



Environmental Defense Fund

Comments on n-Methylpyrrolidone (NMP); Regulation Under the Toxic Substances Control Act (TSCA)

Docket ID: [EPA-HQ-OPPT-2020-0744](#); 89 Fed. Reg. 51134 (June 14, 2024)

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Introduction

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the proposed rule to manage N-methylpyrrolidone (NMP)¹ (hereafter “Proposed Rule”) under section 6 of the Toxic Substances Control Act (TSCA).

EPA determined that NMP poses unreasonable risk, with the primary health impacts attributed to developmental post-implantation fetal loss and reduced fertility and fecundity. As other solvents such as methylene chloride are phased out of use, it is likely that NMP use will increase – barring action to prevent this.

However, EPA’s Proposed Rule bans only 18% of the total production volume of NMP,² relying instead primarily on concentration limits, labels, and limited worker protections such as glove and respirator use. Bans are the most effective, health protective TSCA section 6(a) risk management option to address the unreasonable risks, eliminating exposure to all populations that could come into contact with the chemical throughout its lifecycle. In contrast to EPA’s 2017 proposal to ban NMP in paint strippers,³ EPA’s current proposal would allow for continued NMP commercial use through a 30% concentration limit and personal protective equipment (PPE), and it would allow for consumer use to continue, imposing only a 16-ounce container limit and label requirement.

EDF is concerned that EPA’s failure to prohibit more uses, and to employ more protective risk management actions for those uses allowed to continue, such as more restrictive concentration

¹ We note that EPA refers to N-methylpyrrolidone as n-Methylpyrrolidone. However, the use of a capital N indicates that the methyl is on the nitrogen, while lower case n represents “normal” or linear, which is not needed for methyl. See <https://pubchem.ncbi.nlm.nih.gov/compound/13387>.

² EPA, “n-Methylpyrrolidone (NMP); Regulation under the Toxic Substances Control Act,” 89 Fed. Reg. 51134, 51137, June 14, 2024, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0744>.

³ EPA, “Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a),” 82 Fed. Reg. 7464, Jan. 19, 2017, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0231>.

limits and an Existing Chemical Exposure Limit (ECEL), will continue to put the American public at risk of harm from NMP. In promulgating the final rule, we urge EPA to rectify these shortcomings and implement compliance timelines that comport with TSCA by requiring compliance as soon as is practicable.

Below, we address some of our key concerns about the Proposed Rule.

Table of Contents

Introduction.....	1
I. A phase out of all non-essential uses of NMP is the most protective risk management option to address the chemical’s unreasonable risk	4
II. EPA must take into account and provide risk management for the reasonably foreseen increased use of NMP	4
III. EPA should strengthen its regulation of consumer uses to protect both consumers and workers.....	6
IV. EPA’s proposal is insufficient to protect workers from unreasonable risk.....	8
A. EPA relies on gloves and clothing without sufficient evidence that it will mitigate unreasonable risk from dermal exposure	9
B. EPA found inhalation risk from NMP and should set an ECEL and associated air monitoring to address such risks.....	10
C. Short of a ban, EPA should set concentration limits for certain conditions of use under the WCPP and lower concentration limits for those under prescriptive controls.....	12
D. EPA ignores critical WPCP implementation and enforcement challenges for certain conditions of use	12
E. Workplace protections should be imposed during any period before the prohibitions on NMP conditions of use take effect	13
V. EPA should not leave people subject to unreasonable risk due to federal uses of NMP	13
A. EPA should not allow permanent uses of high-concentration NMP by federal agencies, and should instead employ TSCA Section 6(g) to address any critical uses.....	14
B. EPA should not permit federal agencies and contractors triple the time to implement the WCPP (36 months vs 12 months).....	16
C. The process EPA is considering for granting additional exemptions for federal uses of NMP precludes meaningful notice or participation for the public	17
VI. EPA should finalize shorter compliance timelines to ensure prompt public health protections.....	18
VII. EPA should remove the <i>de minimis</i> exemption.....	19
VIII. EPA’s qualitative description of the avoided health impacts is sufficient from reducing exposure to NMP is sufficient to justify its rule under TSCA	20

I. A phase out of all non-essential uses of NMP is the most protective risk management option to address the chemical’s unreasonable risk

Under TSCA section 6(a), when EPA determines that a chemical poses an unreasonable risk to health or the environment, the Agency must implement regulations to eliminate the unreasonable risk that the chemical poses.⁴ The first option Congress provided to EPA to eliminate the unreasonable risk is a prohibition or restriction on the use of the chemical.⁵ A ban is the most health protective TSCA section 6(a) risk management option to address the unreasonable risks presented by a chemical, because it eliminates exposure to all populations that could come into contact with the chemical throughout its lifecycle.

However, in the Proposed Rule, EPA has only prohibited conditions of use representing less than one fifth of the current NMP production volume. We urge the Agency to prohibit all conditions of use of NMP, in order to ensure that it has fulfilled its duty under TSCA to protect people from unreasonable risk, and to the extent that there are critical uses that cannot currently be replaced, EPA could address those uses via time-limited exemptions under TSCA 6(g).⁶

II. EPA must take into account and provide risk management for the reasonably foreseen increased use of NMP

EPA must consider the potential increases in production and use for certain conditions of use of NMP such as the increases that will result from the ban of products containing methylene chloride or from the increase in demand for specialized electronics.

Instead of taking into account this important reasonably foreseeable increase, EPA actually bases proposed risk management decisions for NMP on an “expected” decrease in certain products containing NMP. But EPA does not provide clear evidence to support this conclusion. EPA states that it “expects the production volume for certain conditions of use to decline over time. For example, EPA expects the industrial and commercial use of NMP in paints and coatings to decline over time as formulators either reformulate to a lower concentration of NMP or away from NMP.”⁷ However, EPA does not present any analysis or supporting information to support this assumption. Considering the full industrial and commercial landscape would suggest the opposite – that NMP use might increase for these conditions of use. Particularly, the effect of methylene chloride bans on the production volume for industrial and commercial use of NMP in paints and coatings and other shared conditions of use would be expected to lead to an increase in the use of NMP as it is a common substitute for methylene chloride.⁸ EPA concluded that

⁴ 15 U.S.C. § 2605(a)

⁵ *Id.* at § 2605(a)(1)

⁶ *Id.* at § 2605(g)

⁷ 89 Fed. Reg. at 51138

⁸ EPA, “Methylene Chloride Alternatives Assessment,” May 8, 2024, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0465-0402>. EPA’s alternatives assessment

prohibiting NMP for conditions of use where alternatives like methylene chloride are equally or more hazardous may not be appropriate, likely because these uses of methylene chloride are also banned.⁹ Thus, it appears that EPA anticipates that NMP will substitute for methylene chloride.

EPA further concluded that “based on market research, the availability of consumer and commercial paint and coating removal products containing NMP has declined.”¹⁰ EPA attributes this decrease in products containing NMP since 2017 to the proposed rule published by EPA in January 2017 that would have regulated certain uses of methylene chloride and NMP.¹¹ However, this proposed rule was withdrawn in January 2021 and it is unclear whether products containing NMP have continued to decrease since the proposed rule’s withdrawal – particularly in light of the new ban on methylene chloride in these products.

For some other NMP conditions of use, EPA does indicate it expects the production volume to increase over time. For example, “EPA expects the industrial and commercial use of NMP in the manufacture of specialized electronics, including semiconductors and lithium-ion batteries, to increase as the global demand for electronic devices increases.”¹² These conditions of use comprise an estimated 44% of the current production volume of NMP and are permitted to continue with workplace restrictions. However, EPA does not account for these increases in its proposed risk management rule but, rather, has proposed restrictions solely based on past NMP data. According to the Semiconductor Industry Association, the U.S. is expected to triple its semiconductor manufacturing from 2022 to 2032, representing the largest projected increase in the world.¹³ Further, demand for lithium-ion batteries in vehicles grew by around 80% in the U.S. from 2021 to 2022,¹⁴ and global lithium-ion battery demand is expected to grow by about 27% annually until 2030.¹⁵

for methylene chloride identifies more than 20 products that contain NMP, many of which are associated with methylene chloride uses that EPA has banned, such as paint strippers.

⁹ 89 Fed. Reg. at 51165

¹⁰ 89 Fed. Reg. at 51174

¹¹ EPA, “Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a),” 82 Fed. Reg. 7464, Jan. 19, 2017, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0231>.

¹² 89 Fed. Reg. at 51137

¹³ Semiconductor Industry Association, “America projected to triple semiconductor manufacturing capacity by 2032, the largest rate of growth in the world,” May 8, 2024, <https://www.semiconductors.org/america-projected-to-triple-semiconductor-manufacturing-capacity-by-2032-the-largest-rate-of-growth-in-the-world/>.

¹⁴ International Energy Agency, “Global EV Outlook 2023,” Accessed: July 25, 2024, <https://iea.blob.core.windows.net/assets/dacf14d2-eabc-498a-8263-9f97fd5dc327/GEVO2023.pdf>.

¹⁵ McKinsey & Company, “Battery 2030: Resilient, sustainable, and circular,” January 16, 2023, <https://www.mckinsey.com/industries/automotive-and-assembly/our-insights/battery-2030-resilient-sustainable-and-circular>.

As the manufacture of specialized electronics constitutes nearly half of NMP’s current production volume, the expected increase in such production will likely result in substantial increased manufacture, exposure, and risk, all of which is unaccounted for in the NMP risk evaluation or considered in the Proposed Rule. EPA asserts that, for these conditions of use in which the production volume is expected to increase, EPA “expects that facilities will already have in place the types of exposure controls that EPA proposes to require.”¹⁶ However, in its 2020 NMP risk evaluation, EPA found multiple acute and chronic risks exceeding benchmarks, for both high-end (100% weight fraction) and central tendency (50% weight fraction) exposures, and with and without certain levels of glove protection and respirators, to workers in the semiconductor manufacturing and lithium-ion manufacturing.¹⁷ In fact, for all occupational uses of NMP in semiconductor and lithium-ion manufacturing, chronic exposures were found to exceed benchmarks for nearly all exposures regardless of glove use, exceeding up to 750 times the benchmarks for the high exposure scenarios.¹⁸ Because of these findings, EPA determined that these conditions of uses contribute to the unreasonable risk posed by NMP.¹⁹ EPA has not demonstrated that following current regulations or current exposure controls will fully mitigate these risks, let alone from reasonably foreseen increases to nearly half of current NMP manufacturing and production. Under TSCA, EPA is required to regulate NMP such that there is no unreasonable risk presented by all of the chemical’s conditions of use, meaning the circumstances under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.²⁰ Thus, EPA must finalize a stronger NMP rule that accounts for these above-described reasonably foreseen increases in production and ensures that no unreasonable risks are left on the table.

III. EPA should strengthen its regulation of consumer uses to protect both consumers and workers

EPA has proposed minimal regulations on most consumer uses, limiting container sizes to 16 ounces and requiring a label indicating that the product is not to be used for commercial purposes.²¹

¹⁶ 89 Fed. Reg. at 51137

¹⁷ EPA, “Risk Evaluation for n-Methylpyrrolidone (NMP), CASRN 872-50-4,” December 2020, at pp. 293-295; 302-303, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.

¹⁸ *Id.*

¹⁹ EPA, “n-Methylpyrrolidone (NMP); Revision to Toxic Substances Control Act (TSCA) Risk Determination,” December 19, 2022, <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0145>.

²⁰ 15 U.S.C. §§ 2602(3); 2605(a); and 2605(b)(4)(A) (“TSCA Sections 3(4); 6(a); and 6(b)(4)(A)”).

²¹ “This product contains n-methylpyrrolidone (NMP) (CASRN 872–50–4), also called nmethyl- 2-pyrrolidone or 1-methyl-2 pyrrolidone, a chemical determined by the Environmental Protection Agency to present unreasonable risk of injury to health under the Toxic Substances Control Act (TSCA), based on

EDF appreciates the agency’s willingness to regulate consumer uses in order to address identified unreasonable occupational risks. EPA has the authority under TSCA to restrict non-occupational uses where needed to address the unreasonable risk identified to workers.

However, EPA’s two proposed restrictions – 16-ounce containers and labels – will not effectively prevent redirection of consumer products to the commercial market. In situations where the commercial products are prohibited but consumer uses are allowed to continue, such as in the context of “automotive care products,” and “cleaning and furniture care products, including wood cleaners and gasket removers,” nothing (except for a label) is stopping businesses from purchasing several 16-ounce containers of consumer products. Even where the commercial product is not prohibited, commercial users may look towards consumer products for higher concentrations of NMP (e.g., for paint and coating removers EPA has documented consumer product weight fractions as high as 60%²²). There is ample evidence, including from EPA itself, that labeling is an ineffective strategy to protect workers. For example, EPA’s 2016 report, “The effectiveness of Labeling on Hazardous Chemicals and Other Products” identified limitations of labeling as an approach changing user behavior, including lack of user attention, comprehension (such as due to language barriers), and motivation to comply.²³ This problem may be particularly salient for hard-to-enforce industries with many discrete practices that may use such products, like auto shops and furniture cleaners. EPA has provided no analysis of the container sizes currently used by those businesses and it has not assessed whether it has the resources to effectively enforce a commercial use prohibition at each autobody shop and other workplace where NMP-containing products may continue to be used. Banning consumer products is the simplest and most health-protective solution to prevent diversion of consumer products to the commercial sector.

Short of a ban, EPA should consider setting concentration limits in consumer products to ensure that risk levels to consumers are not unreasonable or do not become unreasonable in the future (e.g., because of changes in use or concentrations). EPA attributes the “lower risk” to consumers to what it characterizes as currently low concentrations in consumer products and relatively infrequent use by consumers, and therefore imposes no concentration limits on consumer

developmental and reproductive effects. The use of NMP is restricted under 40 CFR part 751, subpart C. *This product is only for sale in containers of 16 ounces or less and is for consumer use only. This product shall not be used for commercial purposes.* Proposed 15 U.S.C. § 751.207(b)(c)(2).

²² EPA, “Risk Evaluation for n-Methylpyrrolidone (NMP), CASRN 872-50-4,” (Dec. 2020), at Table 2-74, p. 87, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.

²³ EPA, “The Effectiveness of Labeling on Hazardous Chemicals and Other Products” [RIN 2070-AK07], Office of Chemical Safety and Pollution Prevention (e.g., “Although users may notice and understand labels on hazardous chemicals and similar products, they may not necessarily change their behavior to correspond with the information they receive.”)

products except for a single condition of use.²⁴ However, EPA's logic does not hold water. First, given that the most sensitive endpoint is reproductive and developmental toxicity, the frequency of product use is not relevant, as a single acute exposure event can result in health harms, such as miscarriage.

Second, EPA's risk evaluation did in fact identify risks exceeding benchmarks from certain consumer products: paint and coating removers (high-intensity user scenario at 60% weight fraction), glues and adhesives including lubricant adhesives (high-intensity user scenario at 85% weight fraction), and cleaning and furniture care products - engine cleaner/degreaser (high intensity user scenario at 40% weight fraction). At a minimum, EPA should accordingly limit NMP's concentration in such products. Of note, Table 2-74 of EPA's Final 2020 NMP Risk Evaluation details concentrations of various consumer products on the market, finding even higher weight fractions for several products than those used to model consumer exposure, including adhesive removers (up to 60%)²⁵ and cleaners/degreasers (up to 100%). Thus, it is unclear whether EPA's risk calculations are reflective of the higher-concentration products that do exist on the market.

Third, as discussed further under Section IV.B., the fact that people may use multiple products (a fact that EPA failed to consider) further supports a requirement of concentration limits. In cases where both occupational and consumer uses are permitted (e.g., NMP paints and paint strippers), such concentration limits should also account for aggregate exposures from occupational and consumer uses in addition to use from multiple products.

Finally, without at least imposing concentration limits in consumer products, there is nothing stopping companies from increasing concentrations in consumer products, perhaps as a response to demand from commercial users to get around commercial limits. This unintended, but entirely foreseeable, consequence would increase exposure to consumers in addition to any workers at workplaces using the high-concentration products, for example because their employer requires them to use consumer products.

IV. EPA's proposal is insufficient to protect workers from unreasonable risk

EPA's Proposed Rule relies heavily on concentration limits and personal protective equipment (PPE), instead of on options higher in the hierarchy of controls, such as alternative products and engineering controls. In particular, for seven conditions of use, EPA proposes "prescriptive controls," which imposes concentration limits and defaults immediately to OSHA glove and respirator standards. EPA has also failed to set an ECEL, instead relying exclusively on respirators to protect workers against inhalation risks. Where concentration limits are required, it is unclear whether they are sufficiently protective to address use of multiple products. Below we further detail our concerns related to dermal exposure, inhalation exposure, and enforcement and compliance.

²⁴ "EPA determined that most consumer uses do not contribute to the unreasonable risk for NMP, largely due to the generally low concentration of NMP in consumer products and the infrequent use by consumers of those products." 89 Fed. Reg. at 55137.

²⁵ EPA modeled adhesives removers at 25% weight fraction.

A. EPA relies on gloves and clothing without sufficient evidence that it will mitigate unreasonable risk from dermal exposure

EPA’s Proposed Rule would address occupational dermal risk primarily through use of protective gear such as gloves and clothing either in restricted areas (under the workplace chemical protection plan, WCPP) or wherever NMP is used (under the prescriptive workplace requirements), consistent with existing OSHA standard 29 CFR 1910.132(f). While the WCPP instructs the owner and operator to follow the hierarchy of controls (“institute one or a combination of elimination, substitution, engineering controls, or administrative controls to prevent all persons from direct dermal contact with NMP except to the extent that the owner or operator can demonstrate that such controls are not feasible”), no specific engineering or administrative controls are actually required beyond the establishment of a restricted area for NMP use where gloves and other protective gear would be donned. Relying so heavily on PPE use places the burden on the worker. Practically speaking, there may be challenges to wearing gloves and other protective gear (“which covers any exposed dermal area of arms, legs, torso, and face”²⁶), for example, on construction sites in the summer where heat exhaustion is a competing health concern.

Furthermore, it is questionable whether glove use will actually mitigate unreasonable risk. Notably, the Agency concluded that “[r]isk exceeding the benchmark was identified even when considering use of chemically resistant gloves in most commercial and industrial conditions of use.”²⁷ To calculate these dermal risks, EPA used default protection factors that were not actually attributed to specific glove types;²⁸ thus, the Agency cannot ensure unreasonable risk is mitigated without requiring data on specific glove types and formulations. In contrast to EPA’s proposed 2017 rule to either ban or restrict NMP in paint stripping products – which would have required product formulators to test gloves for each specific product formulation to identify specialized gloves²⁹ – in the current Proposed Rule, EPA is relying upon manufacturer specifications to identify appropriate gloves.³⁰ Permeation of the chemical through the glove, as well as seepage through the cuff from improper donning of gloves, can lead to occlusion, whereby increased skin exposure occurs as the chemical is trapped inside the glove and cannot evaporate. In its 2020 NMP Risk Evaluation, the Agency acknowledges the problem of occlusion as well other uncertainties in glove use; yet in the Proposed Rule the Agency nonetheless heavily relies on their use without requiring proper glove testing. At the very minimum, EPA should require glove

²⁶ 89 Fed. Reg. at 51154

²⁷ 89 Fed. Reg. at 51153

²⁸ EPA, “Risk Evaluation for n-Methylpyrrolidone (NMP), CASRN 872-50-4,” December 2020, at pp. 83-84, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.

²⁹ EPA, “Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a),” 82 Fed. Reg. 7464, Jan. 19, 2017, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0231>.

³⁰ 89 Fed. Reg. at 51191 (“specifications from the manufacturer or supplier of the clothing, or of the material used in construction of the clothing, to establish that the clothing will be impervious”)

permeation testing, consistent with its 2017 proposed rule, and limit the amount of time an individual worker can enter the restricted area and handle NMP, using PPE, to reduce exposure.

We also note that EPA’s proposed definition of “Restricted Area,” which the Agency indicates would apply to other section 6 rulemakings, is specific to “direct dermal contact.”³¹ To the extent that the Agency intends to use the term “Restricted Area” in the context of inhalation exposure in other rulemakings, it may consider revising its definition.

B. EPA found inhalation risk from NMP and should set an ECEL and associated air monitoring to address such risks

In its revised NMP unreasonable risk determination, EPA concluded that for all occupational conditions of use, acute and/or chronic non-cancer effects from both central tendency and high-end inhalation and dermal exposures contributes to the unreasonable risk of NMP, with no mention of dermal exposures driving this risk.³² Occupational risks were calculated based on internal human doses of aggregated inhalation, dermal, and vapor-through-skin exposures. EPA’s finding of NMP’s dual dermal and inhalation risks further supports a ban on all conditions of use to best manage risks from multiple routes of exposure.

However, short of a ban, EPA should enact an ECEL and associated monitoring to address inhalation risks from NMP rather than default to respirator requirements. This would more fully address the inhalation component to the aggregate exposure of NMP without putting the burden on workers. Use of PPE such as respirators falls at the bottom of the hierarchy of controls due to their many burdens and limitations. In 2016, OSHA determined that respirators are “the least satisfactory approach to exposure control.”³³ EPA aptly describes these limitations in the preamble of the methylene chloride proposed regulation,³⁴ including that respirators:

- Cannot be used by all workers, such as those with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease,
- May not be appropriately worn by individuals with facial hair that interfere with a proper face-to-respirator seal, and
- Can create new safety hazards of its own, due to impacts on vision, movement, worker fatigue, and communication in the workplace.

³¹ 89 Fed. Reg. at 51157; proposed 15 U.S.C. § 751.5 (“Restricted area means an area established by the regulated entity to demarcate areas where direct dermal contact with a specific chemical substance may occur”)

³² EPA, “n-Methylpyrrolidone (NMP); Revision to Toxic Substances Control Act (TSCA) Risk Determination,” December 19, 2022, Table 5-1, <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0145>.

³³ OSHA, “Comment submitted by David Michaels, PhD, Occupational Safety and Health Administration (OSHA),” October 2016, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0041>.

³⁴ EPA, “Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA),” 88 Fed. Reg. 28318, May 5, 2023, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0465>.

EPA puts forth multiple reasons for neglecting to set an ECEL, opting instead to rely heavily on respirators, including:

- “EPA is not proposing an ECEL for NMP because the proportion of the exposure largely driving the unreasonable risk to workers is due to dermal contact with liquid NMP (Ref. 1) and an ECEL would only address risk from inhalation and vapor-through-skin (dermal exposure to vapor but not direct dermal contact with a liquid) exposures without accounting for the risk from direct dermal exposure.”³⁵
- “[T]he Agency is concerned an ECEL value would imply that inhalation is the primary route of exposure.”³⁶
- “EPA believes it would be potentially burdensome and confusing to the regulated entities if there were a multitude of requirements for specific dermal PPE, concentration limits, and inhalation ECELS for each condition of use that would continue under the WCPP.”³⁷

These rationales for not setting an ECEL are insufficient. First, setting an ECEL does not have to be in lieu of dermal controls, and requiring multiple types of exposure controls is not uncommon in addressing risks to workers or in risk management more broadly. For example, the final risk management rule for methylene chloride and the proposed risk management rule for carbon tetrachloride required both inhalation controls, in the form of an ECEL, in addition to dermal controls.³⁸ Further, due to NMP’s inhalation risk, California’s Division of Occupational Safety and Health (Cal/OSHA) has set a Permissible Exposure Limit (PEL) of 1 ppm as an 8-hour time weighted average.³⁹ Therefore, it is unclear why EPA believes that setting an ECEL to address inhalation risks means that dermal controls cannot also be required to address both types of exposures. Additionally, EPA’s concern that an ECEL would imply that inhalation is the primary route of exposure is negligible in comparison to the imperative of comprehensively mitigating all unreasonable risks to workers.

Overall, in the absence of a ban, EPA should set an ECEL with associated monitoring requirements to address the unreasonable risks presented by exposure to NMP through inhalation. Defaulting to respirators to address NMP’s inhalation risk flips the hierarchy of controls. Rather, an appropriately structured ECEL encourages controls higher in the hierarchy of control. EPA can look to the Cal/OSHA PEL and other TSCA section 6 rulemaking, such as methylene chloride, as a starting point for initiating an NMP ECEL. Many industries are already

³⁵ 89 Fed. Reg. at 51142

³⁶ 89 Fed. Reg. at 51172

³⁷ *Id.*

³⁸ EPA, “Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a),” 82 Fed. Reg. 7464, January 19, 2017, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0231>; EPA, “Carbon Tetrachloride; Regulation Under the Toxic Substances Control Act,” 88 Fed. Reg. 49180, July 28, 2023, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0592>.

³⁹ Cal. Code Regs. tit. 8, § 5155 (2024), <https://www.dir.ca.gov/title8/5155.html>.

aware of these regulations and are likely implementing engineering controls to meet these standards.

C. Short of a ban, EPA should set concentration limits for certain conditions of use under the WCPP and lower concentration limits for those under prescriptive controls

Short of a ban, EPA should set concentration limits for conditions of use under the WCPP to avoid risks posed to workers, even with PPE, at high concentrations of NMP. Under the proposed WCPP, EPA requires no concentration limits. For some of these conditions of use, EPA found risks exceeding benchmarks even with gloves and respirators. For example, chronic risks exceed benchmarks at 75-100% weight fraction for use of NMP in manufacturing, repackaging, chemical processing, formulation, semiconductors, other electronics, metal finishing, laboratory use, lithium-ion batteries, recycling and disposal, and cleaning – even with a glove protection factor of 10 or 20 and respirator assigned protection factor of 10.⁴⁰ EPA should enact concentration limits for conditions of use where risk is still found with PPE to fully mitigate the unreasonable risk, as required under section 6 of TSCA.

Further, EPA has ignored exposure to multiple sources or conditions of use when setting prescriptive controls and should set lower concentration limits to account for these aggregate exposures. For example, EPA set multiple concentration limits of NMP to be no greater than 45% in formulated products for use in multiple industrial and commercial uses, in addition to various other concentration limits, down to 1%, for other conditions of use.⁴¹ These decisions appear to be based on the risk calculations for each condition of use at various weight fractions, with the proposed concentration limits exhibiting no risks exceeding benchmarks when paired with gloves and respirators.⁴² However, these risks have been calculated on a single condition of use basis assuming exposure to only one product without considering workers or consumers that use multiple products containing NMP or operate under multiple conditions of use of NMP. EPA should calculate risks from exposure to NMP at the maximum concentration proposed in multiple products and impose lower concentrations limits to mitigate these potential risks.

D. EPA ignores critical WCPP implementation and enforcement challenges for certain conditions of use

EPA has previously rejected a WCPP due to implementation challenges in certain industries, yet nonetheless proposes such an approach for NMP. For example, EPA pointed to implementation challenges for establishing a regulated area in industries taking place in the field, such as use of

⁴⁰ EPA, “NMP Supplemental File with Additional Occupational PBPK Runs – 12 2023,” June 14, 2024, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0084>.

⁴¹ 89 Fed. Reg. at 51157

⁴² EPA, “NMP Supplemental File with Additional Occupational PBPK Runs – 12 2023,” June 14, 2024, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0084>.

adhesives in construction or renovation and paint stripping.⁴³ This is not an insignificant challenge. EPA’s 2020 NMP risk evaluation estimates that there are more than 2 million workers who apply NMP paint, coatings, adhesives and sealants and over 400,000 who remove such products,⁴⁴ many of whom are likely working on individual construction sites and private home renovation projects. EPA has also acknowledged that regulating paints, coatings, adhesives, and sealants via WCPP “would present significant and widespread implementation difficulties across multiple industry sectors, leading to high non-compliance rates.”⁴⁵ Yet in the Proposed Rule, EPA has made no attempt to address implementation and compliance challenges posed by implementing a WCPP across the same conditions of use. Instead, EPA should consider prohibitions of such conditions of use where implementation and enforcement of the WCPP is not feasible.

E. Workplace protections should be imposed during any period before the prohibitions on NMP conditions of use take effect

The Agency has requested comment on whether respiratory and dermal protection should be required for workers before the effective dates of the prohibitions on certain conditions of use of NMP. EDF strongly supports such protections during this time. EPA has made an unreasonable risk determination for NMP and should not allow workers engaging in these uses to continue to face risks during the interim period until the prohibitions take effect. We are also concerned about the plausible scenario in which EPA, at the request of industry, delays the effective date of the prohibitions, such as occurred in the case of the risk management of PIP (3:1). Of course, this would result in prolonged unreasonable risks in the workplace and contribute to the development of NMP-related health problems.

V. EPA should not leave people subject to unreasonable risk due to federal uses of NMP

EPA has inappropriately proposed less stringent controls and longer compliance timelines for federal uses of NMP by DOD and NASA and is contemplating procedures to allow for prohibited uses more broadly throughout the federal government that do not comply with TSCA, all of which could subject federal workers to unreasonable risks from NMP.

⁴³ “Particular factors related to work activities that may make it difficult for certain conditions of use to comply with an ECEL are worth further discussion. One example includes work activities that may take place in the field, such as on-site paint removal or the use of adhesives in construction or renovation, making it challenging to establish a regulated area and conduct monitoring.” EPA, “Methylene Chloride; Regulation Under the Toxic Substances Control Act,” 89 Fed. Reg. 39254, 39283, May 8, 2024, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0465>.

⁴⁴ EPA, “Risk Evaluation for n-Methylpyrrolidone (NMP), CASRN 872-50-4,” December 2020, at Table 2-4, p. 87, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.

⁴⁵ EPA, “Response to Public Comments: Regulation of Methylene Chloride under TSCA Section 6(a),” May 2024 at p. 16, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0465-0424>.

A. EPA should not allow permanent uses of high-concentration NMP by federal agencies, and should instead employ TSCA Section 6(g) to address any critical uses

EPA has proposed to permit NASA, DOD, and their contractors to use highly concentrated NMP products for multiple uses. As EPA acknowledges, this means that these agencies will be permitted to continue to employ 70%-concentration NMP products, or even pure NMP.⁴⁶ EPA proposes to allow the manufacture, processing, and use of these highly concentrated products indefinitely, with no time limitation. Such unrestricted allowances, without adequate justification, are inconsistent with TSCA’s requirement that EPA protect people from the unreasonable risk of the chemical it is regulating.⁴⁷ And EPA has not provided adequate justification for allowing broad use of high-concentration products that it acknowledged are dangerous and has proposed to prohibit in other contexts.

EPA seeks to justify granting NASA and DOD high-concentration NMP exemptions by referencing “mission- or safety-critical uses,”⁴⁸ and proposes to allow NASA and DOD to use these risky high-concentration products for painting and coating, and for removing paint, coating, and adhesive.⁴⁹ However, the label that EPA has proposed to require processors and distributors of the high-concentration NMP products to affix to their products would explain that the product can be used for “DOD and NASA projects,” with no stated requirement that those projects necessitate NMP, much less that the projects are critical.⁵⁰

EPA asserts that, despite the fact that DOD and NASA will be permitted to use NMP concentrations double or more than what the Agency will otherwise be allowing, the Agency “expects it is possible for the unreasonable risk to be addressed by the WCPP.”⁵¹ However, EPA does not provide any meaningful support for its stated expectation that NASA and DOD can successfully protect against the unreasonable risk of these high-concentration products through the WCPP. In fact, EPA found chronic risks exceeding benchmarks, even with a glove protection factor of 5-20 and a respirator assigned protection factor of 10, for many of the conditions of use under this exemption – even at lower concentrations (70% weight fraction) than pure NMP.⁵²

Another crucial problem with the DOD/NASA proposal is that EPA did not propose any time limit on the high concentration uses. The lack of a proposed ending for these uses is particularly

⁴⁶ 89 Fed. Reg. at 51168

⁴⁷ 15 U.S.C. § 2605 (“TSCA section 6”)

⁴⁸ “EPA is aware of specific mission- or safety-critical uses for which the concentration limits EPA is proposing would negatively impact DOD and NASA.” 89 Fed. Reg. at 51159.

⁴⁹ 89 Fed. Reg. at 51153

⁵⁰ 89 Fed. Reg. at 51169

⁵¹ *Id.*

⁵² EPA, “NMP Supplemental File with Additional Occupational PBPK Runs – 12 2023,” June 14, 2024, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0084>.

surprising in light of the fact that EPA invokes Section 6(g) as a guide in the potential granting of waivers to additional federal agencies to engage in prohibited uses.⁵³ The Agency proposes an approach in which a federal agency petitioning for the waiver would be required, within half a year of the petition, to document its efforts to identify or qualify substitutes to the NMP use, along with other requirements.⁵⁴ In the absence of the agencies providing the required information, the category of use allowance would expire within a year of the petition.⁵⁵ But in notable contrast to this approach, in the case of the proposed exempted NASA and DOD uses, EPA has failed to require any end to the exemptions.

These time-unlimited high-concentration uses are not only dangerous for the NASA, DOD, and contractor workers using the products, but also to workers exposed via the processing and manufacturing of the products, and to all others who will be exposed via the likely eventuality that the products will be obtained and used outside of NASA and DOD. (EPA nods to this problem via its self-certification, downstream notification, and recordkeeping provisions, which are unlikely to prevent all unauthorized use.) For example, EPA found chronic risks exceeding benchmarks, even with a glove protection factor of 5-10 and a respirator assigned protection factor of 10, for manufacturing, repackaging, chemical processing, and formulation conditions of use.⁵⁶ EPA has not explained how the unreasonable risks to such groups are addressed, as required by TSCA, under its proposal.

Simply, EPA has failed to justify enshrining permanent, high-concentration uses of NMP by DOD and NASA and the processing and manufacture of these dangerous products that would be necessary to supply the agencies. If EPA concludes that DOD and NASA may have a current need for an exemption to the concentration limits it imposes on other users of NMP, EPA should follow the procedure mandated by TSCA Section 6(g).⁵⁷ Proceeding under Section 6(g) helps to ensure that EPA will analyze the need for each and every proposed exemption, impose conditions on each use exemption necessary to protect health and the environment, and establish an appropriate time limit for each exemption. The Agency addressed certain NASA uses of methylene chloride in this way. Specifically, the Agency put a time limit on the methylene chloride exemptions, which are for specific conditions of use only, and also imposed additional notification requirements, recordkeeping requirements, and controls for exposure.⁵⁸ Here, EPA

⁵³ See 89 Fed. Reg. 51151 and Section IV.C., below.

⁵⁴ See 89 Fed. Reg. at 51151

⁵⁵ *Id.*

⁵⁶ EPA, “NMP Supplemental File with Additional Occupational PBPK Runs – 12 2023,” June 14, 2024, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0084>.

⁵⁷ 15 U.S.C. § 2605(g)(1) (“TSCA section 6(g)(1)”)

⁵⁸ EPA, “Methylene Chloride; Regulation Under the Toxic Substances Control Act,” 89 Fed. Reg. 39254, 39283, May 8, 2024, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0465>. See, e.g., *id.* at 39283:

has provided no adequate justification for abandoning this approach and allowing permanent use of high-concentration NMP products.⁵⁹

Finally, EPA requests comment on whether EPA should require reporting when DOD, NASA, or their contractors purchase NMP. Indeed, to the extent that EPA permits any high concentration uses in the final rule, such reporting “could support . . . enforcement and compliance assurance with this rulemaking by further assuring that distribution of these high concentration NMP products for these uses is limited to DOD, NASA, and their contractors.”⁶⁰ EPA should not only impose reporting requirements on any agencies, and their contractors, who purchase high concentration NMP, but the Agency should make this reporting contemporaneously and easily available to all in an online public database. Any administrative burdens that reporting might impose on the purchasers and users of high concentration NMP (federal agencies and their contractors should be well positioned to perform such reporting) would be outweighed by the enforcement, compliance, and public participation opportunities.

B. EPA should not permit federal agencies and contractors triple the time to implement the WCPP (36 months vs 12 months)

EPA is proposing to permit federal agencies and their contractors triple the time of private NMP users – a full three years – to implement worker protections.⁶¹ Such an approach is backwards. First, to leave our federal service personnel and contract workers unprotected for a prolonged period denigrates the importance of keeping those personnel safe, and of the United States’ responsibility to protect them. This approach is also contrary to the stated national values,

“Specifically, this regulation requires NASA and its contractors to notify the EPA Assistant Administrators of both the Office of Enforcement and Compliance Assurance and the Office of Chemical Safety and Pollution Prevention within 15 days of the emergency use. The notification must include a description of the specific use of methylene chloride in the context of one of the conditions of use for which this exemption is being finalized, an explanation of why the use described qualifies as an emergency, and an explanation with regard to the lack of availability of technically and economically feasible alternatives.

EPA expects NASA and its contractors have the ability to implement a WCPP as described in Unit IV.B. for the identified uses in the context of an emergency, to some extent even if not to the full extent of WCPP implementation. Therefore, NASA and its contractors must comply with the WCPP to the extent technically feasible in light of the particular emergency.

NASA and its contractors would still be subject to the general recordkeeping requirements discussed in Unit IV.B.7.c.”

⁵⁹ EPA also requested comment on whether all users of NMP in paints and coatings, and paint, coating, and adhesive removal, should be permitted to use NMP with no concentration limits and a WCPP only. For all the reasons described in this section, such allowances would not comply with EPA’s responsibilities under TSCA Section 6, and EPA should not finalize such allowances.

⁶⁰ 89 Fed. Reg. at 51160

⁶¹ 89 Fed. Reg. at 51156-57

including of the Biden-Harris administration, that emphasize the importance of addressing toxic exposure harms to those who serve our country.⁶² In addition, the federal government has deep expertise in executing programs, and in light of this, EPA's stated justifications for a three-year compliance delay based on vague references to procurement and budgeting logistics is patently insufficient.⁶³ Finally, EPA, along with the rest of the federal government, has the responsibility to lead in the execution of health and safety regulations, not to follow along as a regulatory laggard with ultralong compliance timelines.

The federal agencies should have no longer than any other NMP users to comply with the WCPP or any other Section 6 requirement.

C. The process EPA is considering for granting additional exemptions for federal uses of NMP precludes meaningful notice or participation for the public

EPA seeks comment on an "appropriate, predictable process" that would allow the Agency to grant "expedited reconsideration" to federal agencies to engage in uses that are prohibited under the final rule.⁶⁴ EPA is considering a blanket exemption provision which would allow federal agencies and their contractors to file petitions seeking exemptions to the final rule and engage in prohibited uses – and EPA would only allow public comment on the exemption requests after it grants or denies the exemptions.⁶⁵ Under this scenario, the public would have no meaningful ability to comment on the exemption requests. In fact, the public would not even be notified about the exemption requests prior to EPA's final decision on them. Under the proposed process, EPA would act on the petition within 30 days and publish its decision in the Federal Register. After making this decision, EPA would then accept public comment for 180 days upon its decision. However, in its proposal EPA provides no indication that it would modify its decision based upon the public comments it receives. Only notifying the public and allowing public comment on an exemption after the decision is made, and not providing any clear indication that public comment could actually impact the results of the decision, effectively eliminates the public's ability to meaningfully comment upon an exemption created under this process.

In the methylene chloride final TSCA section 6 rule, EPA indicated that it would be initiating a notice of proposed rulemaking on a possible process for "emergency or interim" exemption

⁶² See, e.g., The White House, "Fact Sheet: President Biden to Announce 1 Million PACT Act Claims Approved, Benefits Delivered to Veterans in all 50 States and U.S. Territories," May 21, 2024, U.S. Department of Justice, Radiation Exposure Compensation Act (updated July 25, 2024), <https://www.justice.gov/civil/common/reca>.

⁶³ 89 Fed. Reg. at 51157 ("...EPA believes that compliance with this proposed rulemaking would require increased and different preparations on the part of Federal agencies. For example, Federal agencies must follow procurement requirements which will likely result in increased compliance timelines. In addition, these requirements would require support in the Federal budget, which, for some agencies, is a multi-year process").

⁶⁴ 89 Fed. Reg. at 51151

⁶⁵ *Id.*

rulemakings, and added it to the long-term Spring 2024 regulatory agenda.⁶⁶ EDF urges EPA not to take up such a rulemaking; instead, federal agencies, as all chemical users, have the opportunity to seek exemptions under TSCA section 6(g).⁶⁷ Under TSCA, Congress did not permit EPA to authorize prohibited uses of chemicals outside of sections 6(a) and 6(g), or to engage in “emergency rulemakings” to provide exemptions to prohibitions.

VI. EPA should finalize shorter compliance timelines to ensure prompt public health protections

EPA’s proposed lengthy compliance timelines are insufficiently justified under TSCA.

At the earliest, EPA is proposing to allow a full year for certain of the proposed restrictions to come into effect (i.e., the prohibition on certain uses for manufacturers; container size limit and labeling requirements; prescriptive controls for importers). EPA is proposing a full two-year delay for other restrictions (i.e. the prohibition on certain uses for industrial and commercial users; prescriptive controls for industrial and commercial users). These lengthy compliance dates are inadequately justified and do not comport with TSCA Section 6.

In discussing its proposed timeline for the prohibition of certain uses, the Agency states:

EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products to clear the channels of trade.⁶⁸

This statement and others in the proposal indicate that the Agency is ignoring, or has misperceived, the burden that TSCA Section 6 imposes on EPA to require swift compliance. TSCA requires EPA to mandate that its risk management rules take effect, and that compliance occur, “as soon as practicable.”⁶⁹ The Proposed Rule takes an insufficiently narrow approach, asking only whether its proposed compliance dates are feasible for companies. Instead, EPA must demonstrate that it has chosen compliance dates that are the fastest practicable. In other words, the Agency must carry the burden, with factual support, to justify any compliance delay beyond an appropriate transition period.

⁶⁶ EPA, “Methylene Chloride; Regulation Under the Toxic Substances Control Act,” 89 Fed. Reg. 39254, 39283, May 8, 2024, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0465>; EPA, notice for potential action: “Toxic Substances Control Act Risk Management Rules and Critical Uses for Federal Agencies, RIN 2070-AL17,” Spring 2024, <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202404&RIN=2070-AL17>.

⁶⁷ 15 U.S.C. § 2605(g)

⁶⁸ 89 FR 51134, 51150. *See also id.* at 51158 (“EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be impacted, or that additional time is needed for product reformulation and PPE training”).

⁶⁹ 15 U.S.C. § 2605(d)(1) (“TSCA section 6(d)(1)”)

In the case of NMP, EPA has provided no sufficient rationale for why the compliance periods should extend beyond the time needed for transition. Companies were made aware of the likelihood that EPA would take action regarding NMP at least as far back as the Agency's January 2017 proposed risk management rule. More recently, EPA issued its 2020 risk evaluation, and then its 2022 revised risk determination that found that NMP poses an unreasonable risk as a whole chemical.⁷⁰ Industrial and commercial users of NMP were aware that EPA was preparing to regulate in order to eliminate the unreasonable risk – the docket for the Proposed Rule shows that EPA met with members of the industry at least as early as 2021 to discuss risk management for NMP.⁷¹ Entities whose business will be affected by the final rule have had sufficient time to know that EPA may regulate NMP and to prepare for a risk management rule.

In light of TSCA's mandate that EPA institute its risk management regulations as soon as practicable – and considering the notable lack of evidence to support the idea that near-term restrictions are not practicable – implementation of all NMP restrictions imposed in the final rule without delay is appropriate.

EPA's compliance timeline would be in addition to the many months of notice of the ban that EPA will have provided industry, from June 2024 – when EPA released the proposal – to when the rule is finalized, likely in 2025. This would all be on top of the years of notice companies and agencies have been on that EPA was evaluating, and then found unreasonable risk from, NMP.

VII. EPA should remove the *de minimis* exemption

In promulgating the final rule, EPA should remove the allowance of a *de minimis* level of NMP in products. Because a *de minimis* exemption is concentration based, there is no assurance that it would prevent unreasonable risk, such as to workers or communities surrounding facilities, as a relatively small percentage of a large volume can still pose a risk. EPA recently addressed this precise issue in the context of TRI reporting of PFAS, where the Agency appropriately rejected the *de minimis* exemption, explaining that “[s]ince the *de minimis* level is based on relative concentration rather than a specific amount, the application of this exemption to PFAS listed under sections 7321(b) and 7321(c) could allow significant quantities of such PFAS to be excluded from TRI reporting by facilities.”⁷² The same rationale applies here as well. Furthermore, as the *de minimis* level applies to “products containing NMP,” it is possible

⁷⁰ EPA, “NMP; Revision to Toxic Substances Control Act Risk Determination; Notice of Availability,” 87 Fed. Reg. 77596, December 19, 2022, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0743>.

⁷¹ See, e.g., EPA-HQ-OPPT-2020-0744-0002-14; Meetings between EPA and Celanese, Air Liquide, Anderson Development, Household & Commercial Products Association, Semiconductor Industry, Halogenated Solvents Industry Alliance, National Electronics Manufacturers Association, and NMP Producers Group.

⁷² EPA, “Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting,” 87 Fed. Reg. 74379, December 5, 2022, <https://www.regulations.gov/docket/EPA-HQ-TRI-2022-0270>.

that workers could be subjected to higher concentrations in the processing of such products. Individuals can also potentially encounter this toxic chemical through a variety of exposure pathways, and relatively small exposures across multiple pathways can add up.

NMP's potential to cause developmental and reproductive effects further underscores the need to prohibit a *de minimis* exemption for NMP. Developmental and reproductive effects are extreme, determinate effects that can occur from low levels and short frequency exposures to NMP.⁷³ Allowing a *de minimis* level continues to put individuals exposed at risk from these deterministic health effects in short amounts of time. Further, the *de minimis* exemption for individual products does not take into account that an individual could use multiple products containing NMP. Exposure to multiple products containing NMP, even at low concentrations, also increases exposures to NMP to levels that could cause risk. Therefore, a *de minimis* exemption could still result in unreasonable risks from exposure to NMP.

TSCA Section 6(a) requires that EPA apply one or more of the requirements to the extent necessary so that the chemical no longer presents an unreasonable risk, and may consider non-risk factors when choosing *among* the restrictions that mitigate unreasonable risk. EPA cannot simply apply a *de minimis* level without demonstrating that the unreasonable risk is mitigated.

If EPA chooses to retain the *de minimis* level, which we strongly advise against in particular given the developmental and reproductive harms posed by NMP, it should not be higher than 0.1%.

VIII. EPA's qualitative description of the avoided health impacts is sufficient from reducing exposure to NMP is sufficient to justify its rule under TSCA

EPA has not monetized or quantified the direct health benefits from preventing effects from exposure to NMP due to methodological limitations of doing so for the relevant health outcomes of developmental and reproductive effects, including fetal deaths, liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, irritation, and sensitization. Nonetheless, EPA has successfully fulfilled its obligations to consider the costs and benefits of the Proposed Rule as required by TSCA section 6(c)(2) by qualitatively describing the benefits of avoided health impacts from the proposal. The health impacts, including the significant health and emotional impacts of fetal death from miscarriage or stillbirth in particular, should not be diminished or discounted simply due to methodological limitations.

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EDF appreciates EPA's consideration of these comments.

⁷³ EPA, "Risk Evaluation for n-Methylpyrrolidone (NMP), CASRN 872-50-4," December 2020, at Table 2-74, p. 87, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.