



## *New Fluoride Risk Assessment and Relative Source Contribution Documents*

### Summary

Fluoride is an inorganic ion found in drinking water because of its presence in the earth's crust, anthropogenic releases to the environment, and/or due to its addition to treated water to prevent cavities. The decision on whether to add fluoride to drinking water is made by state or local governments with technical support from the Department of Health and Human Services and is not governed by the Safe Drinking Water Act.

### Background

EPA established regulations for fluoride ion in drinking water in 1986. A non-enforceable Maximum Contaminant Level Goal (MCLG) of 4 mg/L was established to protect against crippling skeletal fluorosis. The enforceable Maximum Contaminant Level (MCL) was established at the same time, requiring systems to install treatment to remove some fluoride in situations where the total fluoride concentration of the delivered water exceeds 4 mg/L.

EPA also established a non-enforceable Secondary Maximum Contaminant Level (SMCL) of 2 mg/L to protect against moderate dental fluorosis (discoloration of the tooth enamel), a cosmetic effect. Although water systems are not required to comply with SMCLs, when the SMCL for fluoride is exceeded, systems must inform customers of the risk for dental fluorosis in children. The notification includes recommending that consumers use an alternative drinking water source for those under nine years of age and consult with a dental professional on measures that can reduce total fluoride exposure.

The scientific basis for the health assessments that underlie the MCLG and SMCL was

evaluated by the National Research Council (NRC) at the request of EPA in 1993. In 2003, EPA asked for another NRC review due to the number of new studies on the health effects of ingested fluoride in humans and laboratory animals.

The most recent NRC panel recommended in 2006 that EPA conduct a new quantitative risk assessment for severe dental fluorosis, the risk for increased bone fractures as related to fluoride, and the less than crippling form of skeletal fluorosis (Stage II skeletal fluorosis). Some dose-response data are available for severe dental fluorosis, cavities that may be associated with this defect, and the relation between fluoride and skeletal fractures. The collection of dose-response data on skeletal fluorosis remains a research need.

The findings of the 2006 NRC panel diverged from those of the 1993 panel in categorizing severe dental fluorosis resulting in pitting of the tooth enamel as the health endpoint that should be evaluated. The 2006 panel also concluded that the present MCL of 4 mg/L was not protective for severe dental fluorosis and might not be protective for the skeletal fracture endpoint. The NRC report does not question the beneficial effects for fluoride at levels practiced for fluoridation programs.

### Current Status and Next Steps

EPA has completed and peer-reviewed a quantitative dose-response assessment based on the available data for severe dental fluorosis as recommended by NRC. Additional research will be necessary to obtain dose-response data amenable to a quantitative risk assessment for Stage II skeletal fluorosis and/or skeletal fractures. The dose-response assessment provides a reference dose based on the critical

---

health effect of pitting of the enamel in severe dental fluorosis.

EPA has also completed and peer-reviewed a document on environmental exposure of children and adults to fluoride and the relative source contribution (RSC) for water. The RSC is needed in order to derive the MCLG from the dose-response assessment.

Both documents are posted on EPA's website at: [http://water.epa.gov/action/advisories/drinking/fluoride\\_index.cfm](http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm).

The Agency will review the new risk assessment of fluoride along with other information (e.g., availability of analytical methods, feasibility of treatment, data on occurrence and exposure) to determine whether it is appropriate to revise the drinking water goal and/or standard.

### **For More Information**

Contact Joyce Donohue at 202-566-1098 or by email at [donohue.joyce@epa.gov](mailto:donohue.joyce@epa.gov).

---