

Fluoride in Drinking Water: A Scientific Review of EPA's Standards

After reviewing research on various health effects from exposure to fluoride, including studies conducted in the last 10 years, this report concludes that EPA's drinking water standard for fluoride—a maximum of 4 milligrams of fluoride per liter of water (4 mg/L)—does not protect against adverse health effects. Just over 200,000 Americans live in communities where fluoride levels in drinking water are 4 mg/L or higher. Children in those communities are at risk of developing severe tooth enamel fluorosis, a condition that can cause tooth enamel loss and pitting. A majority of the report's authoring committee also concluded that people who drink water containing 4 mg/L or more of fluoride over a lifetime are likely at increased risk for bone fractures.



Most people associate fluoride with the practice of intentionally adding fluoride to public drinking-water supplies for the prevention of tooth decay. However, fluoride can also enter public water systems from natural sources, including runoff from weathering of fluoride-containing rocks and soils and leaching from soil into groundwater. Fluoride pollution from various industrial discharges and emissions can also contaminate water supplies. In a few areas of the United States, fluoride concentrations in water are much higher than normal, mostly from natural sources. Because it can occur at toxic levels, fluoride is one of the drinking water contaminants regulated by the U.S. Environmental Protection Agency (EPA).

In 1986, EPA established a maximum allowable concentration for fluoride in drinking water of 4 milligrams per liter (mg/L), a guideline designed to prevent the public from being exposed to harmful levels of fluoride. A concentration of 2 mg/L was set to manage the severity and occurrence of a cosmetic consequence of exposure to fluoride (mottling of tooth enamel).

Estimates from 1992 indicate that approximately 1.4 million people in the United States had fluoride concentrations of 2.0 to 3.9 mg/L in the sources of their drinking water, and just over 200,000 people had concentrations equal to or exceeding 4 mg/L. For the vast majority of people in the United States, fluoride concentrations in drinking water without any treatment to remove fluoride are below the EPA standards. Information on the fluoride content of public water supplies is available from local water suppliers and local, county, or state health departments.

Many public health agencies and experts endorse adding fluoride to the water as an effective method of preventing tooth decay in communities where natural fluoride levels are low. The "optimal" concentration range of fluoride in drinking-water for

EPA Drinking Water Standards

EPA sets 3 types of standards for environmental contaminants. The maximum contaminant level goal (MCLG) is a health goal set at a concentration at which no adverse health effects are expected to occur and the margins of safety are judged "adequate." The maximum contaminant level (MCL) is the enforceable standard that is set as close to the MCLG as possible, taking into consideration other factors such as treatment technology and costs. For fluoride, the MCLG and the MCL are both 4 milligrams per liter (mg/L). For some contaminants, EPA also establishes a secondary maximum contaminant level (SMCL) to manage drinking water for aesthetic or cosmetic effects. The SMCL for fluoride is 2 mg/L.

preventing tooth decay was set at a range of 0.7 to 1.2 mg/L more than 40 years ago by the U.S. Public Health Service. In 2000, it was estimated that approximately 162 million people had artificially fluoridated water. The recommended range for artificial fluoridation is below the EPA standards and was designed for a different purpose, so it is important to note that the safety and effectiveness of the practice of water fluoridation was outside the scope of this report and is not evaluated. This report only evaluates EPA's standards.

A 1993 report from the National Research Council had concluded that the EPA standard of 4 mg/L was an appropriate interim standard until more research could be conducted. However, following a comprehensive review of the research conducted since 1993, this report concludes the EPA standard is not protective of health because fluoride exposure at 4 mg/L puts children at risk of developing severe enamel fluorosis that can compromise tooth enamel function and appearance. Fluoride exposure at 4 mg/L could also weaken bone and increase the risk of fractures.

Exposure to Fluoride

Water and water-based beverages are the largest contributors to an individual's total exposure to fluoride, although there are other sources of exposure. For the average person, depending on age, drinking water accounts for 57% to 90% of total fluoride exposure at concentrations of 2 mg/L and accounts for 72% to 94% of total fluoride exposure at concentrations of 4 mg/L.

Non-beverage food sources containing various concentrations of fluoride are the second largest contributor to fluoride exposure. The greatest source of nondietary fluoride is dental products, primarily toothpastes. The public is also exposed to fluoride from background air concentrations and from some pesticide residues. Other sources include some pharmaceuticals and consumer products.

EPA based its standards on the assumption that adults consume 2 liters of water-based beverages per day. People who are exposed to higher concentrations include those who live where there are high concentrations of fluoride in drinking water; those who drink unusually large volumes of water, such as athletes or people with certain medical conditions; and those who are exposed to other important sources of fluoride such as from occupational exposures. On a per-body-weight basis, infants and young children have approximately three to four times greater exposure than do adults. Dental-care products are also a special consideration for children, because many tend to use more toothpaste than is advised and may swallow some.

Dental Effects

Exposure to fluoride can cause a condition known as enamel fluorosis. Depending on the amount of fluoride exposure (the dose) and the period of tooth development at which the exposure occurs, the effects of enamel fluorosis can range from mild discoloration of the tooth surface to severe staining, enamel loss, and pitting. The condition is permanent after it develops in children during tooth formation (from birth until about the age of 8). Severe enamel fluorosis occurs at an appreciable frequency, approximately 10% on average, among children in U.S. communities with water fluoride concentrations at or near the current allowable concentration of 4 mg/L. The prevalence of severe enamel fluorosis is very low below about 2 mg/L of fluoride in drinking water.

The biggest debate concerning enamel fluorosis, particularly the moderate to severe forms, is whether to consider it an adverse health effect or a cosmetic effect. Previous assessments considered all forms of enamel fluorosis to be aesthetically displeasing, but not adverse to health. This view has been based largely on the lack of direct evidence that severe enamel fluorosis results in tooth loss, loss of tooth function, or psychological, behavioral, or social problems.

There was suggestive but inconclusive evidence that severe enamel fluorosis increased the risk of cavities. It is known that restorative dental treatment is often considered for children with the enamel pitting that characterizes this condition.

The committee concludes that the current EPA standard does not protect against severe enamel fluorosis. All members of the committee agreed that the condition damages the tooth and that the EPA standard should prevent the occurrence of this unwanted condition. The majority of the members judged the condition to be an adverse health effect because enamel loss and pitting can compromise the ability of the tooth



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enamel to protect the dentin and, ultimately, the pulp from decay and infection. Two of the 12 members of the committee did not agree that enamel defects alone are sufficient to consider severe enamel fluorosis an adverse health effect, as opposed to a cosmetic one.

Studies relied upon by EPA indicated that the prevalence of moderate enamel fluorosis, which causes staining but not pitting of teeth, at 2 mg/L could be as high as 15%. A 1997 report from the Institute of Medicine recommended tolerable upper intake levels for children of different ages intended to protect against moderate enamel fluorosis. At EPA's current secondary maximum contaminant level of 2 mg/L, between 25% and 50% of infants up to one year of age in EPA's 2004 water intake survey consumed enough water to exceed the tolerable upper intakes for their age groups.

Skeletal Effects of Fluoride

Fluoride is readily incorporated into the crystalline structure of bone, and will accumulate over time. Concerns about fluoride's effects on the musculoskeletal system are focused on a condition called skeletal fluorosis and also on increased risks of bone fracture. Models that estimate the accumulation of fluoride into bone (pharmacokinetic models) have been developed that are useful in understanding fluoride's effect on bone.

Skeletal fluorosis is a bone and joint condition associated with prolonged exposure to high concentrations of fluoride. Fluoride increases bone density and causes changes in the bone that lead to joint stiffness and pain. The condition is categorized into a preclinical stage and stage I, II, and III, the last of which is sometimes referred to as the "crippling" stage because mobility is affected. At stage II, mobility is not significantly affected, but it is characterized by sporadic pain, stiffness of joints, and osteosclerosis (bone thickening) of the pelvis and spine. The committee concluded that both stage II and stage III skeletal fluorosis should be considered adverse.

There are very few known clinical cases of skeletal fluorosis in the United States. Pharmacokinetic models show that bone fluoride concentrations resulting from lifetime exposure to fluoride in drinking water at 2 mg/L or 4 mg/L fall within or exceed the ranges historically associated with stage II and stage III skeletal fluorosis. However, this evidence is not conclusive because the levels at which skeletal fluorosis occurs vary widely, and because it appears to be rare in the United States.

The effects of fluoride exposure on bone strength and risk of bone fracture have been studied in animals. The weight of evidence indicates that,

although fluoride might increase bone volume, fluoride affects the quality of the bone such that there is less strength per unit volume. Evidence for this effect in humans was found in several new studies of populations exposed to fluoride in their drinking water at 4 mg/L, as well as studies of fluoride as a therapeutic agent, which collectively showed an increased risk of bone fracture.

Overall, there was consensus among the committee that there is scientific evidence that under certain conditions fluoride can weaken bone and increase the risk of fractures. The majority of the committee concluded that lifetime exposure to fluoride at drinking water concentrations of 4 mg/L or higher is likely to increase fracture rates in the population, particularly in some demographic subgroups that are prone to accumulate fluoride into their bones (e.g., people with renal disease). However, three of the 12 members judged that the evidence only supported a conclusion that the EPA standard (MCLG) might not be protective against bone fracture, and that more evidence is needed that bone fractures occur at an increased frequency in human populations exposed to fluoride at 4 mg/L before drawing a conclusion that the EPA standard likely poses a risk of increased bone fracture.

There were few studies to assess risks of bone fracture in populations exposed to fluoride at 2 mg/L in drinking water. The best available study suggested an increased rate of hip fracture in populations exposed to fluoride at concentrations above 1.5 mg/L. However, this study alone is not sufficient to judge fracture risk for people exposed to fluoride at 2 mg/L. Thus, no conclusions could be drawn about fracture risks at 2 mg/L.

Studies of Fluoride and Cancer

Whether fluoride might be associated with bone cancer has been a subject of debate. Animal studies have suggested the possibility of increased risk of osteosarcoma (a bone cancer) in male rats, but no new animal bioassays have been performed to evaluate this further. Several new population studies investigating cancer in relation to fluoride exposure are now available. Some of those studies had significant methodological limitations that make it difficult to draw conclusions. Overall, the results were mixed, with some studies reporting a positive association and others no association. The committee concluded that the evidence to date is tentative and mixed as to whether fluoride has the potential to initiate or promote cancers, particularly of the bone.

A relatively large hospital-based case-control study of osteosarcoma and fluoride exposure is under way at the Harvard School of Dental Medicine and is

expected to be published in the summer of 2006. The results of that study might help to identify what future research will be most useful in elucidating fluoride's carcinogenic potential.

Implications for EPA's Drinking Water Standards

In light of the collective evidence on adverse health effects and total exposure to fluoride, the committee concludes that EPA's drinking water standard of 4 mg/L is not adequately protective of health. Lowering it will prevent children from developing severe enamel fluorosis and will reduce the lifetime accumulation of fluoride into bone that the majority of the committee concludes is likely to put individuals at increased risk of bone fracture and possibly skeletal fluorosis, which are particular concerns for those of the public who are prone to accumulating fluoride in their bones.

To develop a standard that is protective against severe enamel fluorosis, clinical stage II skeletal fluorosis, and bone fractures, EPA should update its risk assessment of fluoride to include new data on health risks and better estimates of total exposure (relative source contribution) for individuals. EPA should use current approaches for quantifying risk, considering susceptible sub-populations, and characterizing uncertainties and variability.

From a cosmetic standpoint, EPA's standard for cosmetic effects of 2 mg/L does not completely prevent the occurrence of moderate enamel fluorosis. EPA has indicated that the standard was intended to reduce the severity and occurrence of the condition to 15% or less of the exposed population. Recent EPA water intake survey data indicate that substantial proportions of children

in communities with fluoride at 2 mg/L consume enough water to exceed the age-specific tolerable upper intake levels recommended by the Institute of Medicine. The degree to which moderate enamel fluorosis might go beyond a cosmetic effect to create an adverse psychological effect or an adverse effect on social functioning on children or their parents is not known.

The committee did not evaluate the risks or benefits of the lower fluoride concentrations (0.7 to 1.2 mg/L) used in water fluoridation. Therefore, the committee's conclusions regarding the potential for adverse effects from fluoride at 2 to 4 mg/L in drinking water do not apply at the lower water fluoride levels commonly experienced by most U.S. citizens.

Recommended Research

As noted above, gaps in the information on fluoride prevented the committee from making some judgments about the safety or the risks of fluoride at concentrations between 2 and 4 mg/L and below. The report makes several recommendations for future research to fill those gaps, as well as recommendations to pursue lines of evidence on other potential health risk (e.g., endocrine effects and brain function). Recommendations include exposure assessment at the individual level rather than the community level; population studies of moderate and severe enamel fluorosis in relation to tooth decay and to psychological, behavioral, or social effects; studies designed to clarify the relationship between fluoride ingestion, fluoride concentration in bone, and clinical symptoms of skeletal fluorosis; and more studies of bone fracture rates in people exposed to high concentrations of fluoride in drinking water.

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This report brief was prepared by the National Research Council based on the committee's report. For more information, contact the Board on Environmental Studies and Toxicology at (202) 334-3060 or visit <http://dels.nas.edu/best>. *Fluoride in Drinking Water* is available from the National Academies Press, 500 Fifth Street, NW, Washington, D.C. 20001; (800) 624-6242; www.nap.edu.

