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By Electronic Submission

Re: Review of Science on Fluoride in Drinking Water: Preliminary Assessment Plan and Literature Survey (Docket ID No. EPA-HQ-OW-2025-3823)

The City of New York ("City") is writing to express its serious concerns with the Environmental Protection Agency's ("EPA") Fluoride Human Health Toxicity Preliminary Assessment Plan ("Preliminary Assessment Plan"). Reliance on the Assessment Plan as currently drafted to develop a Fluoride Human Health Toxicity Assessment is inappropriate and threatens the City of New York's ability to promote and protect residents' oral and overall health.

Integrity of Research

The Preliminary Assessment Plan, as written, relies heavily on research with reproducibility, transparency, and internal bias issues. For example, many of the cited studies have not released raw data for independent replication,[1] and several of the meta-analyses on the health risks of fluoride show small, clinically questionable effect sizes that disappear when adjusted for publication bias or specific study exclusions.[2] Some identified reviews, such as the

[1] See, e.g.,M. Bashash et al. (2017). *Prenatal Fluoride Exposure and Cognitive Outcomes in Children at 4 and 6-12 Years of Age in Mexico*, 125 ENVIRON HEALTH PERSPECT. 097017 (2017); R. Green et al., *Association Between Maternal Fluoride Exposure During Pregnancy and IQ Scores in Offspring in Canada*. 173 JAMA PEDIATR. 940-948 (2019); C. Till et al., *Fluoride Exposure from Infant Formula and Child IQ in a Canadian Birth Cohort*, 134 ENVIRON INT. 105315 (2020).

[2] The NTP relied on small pilot studies, such as a study of 51 children in China. A.L. Choi et al., *Association of Lifetime Exposure to Fluoride and Cognitive Functions in Chinese children: A Pilot Study*, 47 NEUROTOXICOL. TERATOL. 96-101 (2021).

NTP 2024,[3] concluded that higher levels of fluoride exposure were associated with adverse cognitive effects in children based in part on poorly designed studies. Despite revisions to its first draft, the NTP report as published showed a lack of transparency and reproducibility. It failed to specify why studies were included or excluded, and did not assess the studies for risk of error or bias.

To resolve these issues, the City urges EPA to prioritize Medline-indexed research, longitudinal designs, and studies with public data availability in developing the Assessment. Adopting these recommendations will help ensure a robust, evidence-based assessment that reflects the highest standards of scientific practice and meets the "use of science" standards mandated under the Safe Drinking Water Act.[4] Studies with a high risk of bias, pilot studies, and studies without publicly available data should be excluded from further analysis.

Scoping and Problem Formulation

The Preliminary Assessment Plan notes that EPA declined to review the full catalog of research to determine the hazards resulting from fluoride, and instead relies solely on the 2024 National Toxicology Program Monograph (NTP), the European Food Safety Agency's (EFSA) 2025 report, and the 2025 Health Canada report. EPA claims that these reports together constitute "consensus findings about health hazards." But merely saying there is consensus on a matter does not make it so. Had EPA conducted a thorough review, including evidence synthesis and integration, it may have reached different conclusions regarding which hazards to advance in the Assessment. While conducting such a systematic review is more time consuming, it is important to avoid inclusion of studies that are biased, have methodological flaws, failed to account for confounding variables, and have other weaknesses. Moreover, it is critical to include all relevant well-designed robust studies regardless of negative or positive findings and to publicly show each step of the process. EPA cannot outsource its responsibility to conduct a thorough analysis to other agencies or countries – it must demonstrate that all of its decisions are rationally based on a full set of evidence.

In discussion of specific hazards identified, EPA inappropriately describes mild fluorosis as a "health effect" rather than a cosmetic condition.[5] This represents a departure from previous scientific consensus[6] and is unjustified by any data showing functional impairment attributable to mild fluorosis.

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[3] National Toxicology Program (NTP), NTP MONOGRAPH ON THE STATE OF THE SCIENCE CONCERNING FLUORIDE EXPOSURE AND NEURODEVELOPMENT AND COGNITION: A SYSTEMATIC REVIEW (2024) https://doi.org/10.22427/NTP-MGRAPH-8.

[4] 42 U.S.C. § 300g-1(b)(3)(A).

[5] See, e.g., Assessment Plan at 1-2, 2-10.

[6] Centers for Disease Control and Prevention, *Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States*. 50 MMWR 6 (2001).

Literature Review

The literature review process indicates a desire to rush the Preliminary Assessment process. Despite discussion of Artificial Intelligence models, automated tools, and search terms, the Preliminary Assessment Plan fails to address the risk of bias and institute appropriate safeguards to ensure any derived reference dose for fluoride is as accurate as possible.

Several steps of the literature search and screening bias the pool of studies that will inform reference dose and dose-response calculations. For example, the database searches to gather the initial set of studies were conducted in November 2024. However, EPA then cherry-picked studies from 2025 that found a cognitive impact associated with exposure to fluoride to include in the reference dose and dose-response calculations. *See* 4-4. EPA even turned to some of these studies to guide the assessment as a whole. *See* 1-1. By contrast, several studies from 2025 that found there was no cognitive impact, or a positive cognitive impact, associated with fluoride were excluded from the literature review pool.[7]

The literature review also relies heavily on categorizing studies as supplemental or not relevant to the PECO (populations, exposures, comparators, outcomes) formulation, but the categorization is completely opaque. If a study is tagged as supplemental or non-PECO relevant, it is excluded from the datasets that will inform the reference dose and dose-response calculations. For example, Linuz Aggeborn and Mattias Öhman's paper, *The Effects of Fluoride in Drinking Water*, was tagged as non-PECO relevant despite meeting all of the PECO requirements. It studied human populations, who were exposed to fluoride orally, including a variety of exposure levels, and it measured cognitive impacts associated with fluoride exposure.[8] If studies that do not find an adverse cognitive impact are improperly tagged as non-responsive or supplemental, this skews the reference dose and dose-response calculations to find an artificially low reference dose.

Discussion of Benefits

While the Assessment itself is not a rulemaking document, it will be used to inform EPA in its rulemaking processes under the Safe Drinking Water Act. Therefore, the Assessment Plan should more clearly describe how the resulting toxicity values will be integrated with benefit–risk considerations in subsequent Safe Drinking Water Act ("SDWA") decision-making. This clarification is important because fluoride has both beneficial and harmful effects that occur across overlapping exposure ranges. Without an explicit framework for incorporating benefits at later policy stages, the toxicity assessment could be misinterpreted as a complete characterization of fluoride's public health impact. For downstream regulatory decisions, a "net health impact" or break-even concept is essential.

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[7] L.G. Do, et al., *Early Childhood Exposures to Fluorides and Cognitive Neurodevelopment: A Population-Based Longitudinal Study,*104 J DENT RES., 243 (2025) (finding no adverse cognitive impact associated with early-life exposure to fluoride); John Robert Warren, et al., *Childhood fluoride exposure and cognition across the life course*, 11 SCIENCE ADVANCES, (2025) (finding slight cognitive improvement associated with early life exposure to fluoride).

[8] 129 J. POL. ECON. 465 (2021).

Accordingly, EPA should:

- Acknowledge the existence of beneficial effects, even if they are outside the scope of the present toxicity assessment.
- Clarify how toxicity values developed here will be used alongside benefit data in future SDWA evaluations.
- Ensure that the toxicity assessment outputs are compatible with benefit–risk modeling, including dose–response relationships for adverse effects, exposure distributions for sensitive populations, and uncertainty bounds that allow comparison with thresholds associated with caries prevention.

The City of New York appreciates the opportunity to comment on this Preliminary Assessment Plan.

Sincerely,

[redacted]

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