

From: lostscience@yahoo.com <lostscience@yahoo.com>

Sent: Saturday, August 17, 2024 8:03 PM

To: Quality <Quality@epa.gov>

Cc: OIG.Hotline <OIG.Hotline@epa.gov>

Subject: Data quality problems with USEPA nitrate and nitrite RfDs and MCLs

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Greetings,

By various forms of communication I have informed numerous USEPA offices to individuals, over the last two years or more, that the nitrate and nitrite IRIS RfDs and Office of Drinking Water (not defunct) regulatory RfDs and MCLs were not scientifically defensible for various reasons. These reason may be found in my Federal Register response to requests for comments on the IRIS website (also found at [https://www.researchgate.net/publication/376613087 Toxicological Basis for Nitrate and Nitrite USEPA RfDs Lack Scientific Merit Submission to USEPA in Response to Call for Comments on Revisions to Nitrate and Nitrite Reference Doses RfDs](https://www.researchgate.net/publication/376613087_Toxicological_Basis_for_Nitrate_and_Nitrite_USEPA_RfDs_Lack_Scientific_Merit_Submission_to_USEPA_in_Response_to_Call_for_Comments_on_Revisions_to_Nitrate_and_Nitrite_Reference_Doses_RfDs)).

Many of the particulars in my FR submission demonstrate that USEPA knows or should have known that their two sets of nitrate and nitrite RfDs are based on two principal studies that are not peer reviewed, data extracted from these studies is not reviewable for data quality, much of the data cited for the dose-response curve and MCLs are not reliable, normal scientific practices were not used to publish these studies or review them for reliability by USEPA, mathematical errors are abundant, and the most fundamental precepts of good science were violated by USEPA. Thus, USEPA knew or should have known, no later than 1976, that the basis for their IRIS nitrate and nitrite RfDs as calculated by USEPA and by the mid-1980s that the basis for USEPA's nitrate and nitrite regulatory RfDs and MCLs (IRIS and ODW RfDs are different in narrative and numerical composition) are unreliable based on data quality issues. Such unreliability has, for many decades, been a key discriminator of the need to revise RfDs and MCLs.

USEPA has purposefully cordoned off any internal review of the basis for the hematological studies it cites for both sets of RfDs and one set of MCLs and their dose-response function. This goes against data quality and information quality laws, guidelines, and Agency requirements. USEPA is delaying immediate evaluation of the most critical data quality problems resulting in unneeded exposures to infants who are currently consuming nitrate and nitrite contamination levels that, were the errors and omissions simply fixed, would result in revised RfDs and MCLGs that would provide exposed individuals with immediate risk reduction.

By way of this email I submit a Request for Correction and Request for Reconsideration of the current RfDs and MCLs based on data quality issues that USEPA is aware of but is using risk management determinations to avoid immediate consideration of identified

data and information quality deficits in their technical support documentation. This violates both statute and various federal data quality and information requirements.

Every day that goes by infants are exposed to unacceptable levels of nitrate and nitrite in their drinking water or formula because of math and science errors in the USEPA RfDs and MCLs are not being corrected. Based on our analysis of the data and proper use of math, science, and USEPA UF/MF procedures, the RfDs and MCLGs should be one or more orders of magnitude lower. What USEPA determines to be proper risk management MCLs is not the basis of this request for consideration.

According to USEPA:

"EPA's goal is to respond to each RFR within 120 days of receipt, by 1) providing either a decision on the request or 2) if the request requires more than 120 calendar days to resolve, informing the complainant that more time is required and indicate the reason why and an estimated decision date."

I look forward to your scientific analysis of my assertions. I have asked USEPA repeatedly for confirmation and peer review that our scientific findings are accurate. I have tried to work with USEPA in a collegial manner. USEPA rebuffed such interactions. USEPA has repeatedly denied such review or has simply not responded to phone calls and emails. The Administrator's Office is aware of these issues and his staff will provide no positive or negative feedback. The same is true for IRIS and Office of Water management who have taken similar positions of non-responsiveness.

Thank you.

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