NMP
N-METHYLPYRROLIDONE PRODUCERS GROUP, INC.
2200 PENNSYLVANIA AVENUE, N.W., SUITE 100W, WASHINGTON, D.C. 20037 • (202) 557-3800 • FAX (202) 557-3836
MANAGED BY B&C® CONSORTIA MANAGEMENT, L.L.C.

June 12, 2025

Via E-Mail

Information Quality Guidelines Staff
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (Mail Code 28221T)
Washington, DC 20460

Re: Request for Reconsideration of EPA's Decision to Deny a Request for Correction of Information under the Information Quality Act: The Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone

Dear Sir or Madam:

B&C® Consortia Management, L.L.C. (BCCM) submits on behalf of the N-Methylpyrrolidone Producers Group, Inc. (NMP Producers Group) this Request for Reconsideration (RFR) of the U.S. Environmental Protection Agency's (EPA) decision to deny the NMP Producers Group's Request for Correction of Information (RFC #23001). The NMP Producers Group submits this RFR under the Information Quality Act (IQA) and EPA and the Office of Management and Budget's (OMB) implementing guidelines.[1]

The NMP Producers Group submitted the RFC to EPA on April 19, 2023, seeking correction of information in the final "Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP) CASRN: 872-50-4" issued by EPA's Office of Pollution Prevention and Toxics

[1] Treasury and General Government Appropriations Act, 2001, Pub. L. No. 106-554, App. C, Tit. V, § 515(a) (2000) (as codified at 44 U.S.C. § 3516 note); "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," 67 Fed. Reg. 8452 (Feb. 22, 2002); EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, EPA/260R-02-008 (Oct. 2002), available at https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf.

(OPPT) in December 2020.[2,3] A copy of RFC #23001 is attached as Exhibit 1. EPA confirmed receipt of the RFC on May 5, 2023, and issued a response denying the request on August 15, 2023.[4] A copy of EPA's letter is attached as Exhibit 2.

EPA denied the RFC on procedural grounds based on two assumptions. First, EPA claimed that its public comment opportunities on the draft NMP risk evaluation (RE) satisfied EPA's Information Quality Guidelines (IQG). Second, EPA claimed that the NMP Producers Group's RFC overlapped with comments and submissions EPA had already reviewed. Both assumptions were erroneous and improper grounds for denying the RFC without substantive review. The RFC submitted new, peer-reviewed information that was published in a scientific journal in February 2023 by Kirman *et al.* that demonstrated the need for the requested corrections.[5] The assessment evaluated EPA's December 2020 final NMP RE. Accordingly, this new information was not available during the public comment period for the *proposed* NMP RE. A copy of Kirman *et al.* (2023) is attached as Exhibit 3. The RFC also included BCCM's re-evaluation of chronic exposure scenarios for workers and occupational non-users (ONU) and

---

2 NMP Producers Group (2023), *Request for Correction of Information on the Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone*, N-Methylpyrrolidone Producers Group, Inc., available at https://www.epa.gov/system/files/documents/2023-05/RFC%2023001%20N-Methylpyrrolidone.pdf.

3 EPA (2020a), *Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidone, 1-Methyl-) (NMP) CASRN: 872-50-4*, EPA Document # EPA-740-R1-8009, Office of Chemical Safety and Pollution Prevention (OCSPP), U.S. Environmental Protection Agency (EPA), available at https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.

4 EPA (2023), *Response to Request for Correction of Information on the Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone*, U.S. Environmental Protection Agency (EPA), available at https://www.epa.gov/system/files/documents/2023-08/23001_RFC_NMP-Producers-Group_EPA-Response_eSigned_2023-08-15.pdf ("IQA Guidelines").

5 Kirman *et al*. (2023), *An evaluation of reproductive toxicity studies and data interpretation of N-methylpyrrolidone for risk assessment: An expert panel review*, Regul. Toxicol. Pharmacol., Vol. 138, 105337, at 2, available at https://doi.org/10.1016/j.yrtph.2023.105337.

supporting analysis (*see* attachment to RFC #23001 labeled "Re-evaluation of worker and ONU COUs.xlsx"). A copy is provided as Exhibit 4. Although the new information is material to the compliance of a significant, influential scientific document (the NMP RE) with EPA's IQG and TSCA Section 26, EPA has never reviewed this information.

We thus resubmit the referenced information to EPA requesting substantive review and corrective action. In brief summation, the NMP Producers Group (and EPA's TSCA Science Advisory Committee on Chemicals (SACC)) first raised information quality concerns to EPA in 2017 during public comments regarding OPPT's reliance on effects from a two-generation reproduction toxicity study in rats (*i.e.*, Exxon 1991)[6] that were not reproducible in two subsequent two-generation reproduction toxicity studies in rats (*i.e.*, NMP Producers Group 1999a,b)[7] and EPA's application of study quality criteria.

After EPA considered and rejected these public comments and published the final NMP RE in December 2020, the NMP Producers Group funded an independent peer-review panel of the three two-generation toxicity studies to further investigate its concerns. The February 2023 results of the panel review in Kirman *et al.* (2023) concluded that Exxon (1991) was not a high-quality study and should not be considered for quantitative risk assessment. The NMP Producers Group then prepared the April 2023 RFC to submit this information to EPA along with additional analysis. This was set forth in the RFC and is resubmitted in this appeal. In support of this RFR response, the NMP Producers Group has prepared a summary that addresses EPA's response to the Group's public comments (referenced in EPA's RFC response) and the substantive issues raised that EPA has not addressed. This is provided as Exhibit 5.

EPA's RFC response highlights critical flaws in EPA's RFC review process. EPA's stated rationale is that the NMP Producers Group had its opportunity to comment, and that EPA addressed all comments in the final RE. In other words, EPA viewed the RFC as merely a "second

---

6 Exxon Biomedical Sciences (1991), *Multigeneration Rat Reproduction Study with N-Methylpyrrolidone, Project Number 236535*, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0070.

7 NMP Producers Group (1999a), *Two Generation Reproduction Toxicity Study with N-Methylpyrrolidone (NMP) in Sprague Dawley Rats -- Administration in the Diet*, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0071; NMP Producers Group (1999b), *Two Generation Reproduction Toxicity Study with N-Mythylpyrrolidone [sic] (NMP) in Wistar Rats -- Administration in the Diet*, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0072.

bite at the apple." This was not the case. If EPA had reviewed the RFC, EPA would have substantively considered the new information and the NMP Producers Group's concerns about the quality of the science in the final RE. Instead, EPA ignored the data and wrongly denied the RFC and did so without adhering to EPA's IQG.

Next, irrespective of the new information submitted in the RFC, we disagree that EPA's response to our comments on the NMP RE satisfied EPA's IQG. Requesting review under EPA's IQG is often the only available recourse to seek correction of information. This includes cases where public comments failed to elicit responses that adhered to EPA's IQG. There is no evidence that EPA's responses to comments on the draft NMP RE adhered to the processes or standards mandated by EPA's IQG. Instead, EPA is claiming that merely accepting and responding to public comments, without ensuring it complies with mandated processes and requirements under EPA's IQG, discharges EPA's obligations under the IQG. It does not. This would permit EPA effectively to evade IQG review and deprive stakeholders of the right to seek correction and reconsideration of a decision under EPA's IQG standards and is impermissible.

EPA's REs are significant, influential public documents that will have a clear and substantial impact on important public policies and private sector decisions. The NMP Producers Group's RFC and this RFR are supported by peer-reviewed science and warrant EPA's substantive review and subsequent corrective action. The NMP Producers Group submitted the RFC and now this appeal in the shared interest of ensuring that EPA's decisions are based on the scientific standards under TSCA and comply with EPA's IQG. We request that EPA review this information and take necessary corrective actions to amend the NMP RE.

We appreciate EPA's time and effort in responding to these submissions. We furthermore hope that the NMP Producers Group's efforts and intentions in submitting these requests to EPA receive reciprocal consideration and that our requests are reviewed on the merits.

I. The NMP Producers Group Submits This RFR Based on the Mutual Aim of Ensuring and Maximizing Information Quality

The NMP Producers Group provides the following statement in support of its submissions. The NMP Producers Group was formed to address regulatory and stewardship issues pertinent to NMP, which has involved developing and submitting information to support EPA's efforts in carrying out the critical requirements of TSCA Section 6.

EPA's TSCA Section 6 REs are complex, multi-year assessments that demand significant resources, stakeholder involvement, and use of the best available science. Adherence to TSCA's scientific standards and EPA's IQG while completing such complex assessments is

challenging -- but necessary. The opportunity to raise concerns about the quality of information relied upon by EPA in the NMP RE is of paramount importance. As contemplated by EPA's IQG, stakeholder involvement via the RFC process helps to maximize the quality, objectivity, and integrity of information disseminated by EPA.

As influential scientific documents, TSCA Section 6 REs have "a clear and substantial impact on important public policies or important private sector decisions."[8] Once published, TSCA Section 6(b) REs play the critical role of informing risk management rules (RMR) under TSCA Section 6(a). EPA must issue requirements to the extent necessary to mitigate the risk identified in the RE.

Simply put, REs are the scientific underpinning of RMRs. Flawed REs can result in under-regulation during risk management, leading to insufficient protection of health and the environment, or over-regulation, leading to control measures and costs that are not justified by the risks.

Furthermore, if the REs do not meet the scientific standards under TSCA Section 26, courts may overturn RMRs, forcing EPA to repeat REs and propose again RMRs. It is in all stakeholders' best interests to ensure that REs meet the scientific standards under TSCA and the IQA prior to EPA proposing a RMR. This avoids the need to repeat the risk management work and potential delay of the protections provided in those rules.

Finally, the utility and functionality of TSCA REs do not end upon the completion of risk management. EPA's REs stand as authoritative documents that stakeholders and regulatory authorities across the globe will rely on in managing human health and environmental risks. As EPA's IQG explains, public access to accurate information is integral to EPA's mission and stakeholder participation in protecting human health and the environment.[9]

Here, the NMP Producers Group has raised serious concerns regarding EPA's reliance upon an unreliable, discredited non-reproducible study as the basis for evaluating chronic exposure scenarios. The NMP RE will inform regulatory and commercial decisions for decades to come. As further stated in OMB's IQA guidelines, "[t]he more important the information, the

---

8 67 Fed. Reg. at 8455.

9 EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, at Section 1.

higher the quality standards to which it should be held."[10] EPA's guidelines confirm influential information subject to OMB's reproducibility standards warrants a "higher degree of transparency."[11]

II. Requests for Clarification Pertaining to EPA's Response to RFC #23001 and EPA's Publication of the Draft Report for Exxon (1991)

A. The NMP Producers Group Is the Sole Submitter of RFC #23001 and This RFR

As a preliminary matter, we wish to address an error in EPA's August 15, 2023, response letter to RFC #23001. Although the NMP Producers Group was the **sole submitter** of RFC #23001, EPA addressed its letter to both the NMP Producers Group and a third party, the Semiconductor Industry Association (SIA). EPA then identified incorrectly the NMP Producers Group and SIA as joint submitters of the RFC throughout its response.

We understand that SIA submitted an RFC relating to the NMP RE (RFC #21004) on June 3, 2021, and that EPA denied SIA's RFC on July 27, 2023.[12] The NMP Producers Group and SIA are separate, unrelated entities that submitted two separate and distinct RFCs. We clarify this issue to prevent any confusion during EPA's review of this RFR and request that EPA review the impact of this error on its response to RFC #23001.

---

10 67 Fed. Reg. at 8452.

11 EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, at Section 6.3.

12 SIA (2021), *Request for Correction by the Semiconductor Industry Association (SIA) On the Toxic Substances Control Act (TSCA)*, available at https://www.epa.gov/sites/default/files/2021-06/documents/nmp_rfc-21004.pdf; EPA (2023), *Response to Request for Correction by the Semiconductor Industry Association (SIA) On the Toxic Substances Control Act (TSCA)*, U.S. Environmental Protection Agency (EPA), available at https://www.epa.gov/system/files/documents/2023-07/21004_RfC_NMP-RiskEvaluation_EPA-Response_2023-07-27.pdf.

B. The NMP Producers Group Requests Clarification as to EPA's Publication of the Draft Report for Exxon (1991)

EPA states that it is committed to a transparent and reproducible systematic review process to ensure that the information the Agency relies on in its REs meets the scientific requirements in TSCA Section 26. To evaluate the quality of a study, EPA has explained that it needs access to the complete study methodology and a complete set of data tables and summary statistics for all endpoints. When preparing the NMP RE, EPA also indicated as a matter of policy that it must make the full study report available to the public to allow for meaningful and informed public comments.[13] Following discussions that sought to balance EPA's policy aims with the ability of data owners to protect the proprietary nature of such information, the NMP Producers Group submitted its studies to EPA on April 28, 2020. In publishing the studies in the public docket, EPA stated that "Releasing these studies ensures EPA's risk evaluation process is transparent, robust, and uses the best available science."[14] It does not appear, however, that EPA published the November 26, 1991, final study report for Exxon (1991).

EPA has instead posted a draft final study report dated September 3, 1991, in the public docket for SACC's review of the NMP RE (EPA Docket No. EPA-HQ-OPPT-2019-

---

13 EPA, *EPA Letter and Response to NMP Producers Group Regarding Submission of NMP Study Reports*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0043 (Dec. 11, 2019), available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0043; EPA, *EPA response to NMP Producers Group (March 9, 2020)*, EPA Docket No. EPA-HQ-OPPT-2016-0743-0108, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0108.

14 EPA, *Summary of External Peer Review and Public Comments and Disposition for n-Methylpyrrolidone (NMP), Response to Support Risk Evaluation of n-Methylpyrrolidone (NMP)*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0082 (Dec. 2020) at 193, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0082.

0236).[15] Although the title of the document states that it is a "Final Report," each page of the study report is stamped with the following disclaimer:[16]

DRAFT
NOT SUBJECTED TO
QA AUDIT

Further confirmation that the study report is not the final study report is on "Page 6 of 1563" of the document (or page 8 of the portable document format (PDF) file).[17] The document has not been signed by laboratory personnel signifying that the report is published in final, has undergone quality assurance, and is therefore no longer subject to change without formal amendment. The document is also missing a quality assurance statement on "Page 7 of 1563" (or PDF page 9 of the file).

In other references to the Exxon (1991) study in the NMP RE and regulatory docket, EPA cites to a copy of the study in EPA's Health & Environment Research Online (HERO) database under HERO ID 3809420 dated September, 3 1991, the date of the draft final study report.[18]

The NMP Producers Group understands that there may be some relevant context to this issue. EPA did not provide inadvertently a copy of Exxon (1991) to SACC in advance of

---

15 EPA, *Signed Transmittal Memo NMP Exxon 1991 12/16/2019*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0035, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0035; EPA, *Exxon Biomedical 1991 Multigeneration Rat Reproduction Study with NMP Project number 236535*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0070, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0070.

16 EPA, *Exxon Biomedical 1991 Multigeneration Rat Reproduction Study with NMP Project number 236535*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0070, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0070.

17 *Id.*

18 Exxon Biomedical Sciences (1991), *Multigeneration Rat Reproduction Study with N-Methylpyrrolidone, Project Number 236535*, full reference available at https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/3809420.

SACC's December 5-6, 2019, Open Meeting on the draft NMP RE.[19] This was raised by the SACC as a significant concern because the fertility "endpoint is based on one study, the Exxon 1991 study; and we do not have access to this full study . . . So, that is the primary endpoint, for a POD, where we could not access the study."[20] Concerns were also raised to EPA during public comments that the final report issued on November 26, 1991, should not be classed as a Good Laboratory Practices (GLP) report and "should not be submitted to regulatory agencies" based on "many instances of questionable or unexplainable procedures that could have had an effect on the study," and because the raw data for major portions of the study were not retained.[21]

EPA did not publish a copy of the Exxon study for public review until December 17, 2019. EPA published the draft NMP RE on November 7, 2019, requested public comments on the draft NMP RE for consideration by the SACC by November 26, 2019, and set a deadline of January 6, 2020 (ultimately extended to January 21, 2020) for submitting all written public comments due to EPA.[22] Accordingly, it was not apparent to stakeholders that were independently aware of the Exxon (1991) study that EPA had reviewed a *draft* and not the *final* report when preparing public comments for consideration by the SACC and EPA.

This leads to the following questions: First, we request confirmation as to whether EPA has access and assessed the final November 26, 1991, study report. If yes, we request confirmation as to whether EPA has provided or intends to provide the public with a copy of the report. If no, we request clarification from EPA on its assessment of Exxon (1991) as a high-quality study in review of only the draft September 1991 report and not the final, audited report.

---

19 *See, e.g.*, EPA, *TSCA SACC NMP Transcript 12.05.19*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0065, at 285-287, 315-316, 321-322, 346-356, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0065.

20 *Id.* at 315.

21 EPA, *NMP 00277342*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0079, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0079.

22 "N-Methylpyrrolidone (NMP); Draft Toxic Substances Control Act (TSCA) Risk Evaluation and TSCA Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Availability, Public Meeting, and Request for Comment," 84 Fed. Reg. 60087 (Nov. 7, 2019); "N-Methylpyrrolidone (NMP); Draft Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability; Extension of Comment Period," 85 Fed. Reg. 310 (Jan. 3, 2020).

III. This RFR Is Timely and Responsive to Recent Developments

Section 8.6 of the EPA IQG recommends that requesters submit RFRs within 90 days of EPA's decision to deny an RFC. "If the RFR is sent after that time, EPA recommends that the requester include an explanation of why the request should be considered at this time."[23] The NMP Producers Group received EPA's response letter on August 15, 2023, and acknowledges that its RFR is outside of the recommended 90-day period. We therefore submit the following explanation in support of this appeal.

After receiving EPA's decision to deny the RFC, the NMP Producers Group had more questions than answers. EPA's misidentification of the NMP Producers Group and SIA as joint submitters raised the first of many concerns. Significantly, EPA's response was non-substantive and not reflective of the information submitted in the RFC. Seeking insight into EPA's review process and any records explaining EPA's decision to deny the RFC, the NMP Producers Group worked with a third-party consultant to submit a Freedom of Information Act (FOIA) request. The scope of the request included any factual information that EPA referenced or relied upon when preparing its response, as this information would be crucial to understanding EPA's decision and considering next steps.

The consultant submitted the FOIA request on September 29, 2023. EPA issued its initial response on May 14, 2024. EPA's initial responsive records included only EPA correspondence and did not include any information that EPA referenced or relied upon in issuing its response. It was unclear whether these records were excluded or simply did not exist. Accordingly, the consultant filed an administrative appeal of the FOIA request. EPA granted that appeal and provided additional records on January 9 and March 31, 2025.

EPA's response to the FOIA request was instrumental in informing the NMP Producers Group's decision to prepare this RFR. We expected to receive records with the facts and information EPA relied upon to help us understand EPA's conclusions. The FOIA request turned up no such results. There were no documents indicating that EPA reviewed the RFC on the merits, which stated clearly that the submission contained new information for EPA's review. There were no documents indicating that EPA sought to verify any of the claims it made in its RFC response, including whether EPA had conducted a substantive, scientific review of the Group's public comments under EPA's IQG, or to verify that its past responses applied to the new information submitted with the RFC.

---

[23] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, at Section 8.6.

Instead, the responsive records demonstrated that upon receipt of the RFC, EPA's first *and only* response was to investigate immediately how to deny the RFC on procedural grounds without conducting a substantive review. EPA correspondence showed that EPA had dismissed the RFC as "disagreement" and "attempted avoidance" and had contemplated potential pathways to "summarily dismiss" or "dispense with" the RFC. It was clear that EPA never intended to review the NMP Producers Group's concerns under IQA standards.

The responsive records also revealed concerns regarding the objectivity of EPA's review process. OMB's IQA guidelines state that "an objective process will ensure that the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement."[24] The responsive records showed that the EPA staff that handled the RFC response had authored the NMP RE in question and, presumably, directed the responses to comments on the RE. This demonstrated that an objective review had not occurred and would only occur by submitting an RFR.

Other correspondence showed that EPA had the opportunity to include an EPA Quality Assurance Manager (QAM) on the RFC response team to ensure that EPA followed quality assurance and quality control policies and protocols and identify potential process improvements for future REs. Early on, EPA *declined* to include this staff member on the response team. EPA's reasoning was that the request was simply an attempt by industry to use the RFC process to "detract and delay" the RE process.

Additionally, Section 8.4 of EPA's IQG states that rejections of a RFC should be decided at the highest level of the information owner office or region. Though Office of Chemical Safety and Pollution Prevention (OCSPP) Assistant Administrator Dr. Michal Freedhoff signed the letter rejecting the RFC, there is no correspondence in the responsive documents indicating that the director of OPPT or Assistant Administrator Freedhoff were consulted substantively on the decision to deny the request.

In both EPA's RFC response and the responsive records, EPA also indicated that submitting an RFC may be premature due to future public comment opportunities on the forthcoming NMP RMR. EPA has since published the proposed RMR for NMP, wherein EPA relied upon Exxon (1991) to establish proposed risk management requirements.[25] The NMP

---

24 67 Fed. Reg. at 8458.

25 "n-Methylpyrrolidone (NMP); Regulation Under the Toxic Substances Control Act (TSCA)," 89 Fed. Reg. 51134 (June 14, 2024) (proposed to be codified at 40 C.F.R. Part 751).

Producers Group submitted public comments repeating its concerns to EPA, but even if EPA were to now review those comments under EPA's IQG, EPA has provided **no indication** that it will reopen the final RE.[26]

EPA has, in fact, indicated the opposite. EPA explained in the proposed RMR that it would modify the *final RMR* in response to comments but made no reference to *modifications of the underlying final NMP RE*. In its response to comments on the revised NMP risk determination addressing EPA's adherence to quality standards, EPA even stated that it would not apply retroactively any adjustments to its draft systematic review protocol because this "would lead to further delays in completing the risk evaluations for the first ten substances contrary to Congressional intent."[27] Understanding EPA's need to adhere to congressional timelines, EPA must still comply with TSCA Section 26 and OMB and EPA's information quality guidelines.

Even if EPA were authorized under TSCA to eliminate its reliance on Exxon (1991) in the final NMP RMR, this would not provide the remedy we are seeking. As it stands, the NMP RE relies upon non-reproducible science. EPA's final RE informs not only the RMR but will be relied upon by regulatory authorities, the scientific community, and other stakeholders for decades to come. The RFR is timely as it remains the *only* recourse available to seek correction of the flawed RE.

Last, we wish to address the statements made by EPA in the FOIA responsive documents regarding potential industry misuse of the IQG process to delay EPA's RE and risk management processes. The NMP Producers Group first notified EPA of its concerns in 2017, engaging in all public comment opportunities, developing and submitting information to EPA, and eventually preparing and submitting its RFC in 2023. EPA has had an opportunity to take

---

26 NMP Producers Group, Re: Comments on N-Methylpyrrolidone (NMP); Proposed Regulation Under the Toxic Substances Control Act (TSCA); Docket EPA-HQ-OPPT-2020-0744 (July 29, 2024), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0744-0305; NMP Producers Group (2024), Re: Oral Comments by the N-Methylpyrrolidone Producers Group, Inc. (NMP Producers Group) during the U.S. Environmental Protection Agency (EPA) Public Webinar Regarding the Proposed Risk Management Rule for N-methylpyrrolidone (NMP), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0744-0268.

27 EPA, n-Methylpyrrolidone (NMP); Revision to Toxic Substances Control Act (TSCA) Risk Determination Response to Public Comments, EPA Document No. EPA-HQ-OPPT-2016-0743-0146 (Dec. 2022) at 3, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0146.

corrective action at each of these junctures. The NMP Producers Group prepared the RFC only after conducting an independent peer review that confirms and supports the Group's concerns. The NMP Producers Group did not submit the RFC to delay, distract, or gratuitously disagree with an unfavorable outcome. It did so based on well-supported concerns and in the mutual interest of ensuring that EPA's REs meet the standards of quality, objectivity, utility, and integrity. The NMP Producers Group would not have had to seek an independent review of the quality of the two-generation studies if EPA had addressed adequately the scientific weakness of the Exxon (1991) study in the final RE. The Group could not have known that such a review would be required prior to EPA's publication of the final RE, so EPA cannot suggest that the development of that review was a ploy to delay EPA's work.

For all of the foregoing reasons, it is evident that we must submit an RFR to ensure a substantive review and correction of these critical issues and ensure objectivity and conformance to EPA and OMB IQA guidelines. We furthermore believe that EPA may correct the underlying final RE without further delaying risk management. Accordingly, this RFR is timely and is the only available recourse to seek correction of the NMP RE.

IV. Basis for Appeal of EPA's Decision to Deny the RFC

EPA states in its response that it denied RFC #23001 after concluding "that the issues raised in this RFC were appropriately addressed in the TSCA Existing Chemical Evaluation public comment period for NMP." EPA asserted that EPA's public comment period provides a more appropriate mechanism for stakeholders to provide comments to EPA than the RFC process and that the RFC is not intended to duplicate or interfere with the public comment process. For the reasons set forth in this RFR, we appeal EPA's decision.

A. The RFC Included New Information for EPA's Review in Support of the RFC under EPA's IQG; This Information Was Not Duplicative of Any Comments or Submissions That EPA Reviewed Previously and Did Not Interfere with EPA's Public Comment Process

The NMP Producers Group's RFC included two "categories" of information. First, the RFC identified information quality concerns that were raised in public comments but that were not addressed by EPA in the final RE in a manner that satisfies OMB and EPA's guidelines. Second, the RFC included **new information** based on the final NMP RE that was developed after the conclusion of the public comment period to address the information quality concern that EPA ignored in the final RE. We refer EPA to page 3 of RFC #23001, which states:

> **Since providing comments to OPPT, the NMP Producers Group funded an independent peer-review panel of the three two-generation reproduction toxicity studies.** The panel was convened by a third-party consultant. The independent peer-review panel included technical experts on the evaluation of these types of studies and the application of these types of data for regulatory risk assessments. The experts utilized the study quality criteria provided in EPA's ORD Staff Handbook for Developing IRIS Assessments to evaluate each of the three studies. **The experts concluded that Exxon (1991) "should not be considered for quantitative risk assessment of NMP."** (Emphasis added.)

The blinded panel of six experts included two former career EPA employees. In addition, the NMP Producers Group re-evaluated the chronic occupational exposure scenarios for workers and ONUs using the alternative points of departure identified by Kirman *et al*. As demonstrated in the RFC, using the points of departure that represent the best available science and weight of scientific evidence changes the unreasonable risk determination for some conditions of use and, more importantly, provides a more accurate description of the potential for unreasonable risk, which must be reflected in OPPT's risk management decisions for NMP.

EPA's IQG does not preclude stakeholders from submitting an RFC with information that only became available after public comments.[28] This additional information (the independent peer review) was developed explicitly to address EPA's lack of rigor in assessing the quality of the studies, so there was no reason for the NMP Producers Group to conduct the independent peer review prior to the issuance of EPA's final RE.

EPA's assertion that it had addressed previously the issues raised in the RFC is clearly erroneous; this would have been impossible. It is evident that EPA did not review the RFC substantively before concluding in error that EPA already reviewed and addressed the issues raised. The FOIA responsive records confirm this finding. The independent peer review of the final NMP RE in Kirman *et al.* (2023) was only needed because EPA's response to public comments dismissed significant information quality concerns and is directly relevant to EPA's compliance with IQG requirements. In short, EPA's past responses to public comments could not have been responsive to the concerns raised in the RFC.

---

[28] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, at Section 8.5.

Moreover, the NMP Producers Group's past submission of public comments alone was not a basis to deny the RFC. OMB and EPA's guidelines identify specific circumstances where EPA can deny an RFC. OMB states that agencies can "reject claims made in bad faith or without justification."[29] EPA's IQG under Section 8.3 also states that EPA may decline to review a request that is frivolous (including claims made in bad faith, without justification, or trivia claims) "and for which a response would be duplicative."[30] None of these criteria applied to the Group's RFC or EPA's RFC response. EPA did not assert that the RFC was frivolous, and a cursory review of the request would have confirmed that EPA's review and response would not be duplicative.

The NMP Producers Group's RFC and previous public comments were made in good faith, contained ample justification, and were not duplicative of any past submissions reviewed under EPA's IQG process. Accordingly, EPA had no basis to deny the RFC and must reverse its error.

B. The RFC Requested EPA Review of the NMP Producers Group's Past Public Comments and New Information under EPA's IQG; EPA Has Yet to Conduct Such Review

OMB's IQA guidelines state that agencies may integrate guideline procedures and requirements "into their existing information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes."[31] Section 8.5 of EPA's IQG permits EPA to respond directly to public comments that raise information quality concerns rather than through a separate response mechanism.

OMB establishes another key requirement -- and one that EPA ignored here. Agencies that merge new IQA requirements with existing procedures must **"ensure that their administrative mechanisms satisfy the standards and procedural requirements in the new agency guidelines**."[32] This includes the requirements under both OMB and EPA's guidelines that

---

29 67 Fed. Reg. at 8458.

30 EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, at Section 8.3.

31 67 Fed. Reg. at 8453.

32 *Id.* (emphasis added).

EPA must establish an administrative appeal process so that stakeholders can seek an objective review of EPA's initial decision.[33]

EPA relied solely on Section 8.5 of EPA's IQG to deny the RFC. EPA asserted that public comment periods throughout the TSCA RE process serve the purpose of EPA's IQG by providing an opportunity to seek correction of information that does not comply with information quality standards. Though EPA asserts that submitting public comments on the NMP RE was a more appropriate mechanism to receive a response from EPA than submitting the RFC, EPA ignores the fact that it repeatedly dismissed, failed to refute, or improperly addressed numerous public comments raising information quality concerns to EPA.

EPA cannot claim that its public comment process is an equivalent substitute for its IQG process unless EPA reviews and responds to public comments using IQG protocols. To be "duplicative," commonly understood as meaning "effectively identical," EPA's response to public comments would need to be identical to a response to an RFC. This did not occur here. EPA's responses to the NMP Producers Group's public comments did not extend to the new information in the RFC. EPA also did not review the Group's public comments under EPA's IQG. If all of the NMP Producers Group's scientific concerns had been resolved in EPA's response to comments, there would have been no need to submit the RFC. Accordingly, EPA cannot summarily decline to review the RFC under EPA's IQG on this basis.

EPA's assertion that it can deny an RFC based on the mere availability of a public comment process does not effectuate OMB's recommendation that EPA integrate guideline procedures into existing review mechanisms. Instead, it creates a loophole where EPA can evade review under OMB and EPA's information quality standards and without accountability for responding substantively and transparently to all comments received during a public comment period. OMB and EPA's IQA guidelines establish an express mechanism for stakeholders to pursue relief on final decisions issued by EPA, which extends to decisions made after notice and comment that fail to comply with those guidelines.

The FOIA responsive records, specifically e-mails of internal conversations and communication between EPA and OMB, show that EPA was focused on finding a justification to deny the RFC quickly and without review. The fact that staff at EPA celebrated finding such a mechanism is, in our view, evidence that EPA was not at all interested in considering the concerns

---

[33] *Id.* at 8459; EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, at Section 8.6.

put forth in the RFC nor whether its RE of NMP indeed meets EPA's IQG. EPA's non-substantive dismissal of the RFC demonstrates a lack of due diligence in ensuring that EPA is upholding its own scientific integrity standards and in meeting the information quality standards. EPA has yet to issue a response to the NMP Producers Group (either in response to its public comments, and now to its RFC) that complies with OMB and EPA's guidelines.

As noted in the RFC, the NMP Producers Group submitted extensive comments and information to EPA on the NMP RE, including the following:

- NMP Producers Group, *Re: Comments on Use and Exposure Information for N-Methylpyrrolidone, Docket ID Number EPA-HQ-OPPT-2016-0743*, EPA Docket No. EPA-HQ-OPPT-2016-0743-0010 (Mar. 2017), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0743-0010.

- NMP Producers Group, *Re: Comments on Draft Risk Evaluation for N-Methylpyrrolidone for Consideration at December 2019 Science Advisory Committee on Chemicals (SACC) Review (EPA-HQ-OPPT-2019-0236)*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0033 (Nov. 2019), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0236-0033.

- NMP Producers Group, *Re: Comments on Draft Risk Evaluation for N-Methylpyrrolidone (EPA-HQ-OPPT-2019-0236)*, EPA Docket No. EPA-HQ-OPPT-2019-0236-0057 (Jan. 2020), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0236-0057.

- NMP Producers Group, *Re: N-Methylpyrrolidone; Draft Revision to Toxic Substances Control Act Risk Determination; Docket EPA-HQ-OPPT-2016-0743*, EPA Docket No. EPA-HQ-OPPT-2016-0743-0135 (Aug. 2022), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0743-0135.

SACC had raised similar information quality concerns.[34] EPA's response to public comments on the December 2020 NMP RE acknowledged but ultimately disregarded the issues

[34] EPA (2020b), *Transmittal of Meeting Minutes and Final Report for the Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals N-Methylpyrrolidone*

raised by the NMP Producers Group and SACC.[35] In the final NMP RE, EPA based its determination of unreasonable risk on the chronic point of departure it identified from Exxon (1991), effectively "denying" the need for corrective action in response to public comments.[36]

Even in the absence of the new information, the NMP Producers Group's RFC was warranted to obtain IQG review of the Group's public comments. At no point during the public comment process did EPA treat the Group's public comments as equivalent to an RFC. EPA neither affirmed in its response to comments that the final RE complied with IQG criteria nor provided a basis for its denial of the requested corrections that complied with IQG requirements. EPA did not notify the NMP Producers Group of the opportunity to appeal EPA's decision under the IQG process. The NMP Producers Group addresses EPA's response to its public comments and substantive issues EPA has not yet addressed in Exhibit 3.

EPA's dismissal of the NMP Producers Group's public comments occurred in the context of ongoing discussions regarding the submission of two studies sponsored by the Group (NMP Producers Group 1999a, 1999b). This background was explained in the public comments cited in the RFC and referenced in EPA's response to public comments.[37] EPA's decision to rely on Exxon (1991) in the 2019 draft RE and the 2020 final RE, despite significant data quality concerns, was based on the timely availability of the two studies funded by the Group.[38] The Group and EPA held extensive conversations about how the Group could provide the full studies for

---

Meeting held December 5-6, 2019, OCSPP, at 16, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2019-0236-0066/content.pdf.

35 EPA, *Summary of External Peer Review and Public Comments and Disposition for n-Methylpyrrolidone (NMP)*, EPA Docket No. EPA-HQ-OPPT-2016-0743-0121 at 104-107 (Dec. 2020), available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0121.

36 EPA (2020a), *Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidone, 1-Methyl-) (NMP) CASRN: 872-50-4*, EPA Document # EPA-740-R1-8009, at 267.

37 EPA, *Summary of External Peer Review and Public Comments and Disposition for n-Methylpyrrolidone (NMP)*, EPA Docket No. EPA-HQ-OPPT-2016-0743-0121 at 104.

38 *See* EPA, EPA response to NMP Producers Group (March 9, 2020), EPA Docket No. EPA-HQ-OPPT-2016-0743-0108, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0108.

EPA's review while protecting the value of the studies.[39] EPA had asserted that unless it received complete, unredacted versions of the study reports, EPA would continue to rely on Exxon (1991). Upon receipt of the two studies, EPA continued to rely on Exxon (1991) in the final RE, despite evidence showing that EPA's characterization of Exxon (1991) as a "high-quality" study was demonstrably false.

EPA's inaction appears to be based on perceived time and resource constraints rather than the weight of the evidence. EPA's rationale, for example, in rejecting calls to revise the final RE to ensure compliance with TSCA Section 26 is that it cannot delay its final RE and associated Risk Determination due to the statutory deadlines.[40] There is no explanation, however, for why EPA will not allocate time or cause "delays" to correct violations of statutory scientific standards but *will do so* to apply new *policy* changes.

In 2021, EPA announced that it was withdrawing and reconsidering the final 2020 NMP Risk Determination and did not publish the updated final Risk Determination until 2022.[41] In that document, EPA repeats cursorily its view that the final RE is based on the "best available science and based on the weight of scientific evidence" without addressing the scientific points raised by the NMP Producers Group or the additional information available to EPA at that time. EPA argues both that it can delay the Risk Determination by two years, but that considering the weight of scientific evidence during that time would unduly delay its progress towards risk management. The position taken by EPA is evidence that EPA had no intention of considering

---

39 Once the Group and EPA could agree on a method that protects the value of the study while making the outcome of the studies public, the Group submitted both studies to EPA. The outcome of those discussions was eventually memorialized in EPA's Confidential Business Information (CBI) rule.

40 EPA, "n-Methylpyrrolidone (NMP); Revision to Toxic Substances Control Act (TSCA) Risk Determination Response to Public Comments," EPA Document No. EPA-HQ-OPPT-2016-0743-0146 (Dec. 2022) at 3.

41 EPA, "EPA Announces Path Forward for TSCA Chemical Risk Evaluations" (June 2021) https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations; "n-Methylpyrrolidone (NMP); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment," 87 Fed. Reg. 39511 (July 1, 2022); "n-Methylpyrrolidone (NMP); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability," 87 Fed. Reg. 77596 (Dec. 19, 2022).

seriously the scientific arguments made by the Group despite the additional two-year delay in EPA's progress towards taking risk management action.

C. The Availability of Public Comment Opportunities on EPA's NMP RMR Does Not Justify Denial of an RFC on EPA's NMP RE

The final RE for NMP, as it stands, contains information that does not accord with information quality standards. This correction process affords the public with an opportunity to rectify discrepancies and to seek reconsideration of EPA decisions. EPA's RE must adhere on its own to the standards of quality, utility, objectivity, and integrity. Future public comment opportunities on EPA RMRs have no bearing on an RFC for a final RE.

In dismissing the RFC, EPA referenced the opportunity to submit comments on the proposed NMP RMR as a more appropriate mechanism for the NMP Producers Group to seek correction of the RE. If not disingenuous, directing the Group to resubmit its RFC as a comment on the proposed RMR to receive EPA consideration was unjustifiably inefficient. If EPA intends to carry out this deferred review, EPA may be asserting that it could modify the final RE using TSCA Section 6(a) risk management rulemaking procedures. It is not clear that TSCA provides this authority. The RE, completed under Section 6(b)(4)(A), is the underlying predicate for risk management. TSCA Section 6(a) directs EPA to apply one or more requirements "to the extent necessary" to address the risk identified in its RE. If the RE is flawed, the RMR will be similarly flawed. If public comments on a proposed RMR raise quality concerns relating to the underlying RE, EPA must still correct the RE. EPA does not have the authority to disregard an unreasonable risk determination in the RE during the risk management rulemaking process, even if EPA agrees retrospectively with quality concerns regarding the final RE.

To that end, EPA raised concerns about duplicating efforts. If EPA has before it an IQG-compliant RFC regarding a RE, there is no basis for EPA not to address those information quality concerns as soon as possible, rather than expend its resources to develop a proposed RMR using a flawed RE, and then asking the submitter to *duplicate its efforts* by *resubmitting the same RFC* as a public comment. By that time, granting such RFC would require EPA to both reopen the RE *and* revise its RMR. EPA's IQG established the RFC process to provide this safeguard and ultimately improve efficiency and conserve Agency resources.

We believe that if EPA had responded to the NMP Producers Group's comments on the draft NMP RE in accordance with EPA's IQG, EPA would have addressed the RFC made during the public comment process. Even if EPA had denied the request at that time, the NMP Producers Group would have still submitted this RFC, because the RFC is based on new, peer-reviewed information demonstrating the need for correction. When EPA summarily denied the

RFC without review, it told the NMP Producers Group to resubmit its RFC in the form of public comments on EPA's proposed NMP RMR, without any guarantee that EPA can or will respond pursuant to EPA's IQG. Accordingly, we request that EPA grant this RFR and the NMP Producers Group's RFC.

V. Recommendation for Corrective Action

BCCM and the NMP Producers Group further request that EPA review the RFC and consider the expert panel evaluation and conclusions presented in Kirman *et al*. (2023) for identifying points of departure that satisfy the scientific standards under TSCA. BCCM and the NMP Producers Group respectfully request that EPA correct the final NMP RE by removing Exxon (1991), a non-reproducible study, as the basis for evaluating chronic exposure scenarios.

VI. Contact Information

Pursuant to Section 8.6 of the IQG, the NMP Producers Group provides below the name and contact information of the individual serving as a contact for the organization:

Name: Heather J. Blankinship
Title: Consortium Manager, NMP Producers Group
Address: 2200 Pennsylvania Avenue NW, Suite 100W, Washington, DC 20037
E-mail: hblankinship@bc-cm.com
Tel: (202) 557-3831

VII. Conclusion

EPA dismissed the RFC without conducting a substantive review based on the erroneous assumption that it had already addressed the request in response to public comments in the NMP RE. EPA's decision did not comply with OMB or EPA's IQA guidelines and should be reversed.

The NMP Producers Group has raised significant quality concerns under IQA guidelines and TSCA's scientific standards that have not been addressed, incorporated, or refuted by EPA and that remain in the final RE for NMP despite the Group's numerous attempts to bring the scientific weaknesses to EPA's attention. We urge EPA to reconsider the RFC under the IQA standards that require EPA to ensure the transparency and reproducibility of information and to take immediate action to correct the NMP RE.

BCCM appreciates the opportunity to provide this RFR on behalf of the NMP Producers Group. We remain committed to working with EPA on the issues outlined in RFC #23001 and look forward to EPA's timely response.

Respectfully submitted,

Heather J. Blankinship

Heather J. Blankinship
Consortium Manager
NMP Producers Group

Attachments