Appendix to Comments of Safer Chemicals Healthy Families on Risk Evaluation Problem Formulation Documents for Ten Chemical Substances under the Toxic Substances Control Act

For N-Methylpyrrolidone (NMP), Docket ID No.: EPA-HQ-OPPT-2016-0743
Submitted via Regulations.gov (August 16, 2018)

This document supplements our general comments on the problem formulations for all 10 chemicals by providing specific details on N-Methylpyrrolidone (NMP).

On March 15, 2017, Safer Chemicals Healthy Families, Environmental Health Strategy Center, and Healthy Building Network provided detailed comments on the scope of the risk evaluation for five of the 10 chemicals EPA designated for initial risk evaluations on December 19, 2016.[1] We summarized information on the chemicals' production and trade, uses, disposal, potentially vulnerable populations, exposure scenarios, and health and environmental hazards, as applicable. We urged the agency to ensure that the risk evaluation for each chemical would reflect the best information available on hazard and exposure, be based on a comprehensive understanding of the chemicals' conditions of use, and employ sound, precautionary methodologies that fully capture the risks they pose to human health and the environment.

The Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone (NMP Problem Formulation),[2] issued by EPA on June 1, 2018, has several critical deficiencies toward meeting those criteria.

I. USES

EPA must evaluate the complete life cycle of the chemical, but currently plans to disregard important sources of exposure to NMP.

A. EPA's list of conditions of use to be included in the risk evaluation does not mention certain products containing NMP that could be significant sources of exposure

In our March 2017 comments, we provided evidence for additional uses of NMP that are not explicitly included in the NMP Scope Document or Problem Formulation.

- Rheology additive in PVC plastisols[3] or in abrasives manufacturing[4]
- Drug solubilizer and penetration enhancer in human topical dosage forms[5]

[1] The March 2017 comments submitted on NMP were assigned the identifier of EPA-HQ-OPPT-2016-0743-0031 and are posted at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0031.
[2] https://www.epa.gov/sites/production/files/2018-06/documents/nmp_pf_05-31-18.pdf (NMP Problem Formulation)
[3] EPA-HQ-OPPT-2016-0743-0031, Technical Appendix, p 10, 19; https://www.byk.com/en/additives/additives-by-name/byk-410.php. The NMP Problem Formulation cites to a 1997 Australian assessment of a polymer in BYK-410, but we want to ensure that the use of BYK-410 itself will be included in EPA's current risk evaluation.
[4] EPA-HQ-OPPT-2016-0743-0031, Technical Appendix, p 10, 20
[5] EPA-HQ-OPPT-2016-0743-0031, Technical Appendix, p 6, 19

- Component of reaction process to create polyphenylene sulfide[6]

We identified these potential uses through an investigation of NMP's production and trade data and from reviewing articles and websites.

The last two uses may be covered by the descriptions in B.1.3.6, Other Uses, in Appendix B of the NMP Problem Formulation.[7] Under "Pharmaceuticals" in that section, EPA states: "NMP is increasingly being used as a solvent and extraction medium for the manufacture and *formulation* of pharmaceuticals" (emphasis added). Under "Reaction Medium," the agency states: "in industry, NMP is often used as a reaction medium for polymerization reactions, because many polymers are soluble in NMP … [including] polyvinyl acetate, polyvinyl fluoride, polystyrene, nylon, polyimides, polyesters, acrylics, polycarbonates and synthetic elastomers." EPA leaves out "polyphenylene sulfide" from this list. Since Table 2-3, "Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation," does not refer to these subcategories, and because the list of polymers in Section B.1.3.6 is incomplete, we want to ensure that these uses will in fact be evaluated.

B. EPA should not disregard historical uses

Our March 2017 comments identified a few uses of NMP that may have been discontinued:

- Component of inner layer of aluminum aerosol or spray cans, such as that used for hairspray or air fresheners[8]
- PCB manufacturing[9]

Even if they are recently discontinued uses, EPA should still consider them in its evaluation. For example, manufacturers of aluminum can linings only recently began moving to NMP-free formulations and nothing prohibits a return to a prior formulation. Such a possibility is a reasonably foreseeable use. Additionally, containers with the prior formulations may remain in circulation, so consumers using aerosols could still be exposed to NMP for the foreseeable future.

C. EPA should finalize the rule proposing a ban on paint stripping uses of NMP instead of using valuable and limited agency resources to re-evaluate these uses

EPA already fully assessed the risk from NMP-based paint strippers in 2015. This evaluation clearly showed the danger posed by these products. With the 2016 amendments to the Toxic Substances Control Act, EPA was given the authority to ban these uses. The agency moved in that direction by issuing a proposed rule and should now finalize it without further delay. There is no need to reevaluate the risk from paint strippers with NMP and doing so would only tax EPA's already limited resources.

II. EXPOSURES

[6] EPA-HQ-OPPT-2016-0743-0031, Technical Appendix, p 15, 16, 19
[7] NMP Problem Formulation, p 81
[8] EPA-HQ-OPPT-2016-0743-0031, Summary Comment, p 5; Technical Appendix, p 11, 18-20
[9] EPA-HQ-OPPT-2016-0743-0031, Technical Appendix, p 10, 20

A. EPA must recognize women of reproductive age and pregnant women as potentially exposed or susceptible subpopulations (PESS) and should determine whether that classification should be accorded to other groups

In the NMP Problem Formulation, EPA identifies a select number of potentially exposed or susceptible subpopulations (PESS) whose risk the agency will consider based on greater exposure: workers and occupational non-users, consumers and bystanders associated with consumer use, and groups within the general population "who live or work near manufacturing, processing, use or disposal sites."[10]

EPA also indicates it may designate other subpopulations as PESS:

> "In developing exposure scenarios, EPA will analyze available data to ascertain whether some human receptor groups may be exposed via pathways that may be distinct to a particular subpopulation or life stage and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population…[and may] identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure…In developing the hazard assessment, EPA will analyze available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s). In the previous risk assessment (U.S. EPA, 2015), EPA identified young children and pregnant women as potentially susceptible subpopulations."[11]

Numerous studies provide clear evidence of NMP's reproductive and developmental toxicity, and so EPA must identify women of reproductive age and pregnant women as PESS for the current risk evaluation.[12] As we stated in our March 2017 comments, this includes women who work directly in manufacturing and with industrial uses of NMP, as well as those who are occupational non-users, who live near the facilities, or who use products containing NMP. In particular, elevated rates of miscarriages have been reported for the electronics industry.[13]

Additionally, EPA must fully assess the NMP exposures faced by workers of color, communities of color, or low-income communities and determine whether these groups constitute a PESS.[14]

B. EPA completely disregards exposures to the general population, including aggregate exposure

EPA states that it intends to effectively disregard in its risk evaluation all aspects of the general population's exposure to NMP, even after the agency lists specific potential exposures from

[10] NMP Problem Formulation, p 37
[11] NMP Problem Formulation, p 37-8, 41
[12] EPA-HQ-OPPT-2016-0743-0031, Summary Comment, p 6
[13] EPA-HQ-OPPT-2016-0743-0031, Summary Comment, p 6 (FN 3)
[14] EPA-HQ-OPPT-2016-0743-0031, Summary Comment, p 6

inhaling polluted air or drinking polluted water.[15] EPA plans to *entirely exclude* exposures from drinking contaminated water and from disposal activities despite air emissions and land releases because the agency believes that other laws address the exposures.[16]

However, this approach fails to account for aggregate exposure, which we called on EPA to assess in our March 2017 comments.[17] Evaluating exposures to media such as air and water only in isolation does not allow for the likelihood that people are exposed to NMP in more than one medium at once, and will underestimate the total risk. The agency may end up finding that inhalation exposures of workers at industrial facilities, for example, are acceptable without accounting for exposures from an incinerator near the neighborhood where the worker lives and thus underestimating the total exposure level.

More broadly, EPA should consider the exposures to the general population together with the exposures faced by workers, those who use NMP-containing products, and those who live close to facilities. The agency should assume that one person might fall into all four categories and assess the aggregate risk.

C. EPA needs to assess cumulative exposure and risk for NMP in combination with other risk factors

The NMP Problem Formulation has no reference to cumulative exposure. EPA must include this in its risk evaluation.

III. DATA GAPS

A. EPA should require industry to fill data gaps

In its Analysis Plan, EPA states that the agency will "attempt to address data gaps" by reviewing "reasonably available exposure data for surrogate chemicals that have uses, volatility and physical-chemical properties that are comparable to NMP" and, "For conditions of use where data are limited or not available, [the agency will] review existing exposure models that may be applicable in estimating exposure levels."[18] Instead of relying on these measures, EPA should ask industry to produce the data that is necessary to complete the risk evaluation.

[15] NMP Problem Formulation, p 36-7
[16] NMP Problem Formulation, p 49-51
[17] EPA-HQ-OPPT-2016-0743-0031, Summary Comment, p 3, 5
[18] NMP Problem Formulation, p 56