



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2025-3823; FRL 13191-01-OW]

Review of Science on Fluoride in Drinking Water: Preliminary Assessment Plan and Literature Survey

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: As the first step in developing the Fluoride Human Health Toxicity Assessment (toxicity assessment), the U.S. Environmental Protection Agency (EPA) is releasing the Fluoride Preliminary Assessment Plan and Literature Survey (Assessment Plan) for public comment to provide transparency and gather early feedback. The objectives of the Assessment Plan are to describe the approach the EPA intends to follow to develop the fluoride toxicity assessment and present the results of the preliminary literature survey. The Assessment Plan is not a toxicity assessment; it does not contain conclusions regarding harmful human health effects of fluoride or determine the level of fluoride exposure at or above which is associated with harmful health effects. Such conclusions about fluoride human health effects will be released as part of the forthcoming draft human health toxicity assessment. The EPA's toxicity assessment will be used to inform future decisions about potential revisions to the existing fluoride drinking water standard under the Safe Drinking Water Act (SDWA). This notice outlines details on how to provide comments and describes the purpose of the Fluoride Preliminary Assessment Plan and Literature Survey.

DATES: Comments must be received on or before states **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OW-2025-3823, by any of the following methods:

- Federal eRulemaking Portal: <https://www.regulations.gov/> (our preferred method).

Follow the online instructions for submitting comments.

- E-mail: ow-docket@epa.gov. Include Docket ID No. EPA-HQ-OW-2025-3823 in the subject line of the message.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Office of Ground Water and Drinking Water Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- Hand Delivery or Courier: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking.

Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the "Public Participation" heading of the

SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Susan Euling, Drinking Water Science and Engineering Division, Office of Ground Water and Drinking Water (Mail Code 4601M), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; email address: fluoride@epa.gov

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I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA-HQ-OW-2025-3823, at

<https://www.regulations.gov> (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to EPA's docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). Please visit <https://www.epa.gov/dockets/commenting-epa-dockets> for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

II. General Information

A. Introduction to the Preliminary Assessment Plan and Literature Survey for the Fluoride Human Health Toxicity Assessment

The EPA is committed to ensuring clean and safe drinking water for all Americans with the goal of protecting human health, including children's health. In response to concerns about fluoride in drinking water, the EPA is developing a new human health toxicity assessment that will review scientific information on the potential health risks of fluoride in drinking water. The toxicity assessment will be based on a systematic review of the scientific information on the potential health risks of fluoride in drinking water. The objective of the toxicity assessment is to determine the fluoride levels that a person can be exposed to and be unlikely to experience harmful health effects; these values are called toxicity values, specifically noncancer reference doses (RfDs).

The Preliminary Assessment Plan and Literature Survey (Assessment Plan) is the first step in developing the toxicity assessment. The objectives of the Assessment Plan are to describe the approach the EPA intends to follow to develop the human health toxicity assessment and present the results of the preliminary literature survey. The preliminary literature survey describes the results of conducting initial systematic review steps to identify relevant health effects studies, consistent with agency human health risk assessment guidance and Executive Order 14303 Restoring Gold Standard Science. A summary of the scoping and problem formulation conclusions is also presented in the Assessment Plan. As part of scoping and problem formulation, the EPA identified key science issues specific to fluoride exposure and health effects measurement that will be evaluated during toxicity assessment development.

The Assessment Plan is not a toxicity assessment; it does not contain conclusions regarding harmful human health effects of fluoride or determine the level of fluoride exposure at or above which is associated with harmful health effects. The EPA is releasing the Fluoride Preliminary Assessment Plan and Literature Survey for public comment to provide transparency and gather early feedback about the assessment scope and identified literature.

The EPA's fluoride toxicity assessment will evaluate human health hazards. The fluoride toxicity assessment, once final, can be used by EPA, states, Tribes, and local communities, along with specific exposure and other relevant information, to determine, under the appropriate regulations and statutes, the potential risk associated with human exposures to fluoride. Specifically, the EPA's toxicity assessment will be used to inform future decisions about potential revisions to the existing fluoride drinking water standard under the Safe Drinking Water Act (SDWA). The results of this toxicity assessment will also be used to inform Centers for Disease Control and Prevention (CDC) recommendations regarding fluoride in drinking water (<https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf>).

B. Next Steps for the Fluoride Human Health Toxicity Assessment

The EPA is accepting public comments on this Assessment Plan for 30 days. The EPA will consider all public comments during the next step in the toxicity assessment process, which is the development of the Systematic Review Protocol (protocol). The protocol will present detailed methods for conducting subsequent steps of the systematic review. The EPA will then follow the protocol to develop a draft Fluoride Human Health Toxicity Assessment. The draft toxicity assessment will follow EPA human health risk assessment methods and guidance, summarize the health effects associated with exposure to fluoride during childhood, and identify the fluoride level at or below which a person can be exposed to and be unlikely to experience harmful health effects. The draft toxicity assessment will be released for external peer review and public comment. The EPA will consider the external peer review and public comments and revise the assessment as appropriate, before publishing a final Fluoride Human Health Toxicity Assessment.

Jessica L. Kramer,

Assistant Administrator.

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