

OFFICE OF RESEARCH AND DEVELOPMENT

WASHINGTON, D.C. 20460

March 11, 2025

Dr. David A. Belluck Lost Science 2515 Smith Valley Road La Crosse, Wisconsin 54601

Dear Dr. Belluck:

This letter is in response to the Request for Correction (RFC) received by the U.S. Environmental Protection Agency (EPA) on August 17, 2024. The RFC request was assigned RFC 24002 for tracking purposes. In the RFC, you assert that the Integrated Risk Information System (IRIS) reference doses (RfDs) for nitrate (1991) and nitrite (1987) and the EPA's Maximum Contaminant Level (MCL; 1991) are not scientifically defensible for various reasons. As stated in the RFC, you also provided these comments to the Agency during the 2023 public comment period on the *Protocol for the Nitrate and Nitrite IRIS Assessment (Oral) (Preliminary Assessment Materials)*. As explained in more detail below, the EPA believes your comments are best considered through the Agency's ongoing efforts to develop a new IRIS assessment for nitrate and nitrite. Hence, the RFC is denied.

In 2017, the EPA announced the reassessment of the health effects of nitrate and nitrite and released the *IRIS Assessment Plan (IAP) for Nitrate and Nitrite* for public comment and discussion by the EPA's Science Advisory Board Chemical Assessment Advisory Committee. While the agency suspended the assessment in 2019, assessment efforts resumed in 2022, and the EPA released the *Protocol for the Nitrate and Nitrite IRIS Assessment (Oral) (Preliminary Assessment Materials)* for public comment in November 2023. The EPA is considering your December 2023 comments on the protocol as we develop the draft assessment, along with other comments received during the public comment period.

The EPA's <u>IRIS process</u> includes multiple opportunities for the public to provide comment and feedback on IRIS assessments under development. In addition to public comment opportunities on assessment plans and protocols, the public is also invited to provide comments on draft IRIS assessments when they are released for external peer review. We encourage you to follow the IRIS assessment development process by joining the EPA's <u>IRIS listserv</u> and by monitoring updates to the nitrate and nitrite assessment via the <u>IRIS Program Outlook</u>, which is updated three times a year (February, June, and October).

In July 2024, the EPA announced the results of the <u>fourth cycle of its Six-Year Review of existing</u> <u>national primary drinking water regulations</u> (NPDWRs). As part of the Six-Year Review, the EPA

evaluated available information for nitrate and nitrite to determine if any new information provided a basis to support a regulatory revision that would improve or strengthen public health protection. Based on the Agency's review, the EPA determined that the nitrate and nitrite NPDWRs were not appropriate for revision, noting the in-progress IRIS assessment. The Agency plans to evaluate whether a revision of the nitrate and nitrite NPDWRs is appropriate once the final nitrate and nitrite IRIS assessment is available.

Consistent with Section 8.5 of the EPA's <u>Information Quality Guidelines</u>, the Agency believes the thorough consideration of public comments throughout the IRIS process serves the purposes of the Guidelines, provides an opportunity for correction of any information that does not comply with the Guidelines, and does not duplicate or interfere with the orderly conduct of an IRIS assessment.

Your Right to Appeal

If you are dissatisfied with this response, you may submit a Request for Reconsideration (RFR) as described in the EPA's Information Quality Guidelines. The EPA requests that any such RFR be submitted within 90 days of the date of the EPA's response. If you choose to submit an RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Staff, Mail Code 2821T, U.S. EPA, 1200 Pennsylvania Ave., NW, Washington, DC 20460) or electronic mail (quality@epa.gov). If you submit an RFR, please reference the case number assigned to this original Request for Correction (RFC #24002). Additional information about how to submit an RFR is included in the EPA's Information Quality Guidelines.

Sincerely,

Maureen R. Gwinn, Ph.D. Acting Assistant Administrator

cc: Vaughn Noga, Chief Information Officer and Deputy Assistant Administrator for Information Technology/Information Management, Office of Mission Support Patrick Grimm, Deputy Office Director, Office of Records, Administrative Systems and e-Discovery, Office of Mission Support