



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 15, 2023

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Heather J. Blankinship
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Semiconductor Industry Association (SIA)
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Via Email: hblankinship@bc-cm.com

Dear Ms. Blankinship:

This letter is the response to the Request for Correction (RFC), dated April 19, 2023, and assigned **RFC # 23001** for tracking purposes¹, that was submitted to the U.S. Environmental Protection Agency pursuant to EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA² (EPA IQG). In the RFC, the NMP Producers Group/SIA seeks the correction of information in the following EPA document disseminated by the Office of Pollution Prevention and Toxics:

“Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP), CASRN: 872-50-4 issued pursuant to section 6 of the Toxic Substances Control Act (TSCA) in October 2020 (herein after referred to in this response as the “NMP Risk Evaluation”)³.

In requesting that the NMP Risk Evaluation be corrected, the NMP Producers Group/SIA claims that the agency continued to rely on effects from a 1991 two-generation reproduction toxicity study in rats⁴ that were not reproducible in two subsequent two-generation reproduction toxicity studies in rats performed by the NMP Producers Group in 1999⁵. NMP Producers Group/SIA claims this violates the Information Quality Act and the scientific standards under section 26 of the Toxic Substances Control Act.

The EPA IQG outlines administrative mechanisms for the EPA's pre-dissemination review of information products and describes mechanisms to enable affected persons to seek and obtain corrections from the EPA regarding disseminated information that they believe does not comply with the EPA IQG or Office of Management and Budget (OMB) guidelines (i.e., OMB Information Quality

¹ A copy of the RFC is posted on the EPA IQG site at: <https://www.epa.gov/quality/rfc-21004-n-methylpyrrolidone-nmp>.

² <https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information>.

³ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-n-methylpyrrolidone-nmp#findings>.

⁴ Exxon Biomedical Sciences (1991), Multigeneration Rat Reproduction Study with NMethylpyrrolidone, Project Number 236535, full reference available at https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/3809420.

⁵ NMP Producers Group (1999a), Two Generation Reproduction Toxicity Study with NMethylpyrrolidone (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 and NMP Producers Group (1999b), Two Generation Reproduction Toxicity Study with NMethylpyrrolidone [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.

Guidelines and Memorandum M-19-15)⁶. EPA is committed to applying these guidelines, including each of the updates outlined in M-19-15 to the EPA IQG. The RFC process under the EPA IQG is intended to provide a mechanism to correct errors where the disseminated product does not meet information quality standards. The EPA IQG specifically states that it is not intended to duplicate or interfere with the orderly conduct of a process involving public comment opportunities that allow for the correction of any information that does not comply with the Guidelines⁷.

A key component of the TSCA Existing Chemical Risk Evaluation process is the reiterative public comment opportunities that are provided throughout each stage of the process, and EPA has concluded that the public comment process is integrated throughout the 3-stages of the TSCA Existing Chemical Risk Evaluation process. Those public comment opportunities serve the purposes of the EPA IQG by providing opportunities for the correction of any information that does not comply with the Guidelines. Public comment data, including EPA's responses, are made available through the web interface Regulations.gov, bulk comment data download feature, and Application Programming Interface (API).

After review of the RFC submitted by NMP Producers Group/SIA, EPA has concluded that the issues raised in this RFC are overlapping with comments and submissions received and addressed in the public comment opportunities⁸ (see pp 97-98; 104-107; 192-196). These were integrated in the TSCA Existing Chemical Risk Evaluation and Risk Management processes for NMP. In fact, your comments were submitted and addressed in the context of the TSCA Existing Chemical Risk Evaluation process. The additional studies were discussed at SACC public meeting and the NMP producers group submitted studies which were reviewed in response to your previous public comments received, see Appendix I, pp 525-531⁹ and systematic review of supplemental file¹⁰ pp 69-78. EPA has concluded that the issues raised in this RFC were appropriately addressed in the TSCA Existing Chemical Evaluation public comment period for NMP. EPA has also determined that the public comment period was a more appropriate mechanism for SIA to provide comments and receive a response from EPA, rather than through a separate response mechanism under the RFC process under EPA IQG. As such, EPA is denying your RFC.

Thank you for your interest in EPA's information quality. Should you have questions or need additional information about the EPA's IQG process, you may contact us via email to quality@epa.gov (our

⁶ <https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information>.

⁷ See Section 8.5 of the EPA IQG.

⁸ See pp 97-98; 104-107; 192-196. https://www.epa.gov/sites/default/files/2020-12/documents/2_summary_of_external_peer_review_and_public_comments_and_disposition_for_n-methylpyrrolidone_response_to_support_risk_evaluation_for_nmp.pdf.

⁹ See Appendix I, pp 525-531. https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.

¹⁰ See pp 69-78. https://www.epa.gov/sites/default/files/2020-12/documents/9_nmp_sr_supplemental_file_data_quality_evaluation_of_human_health_hazard_studies_animal_and_in_vitro_studies.pdf.

preferred method), or via regular mail to the EPA Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

Sincerely,

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Michal Freedhoff, Assistant Administrator

cc: Vaughn Noga, Chief Information Officer and Deputy Assistant Administrator for Environmental Information

Katherine Chalfant, Director of Enterprise Quality Management Division, Office of Mission Support