EPA can proceed to promulgate rules based on its DCM and NMP risk assessments and is under no obligation to withdraw or revise its evaluation, determination or proposed rule. Indeed, Congress included these provisions for the very purpose of grandfathering-in the work plan risk assessments EPA had completed and ensuring its authority to use those assessments as the basis for section 6 risk management rules.

Furthermore, the very high risks EPA has identified for the conditions of use subject to the proposed rule demand that the agency move expeditiously to finalize the rule.

Following the industry's proposal would have the effect of delaying *any* action on existing chemicals under the Lautenberg Act for many years after its enactment. One of the reasons Congress grandfathered in EPA's prior work plan risk assessments and its authority to promulgate section 6 rules based on them was to ensure that the law would begin to work quickly – essential to the shared bipartisan goal of restoring public and market confidence in our federal chemical safety system.

VIII. EPA should finalize the section 6 rule to ban the identified conditions of use of DCM and NMP within one year of its proposal

Section 26(l)(4), cited above, states that section 6 rules that are based on risk assessments completed prior to enactment are to be "consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6." The DCM and NMP proposed rule is "consistent with the scope of the completed risk assessment."

Second, among the "applicable requirements of section 6" are the deadlines for rulemaking specified in section 6(c)(1). Specifically, section 6(c)(1)(B) requires that, once EPA proposes a rule under section 6(a) to regulate a chemical that presents an unreasonable risk, that rule must be finalized within an additional year after proposal, subject to an extension of that deadline made pursuant to section 6(c)(1)(C). An extension under section 6(c)(1)(C) is not available for chemicals drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments "without adequate public justification that demonstrates … that the Administrator cannot complete the

proposed or final rule without additional information regarding the chemical substance." DCM and NMP were drawn from the 2014 update, and the proposed rule establishes that EPA has sufficient information to complete the final rule. Thus, no extension is needed or warranted here.

Additionally, EPA has thoroughly established that the conditions of use of DCM and NMP addressed by the proposed rule present unreasonable risks, and it would be unreasonable for EPA to delay issuing a final rule more than one year. Moving promptly to finalize this rule will also aid EPA in meeting its numerous other mandatory duties and deadlines under TSCA. On December 19, 2016,[62] EPA initiated its risk evaluations for ten chemicals, including other conditions of use of DCM and NMP beyond those addressed in the current proposed rule. EPA has to complete full risk evaluations on all ten chemicals no later than December 19, 2019 (subject to at most a 6-month extension), and completing these rules would better allow EPA to make progress towards that goal by simplifying the risk evaluations for DCM and NMP. Given EPA's numerous obligations, delaying these rules would only help create a backlog of obligations, resulting in further delays and, potentially, statutory deadline violations. Their delay would also mean continued exposures to DCM and NMP that present significant, unreasonable risks to consumer and worker health.

In sum, EDF is strongly in favor of the risk management measures proposed by the agency and strongly urges EPA to finalize the prohibitions and related requirements as expeditiously as possible and no longer than one year from the rule's proposal.

IX. Conclusion

EPA's DCM and NMP risk assessments and associated supplemental technical reports clearly demonstrate unreasonable non-cancer and cancer risks resulting from use of DCM-based paint strippers, and unreasonable non-cancer risks resulting from use of NMP-based paint strippers. Accordingly, EDF strongly encourages the agency to move expeditiously to promulgate a final rule banning the use of both DCM and NMP in paint and coating removal.

EDF strongly opposes EPA's proposed option 2 for NMP, which would rely on a combination of reformulation, labeling, and worker protection programs of highly questionable efficacy. Not only has EPA failed to provide adequate justification, based on section 26 requirements, that such an approach would sufficiently mitigate the unreasonable risk, but this approach would cost much more both for the regulated community and EPA. Given the availability of safer alternatives, there is no reasonable rationale to continue to put the public's health at risk.

In the current proposed rule EPA has applied a benchmark margin-of-exposure approach to determine whether and to what extent unreasonable risk results from acute or chronic exposure to DCM and NMP for non-cancer effects. Using this approach, EPA has more than established that the uses of DCM and NMP in paint and coating removal present unreasonable risk to human health, including to potentially

[62] 81 Fed. Reg. 91,927 (Dec. 19, 2016).

exposed or susceptible subpopulations. As such any delay would deny necessary public health protection.

As it proceeds with future risk evaluations, EDF strongly encourages EPA to adopt the key risk assessment recommendations articulated in the 2009 National Academy of Sciences Report, *Science and Decisions: Advancing Risk Assessment.*[63] Among these recommendations is the need to apply a unified approach for assessments of cancer and non-cancer risks and, relatedly, to reject the assumption for non-cancer endpoints that there is a threshold level of exposure below which no adverse effect occurs. As documented in the 2009 NAS report, this assumption is particularly unwarranted when assessing risks to a highly diverse human population.

[63] National Research Council, Division on Earth and Life Sciences, Board on Environmental Studies and Toxicology. *Science and Decisions: Advancing Risk Assessment*. 2009. Available: https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.

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APPENDIX A: History of the Development of EPA's DCM and NMP Work Plan Risk Assessments and IRIS Assessment for DCM

A brief history of the development of EPA's 2014 DCM and 2015 NMP risk assessments and 2011 IRIS Toxicological Review of DCM. The same peer review panel provided advice on both the DCM and NMP risk assessments.

DCM Work Plan Risk Assessment

- January 2013 – Draft risk assessment released for public comment[64]
- September 2013 – Peer review panel meeting 1[65]
- November 2013 – Peer review panel meeting 2
- December 2013 – Peer review panel meeting 3
- December 2013 – Final peer review panel report for DCM[66]
- August 2014 – EPA summary of external peer review and public comments and disposition published[67]
- August 2014 – Final risk assessment published

NMP Work Plan Risk Assessment

- January 2013 – Draft risk assessment released for public comment[68]
- September 2013 – Peer review panel meeting1[69]
- November 2013 – Peer review panel meeting 2
- December 2013 – Peer review panel meeting 3
- December 2013 – Final peer review panel report for NMP[70]
- March 2015 – EPA summary of external peer review and public comments and disposition

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[64] US, EPA. "Posting EPA-HQ-OPPT-2012-0725 to Regulations.gov for Public Access." January 2013. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0001.

[65] 78 Fed Reg. 64936. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0045.

[66] US, EPA peer review panel. "OPPT Methylene Chloride (DCM) Draft Risk Assessment Final Comments of Nine Member Peer Review Panel." December 2013. Available: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/oppt-methylene-chloride-dcm-draft-risk-assessment-final.

[67] US, EPA. "Summary of External Peer Review and Public Comments and Disposition." Available: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/response-comments-dcm-work-plan-risk-assessment.

[68] US, EPA. "Posting EPA-HQ-OPPT-2012-0725 to Regulations.gov for Public Access." January 2013. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0001.

[69] 78 Fed Reg. 64936. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0045.

[70] US, EPA peer review panel. "OPPT N-Methylpyrrolidone (NMP) Draft Risk Assessment Final Comments of Nine Member Peer Review Panel." December 2013. Available: https://www.epa.gov/sites/production/files/2015-09/documents/nmp_consolidated_peer_review_comments_december_31_2013.pdf.

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published[71]

- March 2015 – Final risk assessment published

DCM IRIS Assessment[72]

- September 2009 –Interagency science consultation draft released
- December 2009 – Interagency science consultation on the draft assessment
- March 2010 – External review draft and the interagency review draft with comments released
- May 2010 – Public listening session
- September 2010 – External peer review meeting
- November 2010 – Comments from the external review meeting published
- August 2011 – Interagency science discussion on the review of the draft assessment
- November 2011 – Final assessment and the interagency review draft with interagency review comments published

[71] US, EPA. "Summary of External Peer Review and Public Comments and Disposition." Available: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/summary-external-peer-review-and-public-comments-and.

[72] More detailed timeline and resources are available via US EPA:

- Webpage (see History tab): https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=70
- Webpage (see Background tab): (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=238086
- Appendix A of the full Toxicological Review provides a summary of external peer review and public comments and disposition: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0070tr.pdf.

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