NMP
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MANAGED BY B&C® CONSORTIA MANAGEMENT, L.L.C.

April 19, 2023

Via E-Mail

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

Re: Request for Correction of Information on the Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone

B&C® Consortia Management, L.L.C. (BCCM) submits on behalf of the N-Methylpyrrolidone Producers Group, Inc. (NMP Producers Group) this request for correction of information (RFC) related to the final "Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP) CASRN: 872-50-4" (Final NMP RE) issued by the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) in December 2020.[1] This RFC is submitted under the Information Quality Act (IQA) and the implementing guidelines issued by the Office of Management and Budget (OMB) and EPA.[2,3,4]

Prior to submitting this RFC, the NMP Producers Group provided extensive comments to OPPT's request for information/comments on the use of NMP for establishing the

[1] 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.

[2] 44 U.S.C. § 3516, available at https://www.govinfo.gov/content/pkg/USCODE-2008-title44/pdf/USCODE-2008-title44-chap35-subchapI-sec3516.pdf.

[3] 67 Fed. Reg. 8452 (Feb. 22, 2002), available at https://www.govinfo.gov/content/pkg/FR-2002-02-22/pdf/R2-59.pdf.

[4] EPA (2002), *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, EPA/260R-02-008 (October 2002), available at https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf.

scope of the risk evaluation, the draft risk evaluation, and the draft revised risk determination, that was re-issued after the Final NMP RE.[5,6,7,8] The NMP Producers Group was disappointed that OPPT neither incorporated the NMP Producers Group's comments nor refuted its points in OPPT's Final NMP RE. The fundamental concern, and the basis for this RFC, is OPPT's continued inappropriate reliance on effects from a two-generation reproduction toxicity study in rats (*i.e.*, Exxon 1991)[9] that were not reproducible in two subsequent two-generation reproduction toxicity studies in rats (*i.e.*, NMP Producers Group 1999a,b).[10,11] Our position remains unwavering that

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5 NMP Producers Group (2017), *Re: Comments on Use and Exposure Information for N-Methylpyrrolidone*, Docket ID Number EPA-HQ-OPPT-2016-0743, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2016-0743-0010/attachment_1.pdf.

6 NMP Producers Group (2019), *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)*, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2019-0236-0033/attachment_1.pdf.

7 NMP Producers Group (2020), *Re: Comments on Draft Risk Evaluation for N-Methylpyrrolidone (EPA-HQ-OPPT-2019-0236)*, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2019-0236-0057/attachment_1.pdf.

8 NMP Producers Group (2022), *Re: N-Methylpyrrolidone; Draft Revision to Toxic Substances Control Act Risk Determination*; Docket EPA-HQ-OPPT-2016-0743, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2016-0743-0135/attachment_1.pdf.

9 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.

10 NMP Producers Group (1999a), *Two Generation Reproduction Toxicity Study with N-Methylpyrrolidone (NMP) in Sprague Dawley Rats -- Administration in the Diet*, full reference available at https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/3809436.

11 NMP Producers Group (1999b), *Two Generation Reproduction Toxicity Study with N-Mythylpyrrolidone [sic] (NMP) in Wistar Rats -- Administration in the Diet*, full reference available at https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/3809437.

OPPT's reliance on the unreproducible findings in Exxon (1991) violates the IQA and the scientific standards under Toxic Substances Control Act (TSCA) Section 26.

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.[12] The experts concluded that Exxon (1991) "should not be considered for quantitative risk assessment of NMP."[13] *See* attached publication titled "An evaluation of reproductive toxicity studies and data interpretation of N-methylpyrrolidone for risk assessment: An expert panel review."

Below, BCCM provides detailed information to support this request according to the information EPA requires for an RFC.

1. Name and contact information for the individual or organization submitting a complaint; identification of an individual to serve as a contact.

Name: Heather J. Blankinship
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2. A description of the information the person believes does not comply with EPA or OMB guidelines, including specific citations to the information and to the EPA or OMB guidelines, if applicable.

The June 22, 2016, amendments to TSCA require EPA under Section 6 to initiate risk evaluations on ten chemical substances selected from the 2014 update of the Work Plan for

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12 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.

13 *Id*. at 1.

Chemical Assessments and to publish this list of ten chemical substances within 180 days of enactment of the TSCA amendments.[14] On December 19, 2016, OPPT published the list of ten chemical substances, which included NMP.[15] Thereafter, OPPT released on November 7, 2019, the draft risk evaluation for NMP with a request for comment.[16]

On December 30, 2020, OPPT announced the availability of the Final NMP RE.[17] OPPT stated in that announcement that it was required, for those conditions of use (COU) for which unreasonable risks were identified, to "initiate regulatory action to address those risks through risk management measures enumerated in 15 U.S.C. 2605(a) [*i.e.*, TSCA Section 6(a)]."[18] OPPT subsequently issued for public comment a draft revision to the risk determination in the Final NMP RE, concluding that three additional COUs (*i.e.*, 29 COUs out of 37 evaluated) would drive an unreasonable risk determination for the "whole chemical."[19] OPPT published the final revision to the risk determination, that included verbatim the proposed revisions to the risk determination, on December 19, 2022.[20]

OPPT based its determination of unreasonable risk for the COUs on the chronic point of departure it identified from Exxon (1991).[21] This study was a point of contention, not only during the public comment period for the draft risk evaluation[22,23] and draft revised risk

14 81 Fed. Reg. 91927 (Dec. 19, 2016).

15 *Id*. at 91929.

16 84 Fed. Reg. 60087 (Nov. 7, 2019).

17 85 Fed. Reg. 86558 (Dec. 30, 2020).

18 *Id*. at 86559.

19 87 Fed. Reg. 39511 (July 1, 2022).

20 87 Fed. Reg. 77596 (Dec. 19, 2022).

21 EPA (2020a), *supra* note 1, at 267.

22 *See, e.g.*, NMP Producers Group (2019), *supra* note 6, at 2-4.

23 *See, e.g.*, NMP Producers Group (2020), *supra* note 7, at 5-9.

determination,[24] but also in the peer review by EPA's TSCA Science Advisory Committee on Chemicals (SACC).

The SACC noted several issues with this study and with OPPT's summary of Exxon (1991). For example, the final report for the SACC review of the draft risk evaluation stated that "The [SACC] discussed reproductive toxicity in terms of male and female fertility and found it difficult to come to any conclusions given the complexity and sometime [*sic*] lack of transparency in the data and analysis provided in the Exxon 1991 study."[25] The SACC report further stated that "The [SACC] found the Exxon (1991) study difficult to read and interpret. [The SACC noted that] The [EPA's] Evaluation disagreed with the conclusions of the study [authors] regarding male and female fertility effects."[26]

Based on the foregoing facts, BCCM concludes that the IQA applies, because the Final NMP RE is information that EPA disseminated to the public.[27] BCCM further notes that the Final NMP RE is "influential" scientific information, because EPA is required under TSCA Section 6 to propose and promulgate a regulation that mitigates the unreasonable risks identified by OPPT in the Final NMP RE. This regulation will have a "clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions."[28] It is imperative, therefore, that OPPT base its risk management actions on the best available science and weight of scientific evidence and not rely on non-reproducible science, as it did in the Final NMP RE. Otherwise, OPPT is likely to set exposure limits based on flawed scientific results.

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24 *See, e.g.*, NMP Producers Group (2022), *supra* note 8, at 28-30.

25 EPA (2020c), *Transmittal of Meeting Minutes and Final Report for the Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals N-Methylpyrrolidone Meeting held December 5-6, 2019*, OCSPP, at 16, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2019-0236-0066/content.pdf.

26 *Id*. at 51.

27 EPA (2002), *supra* note 4, at 15.

28 *Id*. at 19.

3. An explanation of how the information does not comply with EPA or OMB guidelines and a recommendation of corrective action. EPA considers that the complainant has the burden of demonstrating that the information does not comply with EPA or OMB guidelines and that a particular corrective action would be appropriate.

OPPT's selection of Exxon (1991) violates the scientific standards under TSCA Section 26, as explained below. These standards do not supersede the requirements under the IQA or EPA's requirements for complying with the IQA. The scientific standards under TSCA Section 26 are, however, consistent with the intent of the IQA for "Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the [EPA]."[29]

TSCA Section 26 includes the following requirements for "best available science" and "weight of scientific evidence":[30]

> (h) Scientific standards
>
> In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science …
>
> (i) Weight of scientific evidence
>
> The Administrator shall make decisions under sections 2603, 2604, and 2605 of this title based on the weight of the scientific evidence.

EPA interpreted TSCA Section 26(i) in the final "Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act" (the "Final RE Rule") as:[31]

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29 EPA (2002), *supra* note 4, at 1.

30 TSCA § 26(h)-(i), 15 U.S.C. § 2625(h)-(i).

31 82 Fed. Reg. 33726, 33748 (July 20, 2017) (emphasis added), available at https://www.govinfo.gov/content/pkg/FR-2017-07-20/pdf/2017-14337.pdf.

> *Weight of scientific evidence means a systematic review method*, applied in a manner suited to the nature of the evidence or decision, *that uses a pre-established protocol* to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and *to integrate evidence* as necessary and appropriate based upon strengths, limitations, and relevance.

To satisfy the scientific standards under TSCA Section 26 and the Final RE Rule when conducting risk evaluations, EPA released a document in May 2018 titled "Application of Systematic Review in TSCA Risk Evaluations" (2018 SR Document).[32] EPA used the 2018 SR Document for each of the "first 10" risk evaluations, including the risk evaluation on NMP. For example, the Final NMP RE states:[33]

> To meet these TSCA Section 26 science standards [*i.e.*, best available science and weight of the scientific evidence], EPA used the TSCA systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document.

Prior to completing the "first 10" risk evaluations, OPPT requested that the National Academies of Science, Engineering, and Medicine (NASEM) review the 2018 SR Document. In February 2021, NASEM released its consensus study report (Consensus Study Report) on OPPT's 2018 SR Document and concluded that it did not meet the criteria of "comprehensive, workable, objective, and transparent" and that "The OPPT approach to systematic review does not adequately meet the state-of-practice."[34]

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32 EPA (2018), *Application of Systematic Review in TSCA Risk Evaluations*, EPA Document # 740-P1-8001, OCSPP (May 2018), available at https://www.epa.gov/sites/default/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.

33 EPA (2020a), *supra* note 1, at 21 (citation omitted).

34 NASEM (2021), *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, Consensus Study Report, Highlights*, at 4, available at https://www.nap.edu/resource/25952/TSCA%204-pager%20final.pdf.

NASEM recommended that "With regard to hazard assessment for human and ecological receptors, OPPT should step back from the approach that it has taken and consider components of the OHAT,[35] IRIS,[36] and Navigation Guide methods that could be incorporated directly and specifically into hazard assessment."[37] NASEM further stated that "OPPT also should evaluate how the existing OHAT, IRIS, and Navigation Guide methods could be modified for the other evidence streams."[38]

In response to the NASEM review, OPPT revised its systematic review method. On December 20, 2021, EPA released the 2021 Draft Protocol for public comment.[39] OPPT acknowledged in the 2021 Draft Protocol that:[40]

> Previously [in the 2018 SR Document], EPA did not have a complete clear and documented TSCA systematic review (SR) Protocol. EPA is addressing this lack of *a priori* protocol by releasing [the 2021 Draft Protocol].

OPPT further stated that the:[41]

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35 OHAT is the abbreviation for the U.S. National Toxicology Program's Office of Health Assessment and Translation (OHAT).

36 IRIS is the abbreviation for EPA's Integrated Risk Information System (IRIS).

37 Consensus Study Report at 4.

38 *Id*.

39 86 Fed. Reg. 71891 (Dec. 20, 2021), available at https://www.govinfo.gov/content/pkg/FR-2021-12-20/pdf/2021-27437.pdf.

40 EPA (2021), *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0, A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies* (2021 Draft Protocol), OCSPP, EPA Document # EPA-D-20-031 (Dec. 2021) at 25, available at https://www.epa.gov/system/files/documents/2021-12/draft-systematic-review-protocol-supporting-tsca-risk-evaluations-for-chemical-substances_0.pdf.

41 *Id*. at 27.

> [2021 Draft Protocol] is significantly different [from the 2018 SR Document] in that it includes descrition [*sic*] of the Evidence Integration process …, which was not previously included in the [2018 SR Document].

We recognize that the scientific methods used to inform systematic review are not static and that updates will be required as the science evolves. In this instance, however, many of the documents cited as supporting information for updating the 2021 Draft Protocol (*e.g.*, OHAT 2015)[42] were available prior to EPA issuing the 2018 SR Document. NASEM recognized this and concluded that:[43]

> In the committee's judgment, the specific and general problems in TSCA risk evaluations are partially due to the decision to develop a largely de novo approach, rather than starting with the foundation offered by approaches that were extant in 2016.

Rather than using these documents at the time, OPPT developed the 2018 SR Document *de novo*. In other words, OPPT chose to develop its own methodology in 2018, rather than incorporating and adapting existing methodologies that represented the best available science at the time. These problems were pervasive in the first ten risk evaluations. For example, OPPT provided NASEM with example risk evaluations to assess during its review. One of the example risk evaluations was the draft risk evaluation of trichloroethylene (TCE), which OPPT described as representing the "best example of

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42 OHAT (2015), *Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration*, Division of the National Toxicology Program (NTP), National Institute of Environmental Health Sciences (Jan. 9, 2015), available at https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookjan2015_508.pdf.

43 NASEM (2021), *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations*, Washington, D.C.: National Academies Press, at 7, available at https://nap.nationalacademies.org/catalog/25952/the-use-of-systematic-review-in-epas-toxic-substances-control-act-risk-evaluations.

integration,"[44] among the available risk evaluations. NASEM disagreed and concluded that:[45]

> [T]he hazard assessment within the TSCA TCE risk evaluation was of critically low quality, meaning that the review had "more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies."

Though NASEM did not evaluate the risk evaluation for NMP, OPPT's hazard assessment in the Final NMP RE supports that it is also of critically low quality and inconsistent with the scientific standards of TSCA Section 26. For example, OPPT first began evaluating NMP under TSCA in 2012 as a work plan chemical risk assessment. OPPT subsequently published the final work plan chemical risk assessment for NMP in 2015.[46] As part of its hazard assessment at that time, OPPT concluded that the reproduction and developmental study performed by Sitarek and Stetkiewicz (2008) was "unreliable" due to inconsistencies in the published data.[47] In comparison, in the Final NMP RE, OPPT assigned a data quality rating of "High" to Sitarek and Stetkiewicz (2008).[48] Under the systematic review method used in the Final NMP RE, a data quality rating of High was defined to mean:[49]

> No notable deficiencies or concerns are identified in the domain metric that are likely to influence results [score of 1].

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44 *Id*. at 2.

45 *Id*. at 52 (citation omitted).

46 EPA (2015), *N-Methylpyrrolidone: Paint Stripper Use, CASRN 872-50-4, TSCA Work Plan Chemical Risk Assessment*, OCSPP, EPA Document # 740-R1-5002, available at https://www.epa.gov/sites/default/files/2015-11/documents/nmp_ra_3_23_15_final.pdf.

47 *Id*. at 58.

48 EPA (2020a), *supra* note 1, at 227.

49 EPA (2018), *Application of Systematic Review in TSCA Risk Evaluations*, OCSPP, EPA Document # 740-P1-8001, at 33, available at https://www.epa.gov/sites/default/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.

OPPT did not, however, provide its rationale for reassigning a data quality rating of High to Sitarek and Stetkiewicz (2008) in the Final NMP RE, nor did OPPT mention the inconsistencies between its conclusions on this study in the work plan chemical risk assessment versus the risk evaluation. A more problematic example in the Final NMP RE is OPPT's evaluation and use of a two-generation oral dietary study in rats, designated by OPPT as "Exxon (1991)" and discussed below.

OPPT assigned a data quality rating of High to Exxon (1991) in the Final NMP RE and used the data on decreased fertility from this study as the basis for quantifying chronic risks. As with the study performed by Sitarek and Stetkiewicz (2008), however, OPPT's evaluation of the Exxon (1991) study in the Final NMP RE conflicted with its previous evaluation of Exxon (1991) in the final work plan chemical risk assessment for NMP in 2015, and with previous OPPT evaluations of this study. For example, OPPT concluded in the final work plan chemical risk assessment for NMP that development effects were the most relevant for quantifying risks, because the reproductive toxicity findings (*e.g.*, decreased fertility) "lack[ed] consistency in findings, when looking at the complete database."[50] Further, OPPT evaluated the Exxon (1991) study under the Organization for Economic Cooperation and Development's (OECD) Screening Information Dataset (SIDS) Initial Assessment Report for NMP and assigned a data reliability score[51] of 2 (*i.e.*, reliable with restrictions).[52] In comparison, OPPT assigned a data reliability score of 1 (*i.e.*,

50 EPA (2015), *supra* note 46, at 51.

51 Reliability scores were assigned based on the scoring system developed by Klimisch *et al*. (1997) and summarized in European Chemicals Agency (ECHA) (2011), *Chapter R.4: Evaluation of available information*, Version 1.1, Guidance on Information Requirements and Chemical Safety Assessment, at 1 (PDF at 7), available at https://echa.europa.eu/documents/10162/17235/information_requirements_r4_en.pdf/d6395ad2-1596-4708-ba86-0136686d205e?t=1323782558175.

52 OECD (2007), *1-methyl-2-pyrrolidinone, SIDS Initial Assessment Report for SIAM 24, 19-20 April 2007, Paris, France*, at 41, available at https://hpvchemicals.oecd.org/ui/SponsoredChemicals.aspx (click "Pyrrolidinone, 1-methyl- (CAS 872-50-4), then click on file titled "SIDS_872504.zip").

reliable without restrictions) to the subsequent two-generation studies that were unable to reproduce the findings of decreased fertility from the Exxon (1991) study.[53]

These discrepancies with OPPT's evaluations of Sitarek and Stetkiewicz (2008) and Exxon (1991) in the Final NMP RE are problematic. OPPT did not use established systematic review methods when evaluating these studies in the work plan chemical risk assessment for NMP, nor did OPPT use a systematic review method when evaluating Exxon (1991) in the SIDS Initial Assessment Report for NMP. Therefore, it is unclear how OPPT concluded that these studies warranted higher data quality and reliability ratings under its application of the 2018 SR Document as used in the Final NMP RE, recognizing that such a method should be more, not less, critical of the quality and reliability of the studies.

OPPT does not explain in the final revised risk determination for NMP if or when OPPT will remedy the failure to conduct properly a robust systematic review and update the Final NMP RE as warranted by the result of that review. In fact, OPPT stated the following, which supports an interpretation that it does not intend to do so:[54]

> EPA views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

Further, OPPT has chosen to issue the final revised risk determination for NMP when there is reasonably available information that the Semiconductor Industry Association filed with OPPT that would change OPPT's conclusions of unreasonable risks under multiple conditions of use.[55] As of the date of this RFC, OPPT has not provided its evaluation and conclusions on this information. OPPT's decision to issue the final revised risk determination for NMP with open scientific questions that are informed by reasonably

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53 *Id*. at 40 (citing NMP Producers Group, 1999b [identified as "1999a" herein] and NMP Producers Group, 1999c [identified as "1999b" herein]).

54 87 Fed. Reg. at 77599.

55 Cardno (2021), *Review of TSCA Section 6 Risk Evaluation of the Conditions of Use of NMP in the Semiconductor Industry* (May 24, 2021), available at https://www.epa.gov/sites/default/files/2021-06/documents/final-chemrisk-review-nmp.pdf.

available information could lead to an inference that OPPT is using selectively information to arrive at a pre-determined outcome for the risk evaluation, the risk determination, and risk management. Using poor quality data to support a preferred outcome fails to meet the statutory standard regardless of whether the preferred outcome is more or less protective than that supported by the best available science.

4. An explanation of how the alleged error affects or how a correction would benefit the requestor.

BCCM re-evaluated the chronic occupational exposure scenarios for workers and occupational non-users (ONU).[56] For these scenarios, OPPT based its determination of unreasonable risk on the point of departure from Exxon (1991) (*i.e.*, 183 mg*hr/L blood).[57,58] In comparison, BCCM calculated the margins of exposure for each of these exposure scenarios using the alternative points of departure identified by Kirman *et al*. (2023) (*i.e.*, 410 mg*hr/L blood (EPA (2015)) or 470 mg*hr/L blood (Poet (2016)).[59]

Using the point of departure of 410 mg*hr/L of blood, BCCM recalculated the chronic worker scenario margins of exposure. BCCM identified 19 "What-if" exposure scenarios, 19 "Central Tendency" exposure scenarios, and six "High-end" exposure scenarios that indicate an acceptable level of risk (*i.e.*, margin of exposure above the benchmark of 30) for these exposure scenarios when using a point of departure of 410 mg*hr/L of blood. In comparison, OPPT identified unreasonable risks for these scenarios using the point of departure from Exxon (1991). *See* attached document labeled "Re-evaluation of worker and ONU COUs.xlsx" under "Chronic Worker" tab at column "I."

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56 EPA (2020d), *Supplemental Information File on Occupational Risk Calculations, Final Risk Evaluation for n-Methylpyrrolidone, CASRN: 872-50-4*, Microsoft Excel file name: 16._nmp_supplemental_information_file_on_occupational_risk_calculations_0.xlsx, available at https://www.epa.gov/sites/default/files/2020-12/16._nmp_supplemental_information_file_on_occupational_risk_calculations_0.xlsx.

57 EPA (2020a), *supra* note 1, at 264.

58 EPA (2020d), *supra* note 56, *see* "Chronic Worker" tab at column "Z" and "Chronic ONU" tab at column "Z."

59 Kirman *et al*. (2023), *supra* note 12, at 11.

BCCM performed the same evaluation using the alternative point of departure of 470 mg*hr/L of blood. BCCM identified 25 "What-if" exposure scenarios, 32 "Central Tendency" exposure scenarios, and seven "High-end" exposure scenarios that indicated an acceptable level of risk (*i.e.*, margins of exposure above the benchmark of 30). OPPT identified unreasonable risks for these scenarios using the point of departure from Exxon (1991). *See* attached document labeled "Re-evaluation of worker and ONU COUs.xlsx" under "Chronic Worker" tab at column "N."

BCCM performed the same evaluation on the exposure scenarios for Chronic ONUs in which OPPT identified seven scenarios with unreasonable risk. Using the point of departure of 410 mg*hr/L of blood, all the Chronic ONU margins of exposure were above the benchmark of 30. *See* attached document labeled "Re-evaluation of worker and ONU COUs.xlsx" under "Chronic ONU" tab at column "I."

BCCM notes that using the points of departure that represent the best available science and weight of scientific evidence does not change the unreasonable risk determination for every chronic worker scenario. The points of departure do, however, provide a more accurate description of the potential for unreasonable risk, which would impact OPPT's risk management decisions for NMP.

Based on the above information, BCCM respectfully requests that EPA correct the Final NMP RE by removing Exxon (1991), a non-reproducible study, as the basis for evaluating chronic exposure scenarios. BCCM further requests that EPA 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. Finally, BCCM requests that EPA share its draft response to this RFC with OMB prior to releasing the response.[60] BCCM notes that EPA's current plan to address RFCs during risk management rulemaking will not address adequately the scientific deficiencies in the Final NMP RE.[61] In fact, EPA's plan contradicts its own IQA guidelines, which

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60 OMB (2019), *Memorandum for the Heads of Executive Departments and Agencies, M-19-15, Subject: Improving Implementation of the Information Quality Act*, Executive Office of the President, at 10, available at https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.

61 Chemical Watch (2023) *Requests to 'correct' TSCA risk evaluations will be addressed in rulemaking, EPA says*, News, March 16, available at https://chemicalwatch.com/703577/requests-to-correct-tsca-risk-evaluations-will-be-addressed-in-rulemaking-epa-says.

state in part, "In cases where the Agency disseminates a study, analysis, or other information prior to the final Agency action or information product, it is EPA policy to consider requests for correction prior to the final Agency action …."[62]

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

Respectfully submitted,

Heather J. Blankinship

Heather J. Blankinship
Consortium Manager
NMP Producers Group

Attachments:

Kirman *et al*. 2022.pdf
Re-evaluation of worker and ONU COUs.xlsx

62 EPA (2002) *supra* note 4, at 32.