FLUORIDE TOXICITY ASSESSMENT PROTOCOL

EPA is in the process of evaluating the toxicity of fluoride under the Safe Drinking Water Act. EPA's human health assessment of fluoride will help ensure that drinking water standards protect Americans' health.

On August 3, 2026, EPA marked a key milestone in its effort to evaluate fluoride under the Safe Drinking Water Act by publishing the *Protocol for Developing the Fluoride Human Health Toxicity Assessment*. This Protocol transparently describes how EPA will conduct the toxicity assessment through a comprehensive and systematic review and analysis of high-quality scientific literature. The protocol reflects public input received on the agency's January 2026 *Preliminary Assessment Plan and Literature Survey*.

Health Hazards Being Assessed:

EPA's toxicity assessment will focus on two children's health hazards and will be informed by the latest peer reviewed science. These health effects are expected to be the most sensitive to fluoride exposure, meaning that they may occur at the lowest levels. Over the last few decades there have been several peer-reviewed studies published on neurodevelopmental effects of fluoride. EPA will place an emphasis on evaluating these potential health effects. EPA will also assess dental fluorosis.



Neurodevelopmental effects[3,4,5]

Can include effects on cognition (such as changes in intelligence quotient (IQ)), behavior, and sensory/motor effects.

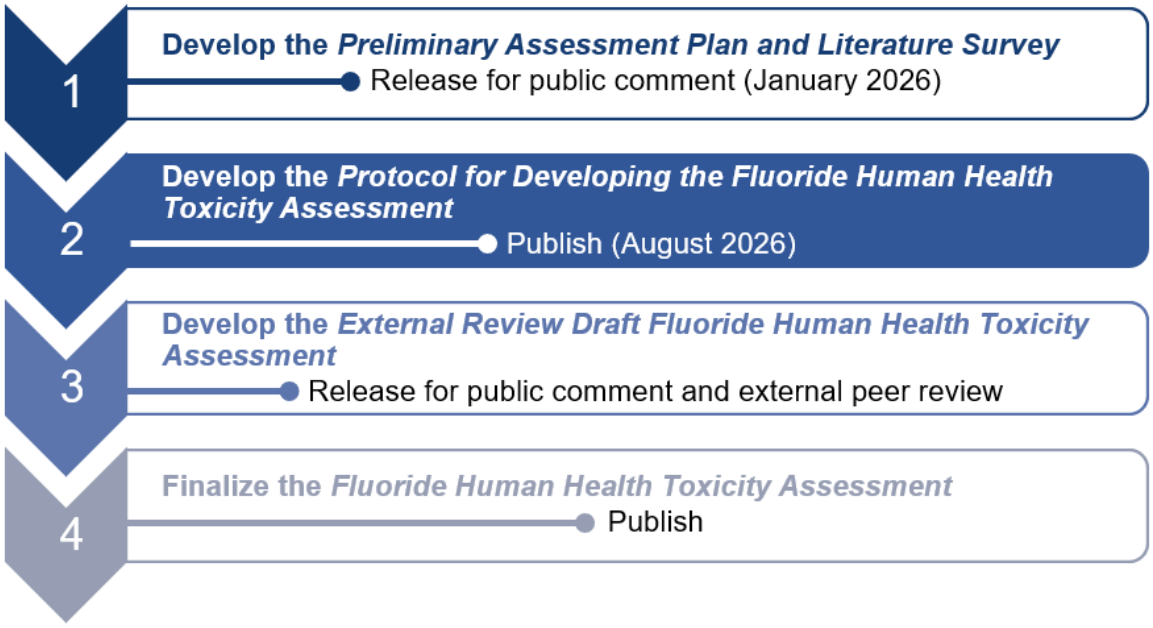


Dental fluorosis[1,2,3,4]

Is characterized by discoloration and/or pitting of the tooth enamel. At its severest forms, it is associated with weakened teeth.

[1]NRC 2006, [2]EPA 2010, [3]HC 2024, [4]EFSA 2025, [5]NTP 2025

EPA's process for evaluating the toxicity of fluoride under the Safe Drinking Water Act follows four transparent steps. The Assessment Protocol is the second step and provides a roadmap of how the Assessment will be conducted in the third step.



Step 2: Assessment Protocol

Roadmap for how EPA will conduct the Fluoride Health Assessment, including:

Updated Assessment Plan that Reflects Public Comments

Solidified the scope and literature survey to be used in the Assessment.

Plan for Study Evaluation

Describes methods to evaluate fluoride health effect studies and implement Gold Standard Science.

Plan for Developing Scientific Models

Describes approach for evaluating how fluoride is absorbed, moves through, and leaves the human body to develop a model showing the relationship between exposure and concentrations inside the body.

Plan for Dose-Response Modeling

Details the approach for analyzing the dose-response relationship for Gold Standard Science studies to estimate the fluoride exposure that would result in a harmful health effect.

Plan to Derive a Toxicity Value

Details the steps for deriving a toxicity value – a level of fluoride exposure where harmful health effects are not likely to occur – based on Gold Standard Scientific studies and models.

See an Expanded Fact Sheet on the Assessment Protocol here.