

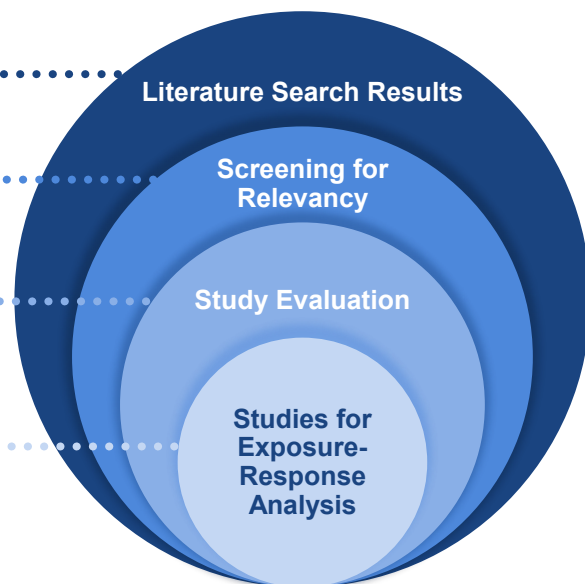


FLUORIDE IN DRINKING WATER: TOXICITY ASSESSMENT

EPA is working to develop a new Fluoride Human Health Toxicity Assessment that will:

Use gold standard systematic review methods

- Collect the best available science from numerous sources
- Transparently and consistently filter results to identify relevant studies
- Perform study evaluation to identify well- conducted studies and determine the sensitive health effects
- Determine the fluoride levels that a person can be exposed to without being likely to experience harmful health effects



Use the best available science, as required under the Safe Drinking Water Act

Peer-reviewed health effects studies collected using gold standard systematic review methods

Critical evaluation of recent health effects documents including NIH's NTP Fluoride Report (2024)

Health effects studies assessed and used by other health agencies

Health effects studies cited in previous EPA assessments and evaluations

Focus on two known harmful health effects in children, based on published assessments:

CHILDHOOD BRAIN DEVELOPMENT



TOOTH DEVELOPMENT



Future Steps: During development of the toxicity assessment, EPA will evaluate human studies reporting priority childhood health outcomes and determine the fluoride exposure levels at and below which a person can be exposed to and be unlikely to experience harmful health effects.

The Preliminary Assessment Plan and Literature Survey (Assessment Plan) describes *what* will be analyzed in EPA's new Fluoride Human Health Toxicity Assessment

The Assessment Plan includes:

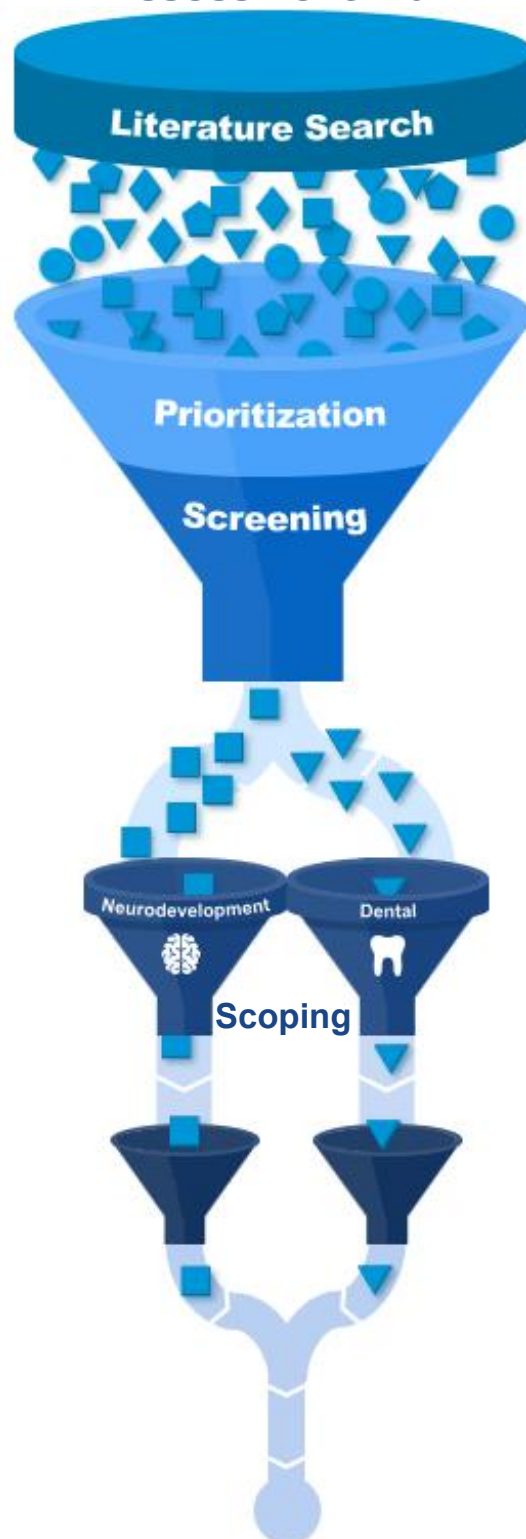
- Scoping and problem formulation informed by recent peer-reviewed health effects reports published by other health agencies to ensure a focused, fit-for-purpose assessment
- Preliminary literature survey results that help identify relevant health effects studies
- Key science issues needing evaluation
- Criteria used to identify the best available, unbiased science

As described in the Assessment Plan, EPA:

- Identified over 260,000 studies
- Used AI tools to prioritize over 70,000 studies
- Screened and identified over 500 studies relevant to two sensitive harmful health outcomes in children (dental fluorosis and neurodevelopmental effects)

The Preliminary Assessment Plan and Literature Survey is available for a 30-day public comment period at [regulations.gov](https://www.regulations.gov) (docket EPA-HQ-OW-2025-3823).

Steps Described in the Assessment Plan





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The next steps of EPA's fluoride toxicity assessment are:

Develop a Systematic Review Protocol

EPA will consider public comments received on the Preliminary Assessment Plan and Literature Survey and incorporate them as the agency develops a Systematic Review Protocol for fluoride. The Systematic Review Protocol will present detailed methods for conducting the next steps of the systematic review, including how EPA will:

- Use automated systematic review tools, including artificial intelligence (AI), to prioritize the most informative studies
- Develop fluoride-specific study evaluation considerations to transparently and consistently review each study
- Identify studies best-suited to determine what fluoride exposure levels result in harmful human health effects

Develop a Draft Assessment

EPA will follow the Systematic Review 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 based on the best available science
- Identify the most sensitive health effects in children
- Identify the fluoride levels that a person can be exposed to without being likely to experience harmful health effects

Release the Draft Assessment for External Review

EPA will release the draft Fluoride Human Health Toxicity Assessment for external expert peer review and public comment.

Develop a Final Assessment

EPA will consider the external peer review and public comments and revise the toxicity assessment as appropriate before publishing the final Fluoride Human Health Toxicity Assessment.