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The Development of Federal Recommendations and Regulations for Fluoride in Drinking Water

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SUMMARY

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Elena H. Humphreys, Coordinator
Analyst in Environmental Policy

Alexandria K. Mickler
Analyst in Health Policy

Jerry H. Yen
Analyst in Environmental Policy

Jason O. Heflin
Legislative Attorney

Fluoride is a naturally occurring mineral present at some level in virtually all water. *Fluoridation* is the process of adding fluoride to a water supply. Since 1962, federal agencies have recommended certain levels of drinking water fluoridation to promote dental health. Water fluoridation is not required by federal law. The decision to add fluoride to a community's water supply is made by a state or local government. Recent state and local actions to prohibit the addition of fluoride to community water supplies have garnered congressional attention. In addition, in April 2025, the Secretary of the U.S. Department of Health and Human Services (HHS) and the Administrator of the U.S. Environmental Protection Agency (EPA) announced planned actions related to fluoride and drinking water. These developments have raised interest in the federal guidelines for the fluoridation of water supplied by community water systems (i.e., community water supplies), federal regulations for fluoride in drinking water, and research on the health effects of fluoride exposure.

Since 1962, the U.S. Public Health Service (PHS) has recommended community water fluoridation to prevent dental caries (i.e., cavities). In 2015, the PHS reaffirmed its recommendation, stating that the optimal concentration of fluoride in drinking water is 0.7 milligrams per liter (mg/L), which "provides the best balance of protection from dental caries while limiting the risk of *dental fluorosis*" (i.e., discoloration or pitting). Multiple entities within HHS have examined water fluoridation. These agencies consider the optimal levels of water fluoridation that maximize health benefits and minimize health risks. The fluoride concentration as summarized and recommended by HHS agencies (0.7 mg/L) focuses on the optimal level of water fluoridation that balances the prevention of health effects associated with, or potentially exacerbated by, a lack of fluoride (e.g., dental caries) with the health effects linked to exposures to higher levels of fluoride (e.g., dental fluorosis).

In 1986, the EPA established a drinking water regulation under the Safe Drinking Water Act (SDWA) for community water supplies that includes a maximum, enforceable level of fluoride of 4.0 mg/L to protect against adverse health effects. EPA's drinking water regulation—with its enforceable level of fluoride and subsequent reviews of this level—was informed by HHS research and other studies, along with HHS water fluoridation guidelines and recommended community water fluoridation levels. In November 2024, a federal district court found that potential neurodevelopmental effects from fluoride exposure present an unreasonable risk of injury to human health under the Toxic Substances Control Act (TSCA) and ordered EPA to initiate a rulemaking under TSCA to regulate the fluoridation of water supplies. On January 17, 2025, EPA appealed that decision. Due to this litigation and other developments, it is uncertain whether the PHS recommendation or EPA drinking water regulation may be reexamined and potentially revised.

Federal agencies rely on health research to make recommendations or establish regulatory levels, as statutorily authorized. Research on the health effects associated with fluoride is complicated by a number of factors. The strength of the evidence indicating a causal relationship between fluoride and certain health effects (both benefits and risks) can vary by the health outcome measured, how the research study was designed (e.g., observational versus experimental), and other variables. Accordingly, the varied strengths and limitations of research can contribute to some of the debate on the health effects linked to fluoride exposures. For example, research on fluoride's effect on dental health is generally accepted, while evidence regarding potential other health effects (e.g., neurodevelopmental effects) is less well established, and may require more research than has been conducted to date. The relative strength of the evidence from such research may inform federal agency action.

In April 2025, the HHS Secretary directed the end of its water fluoridation recommendation, and the EPA Administrator announced that EPA would review scientific information on fluoride. On March 27, 2025, HHS announced a restructuring; how a restructuring may affect HHS water fluoridation activities or specific agency roles remains unknown. On May 2, 2025, EPA announced reorganization plans; whether EPA's reorganization plans would affect the agency's scientific or funding priorities remains to be seen. These announcements and associated planned actions raise several federal policy considerations pertaining to fluoride-related research, regulation, and implementation.

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Introduction

Fluoridation is the process of adding fluoride to a water supply. The decision to add fluoride to a community's water supply is made by a state or local government. Water fluoridation is not required by any federal agency, though some federal agencies set fluoride guidelines and regulations, among other activities.[1]

Recent state and local actions to prohibit the addition of fluoride to community drinking water supplies have garnered attention from both the legislative and executive branches. For example, in March 2025, the Governor of Utah signed a bill prohibiting the addition of fluoride in water provided by public water systems operating in the state beginning May 7, 2025.[2] In May 2025, the Governor of Florida signed legislation to prohibit local governments from "unilaterally" adding fluoride to public drinking water.[3] Press releases from the U.S. Department of Health and Human Services (HHS) note that Secretary Robert F. Kennedy Jr. has highlighted state legislative actions to ban the addition of fluoride to public drinking water during a multistate tour.[4] In April 2025, news reports also indicated that Secretary Kennedy would (1) direct the Centers for Disease Control and Prevention (CDC) to stop recommending community water fluoridation, (2) assemble a task force to study the issue, and (3) make new recommendations regarding fluoridation.[5] As of the date of this report, no official agency statement on HHS agency actions related to fluoridated drinking water has been released.[6] Also in April 2025, U.S. Environmental Protection Agency (EPA) Administrator Lee Zeldin announced that the agency intends to review "new" scientific information on fluoride to inform future agency decisions.[7]

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[1] Under Section 1412(b)(11) of the Safe Drinking Water Act (SDWA), national primary drinking water regulations are prohibited from requiring the addition of any substance for preventive health care purposes unrelated to the contamination of drinking water (42 U.S.C. §300g-1 (b)(11)). Maximum levels of fluoride in public water supplies are regulated under SDWA. Federal agencies that operate community water systems, such as those that operate on U.S. military installations, may fluoridate community water supplies to recommended levels.

[2] See H.B. 81, *Fluoride Amendments,* https://le.utah.gov/~2025/bills/static/HB0081.html.

[3] Executive Office of the Governor of Florida, "Governor Ron DeSantis Celebrates Action to Protection Floridians from Chemical and Technological Interference," press release, May 6, 2025, https://www.flgov.com/eog/news/press/2025/governor-ron-desantis-celebrates-action-protect-floridians-chemical-and. See also, Emily Cochrane, "Florida Just Banned Fluoride From Public Water. Here's What to Know," *The New York Times,* May 15, 2025.

[4] U.S. Department of Health and Human Services (HHS), "Secretary Kennedy Embarks on MAHA Tour," press release, April 4, 2025, https://www.hhs.gov/press-room/hhs-secretary-kennedy-embarks-maha-tour.html; and HHS, "HHS Celebrates 100 Days of Big Wins to Make America Healthy Again," press release, April 27, 2025, https://www.hhs.gov/press-room/hhs-celebrates-100-days-big-wins-maha.html.

[5] See, for example, Hannah Schoenbaum and Mike Stobbe, "RFK Jr. Says He Plans to Tell CDC to Stop Recommending Fluoride in Drinking Water," Associated Press, April 6, 2025.

[6] Although not related to drinking water fluoridation, HHS agencies have announced other plans related to fluoride. On May 13, 2025, the Food and Drug Administration (FDA) announced plans to phase out concentrated ingestible fluoride prescription drug products for children from the market. FDA Commissioner Marty Makary stated that the Center for Drug Evaluation and Research will conduct an evidence review and complete a public comment period by a goal date of October 31, 2025. The announcement also stated that in conjunction with this review, the HHS planned "to disseminate best practices for dental hygiene in children that are feasible, effective, and do not alter gut health." Since this announced action does not specifically pertain to fluoridated drinking water, it is not further discussed in this report. For more information, see U.S. Food and Drug Administration (FDA), "FDA Begins Action To Remove Ingestible Fluoride Prescription Drug Products for Children from the Market," press release, May 13, 2025, https://www.fda.gov/news-events/press-announcements/fda-begins-action-remove-ingestible-fluoride-prescription-drug-products-children-market.

[7] U.S. Environmental Protection Agency (EPA), "EPA Will Expeditiously Review New Science on Fluoride in Drinking Water," press release, April 7, 2025, https://www.epa.gov/newsreleases/epa-will-expeditiously-review-new-science-fluoride-drinking-water.

Federal agencies rely on health research to make recommendations or establish regulatory levels, as statutorily authorized. Research on the health effects associated with fluoride is complicated by a number of factors. The strength of the evidence indicating a causal relationship between fluoride and certain health effects (both benefits and risks) can vary by the health outcome measured, how the research study was designed (e.g., observational versus experimental), and other variables. Accordingly, the varied strengths and limitations of research can contribute to some of the debate on the health effects linked to fluoride exposures. For example, research on fluoride's effect on dental health is generally accepted, while evidence regarding potential other health effects (e.g., neurodevelopmental effects) is less well established, and may require more research than has been conducted to date. The relative strength of the evidence from such research may inform federal agency action.

On March 27, 2025, HHS issued a press release and fact sheet announcing that HHS is being restructured.[8] The fact sheet indicated that this restructuring would include a reduction of approximately 1,400 employees from CDC's workforce.[9] CDC is one of the main HHS agencies engaged in efforts to study and promote oral health, including water fluoridation. At the time of this report's publication, the potential effect of this restructuring on fluoride-related activities within CDC and the U.S. Public Health Service (PHS) is unknown. This report discusses HHS's fluoride-related activities and roles as they were prior to the restructuring announcement. For additional discussion on the HHS reorganization, see CRS Legal Sidebar LSB11311, *The Reorganization of the U.S. Department of Health and Human Services: Selected Legal Issues*.

In addition, on May 2, 2025, EPA issued a press release announcing a reorganization of the agency's functions.[10] This report discusses EPA's actions regarding fluoride under the agency's statutory authorities rather than program office. It remains to be seen whether EPA's reorganization would affect the agency's scientific or funding priorities.

This report provides an overview of the federal recommendations for community water fluoridation and the regulation of fluoride in drinking water, and related topics. Specifically, the first section of this report provides background information on fluoride and community water fluoridation, an overview of research challenges, and an introduction to the concept of a *reference dose* and to the units of measurement used in the report. Subsequent sections discuss the following:

- research on the health effects of fluoride;
- the PHS recommendations and other relevant HHS activities pertaining to community water fluoridation;[11]

[8] HHS, "HHS Announces Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/press-room/hhs-restructuring-doge.html.

[9] HHS, "Fact Sheet: HHS' Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/press-room/hhs-restructuring-doge-fact-sheet.html.

[10] EPA, "EPA Announces Next Phase of Organizational Improvements to Better Integrate Science into Agency Offices, Deliver Clean Air, Land, and Water to All Americans," press release, May 2, 2025, https://www.epa.gov/newsreleases/epa-announces-next-phase-organizational-improvements-better-integrate-science-agency.

[11] At the time of the March 2025 restructuring announcement, the Public Health Service (PHS) was composed of the nine health-related agencies within HHS and is overseen by the Assistant Secretary for Health. For more information, see the section "U.S. Public Health Service (PHS)". It remains to be seen if the recently announced HHS reorganization may affect the structure or purpose of the PHS. Prior to 1962, the National Institute of Health's (NIH's) Dental Hygiene Unit undertook certain federal efforts to evaluate fluoride and dental health. Starting in the late 1930s, the unit's director, H. Trendley Dean, used an NIH-developed analytical method to evaluate naturally occurring fluoride in drinking water and associated dental fluorosis. For more information, see National Institute of Dental and Craniofacial (continued...)

- the EPA's[12] Safe Drinking Water Act (SDWA) regulation, and periodic reviews of the regulation;
- litigation under the Toxic Substances Control Act (TSCA);[13] and
- policy considerations pertaining to fluoride-related research, regulation, and implementation.

Background

Fluoride is a naturally occurring mineral present at some level in virtually all water.[14] Well water may have higher concentrations of fluoride, as fluoride may dissolve out of certain rock formations into groundwater. A substantial body of scientific studies has found that ingesting fluoride mitigates or reverses tooth decay or dental caries and stimulates the formation of new bone throughout the body.[15] Therefore, fluoride at low levels is considered to have beneficial effects on dental health; however, prolonged exposure to higher concentrations of fluoride may lead to harmful effects that range in severity (e.g., mild to severe dental fluorosis to crippling skeletal fluorosis).[16]

Some communities began actively fluoridating water supplies in the mid-1940s, after scientists discovered that with higher levels of fluoride in a community's water supply there were fewer cavities recorded among residents.[17] To adjust fluoride concentrations in community water supplies, systems generally use one of three chemicals—sodium fluoride, hexafluorosilicic acid, or sodium fluorosilicate.[18] Over time, more communities added fluoride to their water supplies as a means to support dental health. By 2022, the CDC estimated that roughly 209 million (72.3%) of the 289 million people served by community water systems in the United States received

Research, "The Story of Fluoridation," December 2024, https://www.nidcr.nih.gov/health-info/fluoride/the-story-of-fluoridation.

[12] In 1970, with congressional approval, the Nixon Administration established EPA under an executive branch reorganization plan, which consolidated numerous federal pollution control responsibilities that had been divided among several federal agencies. Among these responsibilities, several environmental health functions and programs transferred from the U.S. Public Health Service (PHS) to EPA. The PHS has retained its role in issuing guidance related to community water fluoridation; however, the primary authority over drinking water was transferred to EPA. EPA, *EPA and HHS Announce New Scientific Assessments and Actions on Fluoride / Agencies Working Together to Maintain Benefits of Preventing Tooth Decay While Preventing Excessive Exposure*, January 7, 2011, https://www.epa.gov/archive/epapages/newsroom_archive/newsreleases/86964af577c37ab285257811005a8417.html.

[13] Food & Water Watch, Inc. v. EPA, No. 17-cv-02162 EMC, 2024 WL 4291497 (N.D. Cal., Sept. 24, 2024). The Toxic Substances Control Act (TSCA) is codified at 15 U.S.C. §2601 et seq.

[14] Fluoride is the ionic form of the element fluorine.

[15] Institute of Medicine, Food and Nutrition Board, *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride* (Washington, DC: National Academies Press, 1997).

[16] Studies have found that exposure to fluoride concentrations of 10 milligrams per liter (mg/L) for 20 years or more has toxic effects such as crippling skeletal fluorosis, a long-term bone disease characterized by osteosclerosis and bone deformities that result in crippling pain and debility. EPA, "National Primary Drinking Water Regulations; Fluoride," 50 *Federal Register* 47144, November 14, 1985. EPA, *New Fluoride Risk Assessment and Relative Source Contribution Documents*, EPA-822-F-11-011, January 2011, https://www.epa.gov/sites/default/files/2019-03/documents/fluoride-risk-assess-factsheet.pdf.

[17] National Cancer Institute (NCI), "Fluoridated Water," May 15, 2017, https://www.cancer.gov/about-cancer/causes-prevention/risk/myths/fluoridated-water-fact-sheet#:. Hereinafter NCI, "Fluoridated Water," May, 2017. According to the NCI, Grand Rapids, MI, began adjusting the fluoride content of its water supply to 1.0 milligram per liter (mg/L) in 1945. NCI identified Grand Rapids as the first city in the United States to implement community water fluoridation.

[18] CDC, "Engineering and Administrative Recommendations for Water Fluoridation, 1995," *Morbidity and Mortality Weekly Report*, vol. 44, no. RR-13 (September 29, 1995), https://www.cdc.gov/mmwr/pdf/rr/rr4413.pdf. Hexafluorosilicic acid is also known as fluorosilicic acid or hydrofluorosilicic acid.

fluoridated water.[19] This figure represents an increase of 6.3 percentage points from 2000, when 66% of individuals served by water systems were provided with fluoridated water.[20] CDC, the American Medical Association, the American Dental Association, the American Academy of Pediatric Dentistry, and other organizations[21] recommend fluoridation of water supplies as a way to protect dental health, particularly in low-income communities where children are less likely to receive adequate dental care.[22]

In addition to exposure through fluoridated water supplies, individuals may ingest fluoride at varying concentrations from substances like fluoridated toothpastes, mouth rinses, dietary supplements, or professionally applied fluoride compounds, like varnish or gels.[23] Fluoride may also be present in soil, plants, and certain foods.[24] Food or beverage products prepared with water may be naturally or supplementally fluoridated;[25] for example, some infant formulas may be either developed or reconstituted with fluoridated water. The following section describes some of the challenges that these varied sources of fluoride pose when weighing the health benefits and risks of water fluoridation.

Overview of Research Challenges

Scientists and public health agencies have examined the effectiveness of water fluoridation in protecting dental health for nearly a century. At the same time, the safety and efficacy of fluoridation continues to be questioned, debated, and studied, particularly as presumptions about fluoride ingestion have changed since 1987.[26] Some research has aimed to compare the relative effects on health outcomes from different factors, including various fluoride sources, as well as

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[19] Individuals who are not served by a community water system may have their own private residential well or may be served by a system that serves fewer than 25 individuals year-round. CDC, "2022 Water Fluoridation Statistics," June 6, 2024, https://www.cdc.gov/fluoridation/php/statistics/2022-water-fluoridation-statistics.html. Some communities choose to not adjust fluoride in water supplies for a variety of reasons.

[20] CDC, "Populations Receiving Optimally Fluoridated Public Drinking Water—United States, 2000," *Morbidity and Mortality Weekly Report*, vol. 51, no. 7 (February 22, 2002), pp. 144-147.

[21] See, for example, CDC, "CDC Scientific Statement on Community Water Fluoridation," press release, May 15, 2024, https://www.cdc.gov/fluoridation/about/statement-on-the-evidence-supporting-the-safety-and-effectiveness-of-community-water-fluoridation.html; American Medical Association, "Water Fluoridation H-440.972.," press release, 2021, https://policysearch.ama-assn.org/policyfinder/detail/h%20440.972?uri=%2FAMADoc%2FHOD.xml-0-3987.xml; American Dental Association, "Community Water Fluoridation is Effective at Preventing Cavities," press release, October 4, 2024, https://www.ada.org/about/press-releases/community-water-fluoridation-is-effective-at-preventing-cavities; and American Academy of Pediatric Dentistry, "Policy on Use of Fluoride," press release, 2023, https://www.aapd.org/media/policies_guidelines/p_fluorideuse.pdf.

[22] See, for example, Anne Sanders et al., "Association Between Water Fluoridation and Income-Related Dental Caries of US Children and Adolescents," *JAMA Pediatrics*, vol. 173, no. 3 (January 28, 2019), pp. 288-290.

[23] CDC, *About Fluoride*, May 15, 2024, https://www.cdc.gov/oral-health/prevention/about-fluoride.html. See also U.S. Food and Drug Administration (FDA), "FDA Begins Action To Remove Ingestible Fluoride Prescription Drug Products for Children from the Market," press release, May 13, 2025, https://www.fda.gov/news-events/press-announcements/fda-begins-action-remove-ingestible-fluoride-prescription-drug-products-children-market.

[24] The Food and Nutrition Board of the National Academies of Sciences, Engineering, and Medicine has evaluated fluoride as a component of its Dietary Reference Intakes (DRIs), which are used for assessing the nutrient intakes of healthy people. Institute of Medicine, Food and Nutrition Board, *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride* (Washington, DC: National Academies Press, 1997); and National Institutes of Health (NIH), Office of Dietary Supplements, "Dietary Supplement Fact Sheet for Health Professionals: Fluoride," June 26, 2024, https://ods.od.nih.gov/factsheets/Fluoride-HealthProfessional/.

[25] NIH, Office of Dietary Supplements, "Dietary Supplement Fact Sheet for Health Professionals: Fluoride," June 26, 2024, https://ods.od.nih.gov/factsheets/Fluoride-HealthProfessional/.

[26] For additional discussion of fluoride ingestion assumptions, see "EPA's Safe Drinking Water Act (SDWA) Regulation" and "Reviews of the Fluoride Regulation and Its Scientific Basis."

changes in behavior (i.e., oral hygiene practices).[27] Variability across each of these factors poses an ongoing challenge to research studies. When evaluating whether exposure to fluoride may be beneficial or harmful to human health based on the findings of various research studies, critical aspects to consider are the sources of fluoride exposure, whether fluoride is ingested or topically applied, the duration of the exposure, the amount (or concentration) of the fluoride, and the health outcomes associated with various exposure levels. Other aspects to consider include the age and underlying health conditions of those who are exposed and other environmental exposures that may be encountered.

Units of Measurement

The unit of measurement is key to evaluating the amount (or concentration) of fluoride that may be beneficial for dental health or pose potential adverse health effects. For fluoride that may be ingested through water, the weight of fluoride, expressed in milligrams (mg), present in a particular volume of water, expressed in liters (L), is typically used (i.e., mg/L). To account for variability among adults and children, toxicologists and risk assessors may focus on the total weight of fluoride, typically expressed in milligrams (mg), that an individual may ingest in one day (i.e., mg/day). Because children generally weigh less than adults, exposure to the same amount of fluoride for children is expected to result in a higher amount of fluoride spread throughout the entire body than for adults. To account for relative bodyweight between children and adults, toxicologists and risk assessors may also compare the total weight of fluoride, typically expressed in milligrams (mg), to bodyweight, expressed in kilograms (kg), over one day (i.e., mg/kg/day).

Reference Dose

To determine the acceptable exposure from ingestion of a particular substance, toxicologists and risk assessors typically calculate a *reference dose*, which is "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime."[28] Calculating a reference dose requires researchers to (1) identify the lowest dose level at which adverse health effects are observed, or (2) identify the highest dose level at which adverse health effects are not observed and to lower either level further to account for uncertainties. Due to variations and uncertainties inherent in such a process, calculating a reference dose relies on some degree of professional judgment.

Reference doses for fluoride may be expressed using different units of measurement, depending on assumptions regarding bodyweight or drinking water consumed. For example, a reference dose may be expressed as total fluoride relative to bodyweight per day or total fluoride in drinking water. For total fluoride in drinking water, a particular bodyweight and drinking water consumption rate must be assumed to expect protectiveness for those who weigh more or drink less. In addition, reference doses can be expressed as total fluoride in different bodily fluids (e.g., urinary fluids or blood serum) and other components of the body (e.g., hair or stool), as an estimate of total exposure to fluoride in an individual.

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[27] NIH, National Institute of Dental and Craniofacial Research (NIDCR), *Oral Health in America: Advances and Challenges*, 2021, p. 2A-2, https://www.nidcr.nih.gov/sites/default/files/2021-12/Oral-Health-in-America-Advances-and-Challenges.pdf#page=160; and EPA, *Fluoride: Exposure and Relative Source Contribution Analysis*, 820-R-10-015, December 2010, https://www.epa.gov/sites/default/files/2019-03/documents/fluoride-exposure-relative-report.pdf.

[28] EPA, *A Review of the Reference Dose and Reference Concentration Processes*, 630-P-02-002F, December 2002, p. 4-4, https://www.epa.gov/sites/default/files/2014-12/documents/rfd-final.pdf.

Certain reference doses for fluoride have been widely accepted among the scientific community, while others have been the subject of substantial disagreement, especially if the underlying scientific information used to support the calculation of a reference dose is evolving. Reference doses for fluoride based on dental health and bone health are widely accepted and form the basis of the current drinking water regulation.[29] However, some have proposed lower reference doses for fluoride exposure based on potential adverse health effects, discussed in several sections of this report (e.g., "The Court's Order").

Research on Health Effects of Fluoride

Broadly, research and public debate surrounding the benefits and risks of fluoridated water have focused on dental care and neurodevelopmental outcomes, particularly in children. Other topics, including bone health and outcomes related to fluoride exposure through infant formula, have also been explored. The following section provides a brief overview of the scientific research and debate related to these topics and includes summaries of some research utilized to form PHS recommendations or EPA regulations. This section is not intended to be a comprehensive analysis, nor does it draw independent conclusions based on the evidence summarized below.[30]

Dental Care

Fluoride is most commonly discussed in the context of preventing *dental caries.* This term refers to tooth decay, including cavities, which can vary based on how severely the tooth enamel has been worn down by naturally occurring and diet-related acids.[31] Tooth decay, particularly when left untreated in children, can exacerbate into worsened cavities, pain, and secondary outcomes like school absences and poorer school performance—particularly among children of lower socioeconomic status.[32] An HHS report published in 2000 characterized dental caries as the "single most common chronic childhood disease."[33] Data from CDC indicate that from 1999 to 2002, approximately one-quarter (22.5%) of U.S. children aged 5-19 had untreated dental caries; more recent data from 2015 to 2018 indicate that 13.2% of children aged 5-19 have untreated dental caries.[34]

Fluoride works to prevent new dental caries or mitigate existing caries by remineralizing and restrengthening tooth enamel. A substantial body of research has indicated that community water fluoridation can effectively decrease the prevalence and severity of dental caries, regardless of an individual's age or socioeconomic status.[35]

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[29] EPA, "National Primary and Secondary Drinking Water Regulations: Fluoride," 51 *Federal Register* 11396-11412, April 2, 1986.

[30] As discussed in the introduction to this report, federal agencies rely on health research to make recommendations or establish regulatory levels. The recommendations and standards discussed throughout this report were developed across a range of years and thus relied upon the available evidence at the time. Due to the evolving nature of research and the scientific process, not all of the evidence presented in the "Research on Health Effects of Fluoride" section may be incorporated into the various standards or recommendations discussed herein.

[31] NIDCR, "Tooth Decay," https://www.nidcr.nih.gov/health-info/tooth-decay, accessed March 6, 2025.

[32] NIH, *Oral Health in America: Advances and Challenges*, Bethesda, MD, 2021, p. 1-23.

[33] HHS, PHS, *Oral Health in America: A Report of the Surgeon General*, 2000, p. 2, https://www.nidcr.nih.gov/sites/default/files/2017-10/hck1ocv.%40www.surgeon.fullrpt.pdf.

[34] "Morbidity" in CDC, Centers for Disease Control and Prevention, National Center for Health Statistics, "Oral and Dental Health," September 24, 2024, *United States*, Trend Tables, 2019, p. 1, https://www.cdc.gov/nchs/fastats/dental.htmhttps://www.cdc.gov/nchs/data/hus/2019/028-508.pdf.

[35] HHS, "Public Health Service Recommendation for Fluoride Concentration in Drinking Water for Prevention of (continued...)

Exposure to heightened levels of fluoride—particularly when teeth are still developing in young children—can result in dental fluorosis. Dental fluorosis can range from mild cases characterized by white spots on teeth to more severe symptoms, including tooth pitting or discoloration. The risk and severity of dental fluorosis depends on the amount, duration, and frequency of exposure to fluoride, with the risk period extending from birth through eight years of age.[36] Infant formula exclusively mixed with fluoridated water has been linked to an increased risk for mild dental fluorosis. According to the Office of Dietary Supplements within the National Institutes of Health, fluoride levels in infant formula can range from 0.2 mg/L to 0.3 mg/L, excluding the tap water used to reconstitute the formula.[37] CDC recommends using bottled water that has low water fluoridation to minimize this risk.[38]

National estimates of dental fluorosis are provided from the National Health and Nutrition Examination Survey (NHANES),[39] which has observed variability in the prevalence and severity of dental fluorosis over time. For example, across individual survey years from 2011 to 2016, "mild" fluorosis in youth aged 6-19 years ranged from a low of 9.1% (2015-2016) to a high of 40.4% (2013-2014), "moderate" ranged from 1.3% (2015-2016) to 20.6% (2011-2012), and "severe" fluorosis ranged from 0.1% (2015-2015) to 2.0% (2011-2012).[40] These categories, as defined by the "Dean's Fluorosis Index," are based upon the presentation of tooth enamel; for example, "mild" refers to white opaque areas across less than 50% of the enamel, and "severe" refers to cases where all enamel surfaces are affected, among other attributes.[41] A data quality evaluation conducted by CDC notes that some of this variability across severity categories may be explained by changes in how examiners assess the level of fluorosis over time, and that distinguishing between "very mild" and "mild" levels can be difficult given the subjectivity of the index.[42]

Dental Caries," 80 *Federal Register* 24936-24947, May 1, 2015, p. 320. Hereinafter "*PHS Recommendations for Fluoride Concentration*."

[36] Eugenio D. Beltran-Aguilar et al., *Prevalence and Severity of Dental Fluorosis in the United States, 1999-2004*, NCHS Data Brief No. 53, November 2010, https://www.cdc.gov/nchs/data/databriefs/db53.pdf.

[37] NIH, Office of Dietary Supplements, "Dietary Supplement Fact Sheet for Health Professionals: Fluoride," June 26, 2024, https://ods.od.nih.gov/factsheets/Fluoride-HealthProfessional/.

[38] CDC, "Community Water Fluoridation Frequently Asked Questions," May 5, 2024, https://www.cdc.gov/fluoridation/faq/index.html; National Toxicology Program (NTP), *NTP Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition: A Systematic Review*, August 2024, https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride_final_508.pdf.

[39] The National Health and Nutrition Examination Survey (NHANES) is a nationally representative survey that collects data about the health of adults and children in the United States. NHANES collects data on a range of health topics, including interviews about health, diet, and socioeconomic characteristics, and may also collect data from dental exams and laboratory tests, among other topics. For more information, see the CDC National Center for Health Statistics, *About NHANES*, https://www.cdc.gov/nchs/nhanes/about/index.html.

[40] See Figure 1 in National Center for Health Statistics, Data Quality Evaluation of the Dental Fluorosis Clinical Assessment Data from the National Health and Nutrition Examination Survey, 1999–2004 and 2011–2016, Data Evaluation and Methods Research, Hyattsville, MD, April 2019, https://www.cdc.gov/nchs/data/series/sr_02/sr02_183-508.pdf.

[41] For more information on Dean's Fluorosis Index, see Table 1 in National Center for Health Statistics, Data Quality Evaluation of the Dental Fluorosis Clinical Assessment Data from the National Health and Nutrition Examination Survey, 1999–2004 and 2011–2016, Data Evaluation and Methods Research, Hyattsville, MD, April 2019, https://www.cdc.gov/nchs/data/series/sr_02/sr02_183-508.pdf.

[42] National Center for Health Statistics, Data Quality Evaluation of the Dental Fluorosis Clinical Assessment Data from the National Health and Nutrition Examination Survey, 1999–2004 and 2011–2016, Data Evaluation and Methods Research, Hyattsville, MD, April 2019, https://www.cdc.gov/nchs/data/series/sr_02/sr02_183-508.pdf. See "Summary" section beginning on p. 11.

As discussed below in the "U.S. Public Health Service (PHS)" section, the PHS recommends an optimal fluoride concentration of 0.7 mg/L as the safe and effective community water fluoridation level to prevent tooth decay while also limiting the risk of dental fluorosis.[43] For a discussion of EPA's role in regulating fluoride levels in community water supplies, see the section below on "EPA's Safe Drinking Water Act (SDWA) Regulation."

Bone Health

Prolonged exposure to heightened levels of fluoride is also linked to skeletal fluorosis, characterized by weakened bones and joints, and may potentially lead to arthritis or osteoporosis.[44] Cases of skeletal fluorosis are rare in the United States, but more common in countries with groundwater with excessive amounts of fluoride.[45] According to data presented by the HHS Office of the Assistant Secretary for Planning and Evaluation in 2003, fewer than five cases of severe skeletal fluorosis had ever been reported in the United States at the time.[46] These individuals were exposed to a total fluoride intake of 15-20 mg of fluoride per day for 20 years.[47] CRS was unable to identify more recent estimates, likely explained in part by a lack of surveillance and the relatively rare nature of the disease in the United States.

Other research has examined whether fluoride exposure can cause cancer, particularly a type of bone cancer called osteosarcoma. A 1990 study by the National Toxicology Program (NTP) found an increased incidence of osteosarcoma in male rats given high doses of fluoride over a prolonged period;[48] however, a subsequent PHS report in 1991 stated that after reviewing more than 50 studies in humans conducted across the prior 40 years, water fluoridated to optimal levels "does not pose a detectable cancer risk to humans."[49] Later research in 2006 by the National Research Council (NRC; see text box below) studied potential cancer risks and identified that, overall, the literature did not clearly indicate that fluoride either is or is not carcinogenic in humans (this research is also discussed in "Carcinogenicity").[50] Additional research over subsequent years, including studies using new methodologies to examine possible relationships between osteosarcoma and fluoride, has not demonstrated an association between osteosarcoma and water

[43] *PHS Recommendations for Fluoride Concentration*, 2015, p. 318.

[44] *PHS Recommendations for Fluoride Concentration*, 2015.

[45] Cleveland Clinic, "Fluorosis," https://my.clevelandclinic.org/health/diseases/23227-fluorosis.

[46] Prior to the March 27, 2025, restructuring announcement, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) was responsible for advising the HHS Secretary on "policy development in health, disability, human services, data, and science" in addition to other tasks. See Office of the Assistant Secretary for Planning and Evaluation, *About ASPE*, https://aspe.hhs.gov/about. The reorganization indicates that HHS may merge ASPE with the Agency for Healthcare Research and Quality to create a new Office of Strategy. See HHS, "HHS Announces Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/press-room/hhs-restructuring-doge.html.

[47] Office of the Assistant Secretary for Planning and Evaluation, *CDC-Fluoridation: HHS Response to Rfr*, August 2004, https://aspe.hhs.gov/cdc-fluoridation-hhs-response-rfr.

[48] NTP, *NTP Toxicology and Carcinogenesis Studies of Sodium Fluoride (CAS No. 7681-49-4) in F344/N Rats and B6C3F1 Mice (Drinking Water Studies)*, December 1990, p. 442.

[49] Ad Hoc Subcommittee on Fluoride of the Committee to Coordinate Environmental Health and Related Programs, *Review of Fluoride: Benefits and Risks*, PHS, February 1991, https://stacks.cdc.gov/view/cdc/7105/cdc_7105_DS1.pdf.

[50] NRC, *Fluoride in Drinking Water*, 2006, p. 8, and pp. 274-284. The NRC was previously referred to as the operational arm of the National Academy of Sciences (NAS) and the National Academy of Engineering (NAE). After 2015, the NRC name was phased out and all NRC, NAS, NAE, and National Academy of Medicine (NAM) activities are collectively referred to as the National Academies of Sciences, Engineering, and Medicine (NASEM). See NASEM, *A History of the National Academy of Medicine*, 50 Years of Transformational Leadership, Washington, DC, 2022, https://doi.org/10.17226/26708.

fluoridation. A summary of some of these studies can be found on the National Cancer Institute's webpage and within the 2015 PHS recommendations.[51]

Neurodevelopmental Effects

Research regarding the health effects of fluoride exposure has also examined the linkages between fluoride and adverse neurodevelopmental outcomes in children. The NTP, detailed in the "National Toxicology Program (NTP)" section below, in 2024 published a systematic review of the scientific literature to evaluate "the extent and quality of the evidence linking fluoride exposure to neurodevelopmental and cognitive effects in humans."[52] This review, also known as a monograph, assessed research published through May 1, 2020. It examined research exclusively in humans due to concerns that animal-based studies contained poor-quality data. The review included research on fluoride exposures during pregnancy and studies examining fluoride ingested by children. Originally, the draft monograph also included a meta-analysis which, by definition, pools and analyzes data across studies to assess overall trends. However, the National Academies of Sciences, Engineering, and Medicine (NASEM; see text box below) raised concerns about some of the conclusions drawn from the draft monograph.

Upon NTP's request, NASEM reviewed a 2019 draft of the monograph and outlined multiple suggestions for improvement related to the methods utilized in both the systematic review and meta-analysis, as well as the risk of bias from human and animal-based evidence, among other concerns.[53] NASEM reviewed a subsequent update in which NTP attempted to respond to NASEM's recommendations. Upon review of the NTP's 2020 update, NASEM concluded that although some of the recommendations were addressed, the revised monograph "falls short of providing a clear and convincing argument that supports its assessments."[54] In response to NASEM's second review, NTP revised some of the methods used in the monograph and excluded the meta-analysis component of the monograph, resulting in a systematic review that exclusively evaluated the quality of the scientific evidence and did not develop quantitative estimates.[55]

About the National Academies of Sciences, Engineering, and Medicine (NASEM)

The National Academies of Sciences, Engineering, and Medicine (NASEM; also known collectively as "The National Academies") are a group of three private, nonprofit institutions and related programmatic units that "provide independent, objective advice to inform policy with evidence, spark progress and innovation, and confront challenging issues for the benefit of society."[56] The National Academy of Sciences (NAS) was established by Congress in 1863 as a private, nongovernmental institution tasked with advising the government on issues related to science and technology[57]. The National Academy of Engineering (NAE) was later founded in 1964, followed by the National Academy of Medicine (NAM) in 1970 (previously known as the Institute of Medicine; IOM)—both

[51] NCI, "Fluoridated Water," May, 2017*; PHS Recommendations for Fluoride Concentration*, 2015.

[52] NTP, *NTP Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition: A Systematic Review*, August 2024, p. xviii, https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride_final_508.pdf. Hereinafter *NTP Monograph,* August 2024.

[53] NASEM, *Review of the Draft NTP Monograph: Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects*, Consensus Study Report, Washington, DC, 2020, https://doi.org/10.17226/25715.

[54] NASEM, *Review of the Revised NTP Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects: A Letter Report,* Washington, DC, 2021, https://doi.org/10.17226/26030.

[55] *NTP Monograph,* August 2024, p. xi. The meta-analysis results were published separately in January 2025. See final paragraph in the "Neurodevelopmental Effects" section for more information.

[56] National Academies, "About Us," https://www.nationalacademies.org/about.

[57] See NAS, *An Act to Incorporate the National Academy of Sciences*, March 3, 1863, https://www.nasonline.org/about-the-nas/leadership/governing-documents/an-act-to-incorporate-the-national-academy-of-sciences/.

NAE and NAM were established under the charter of the NAS, which was later codified in P.L. 105-225 (36 U.S.C. §150301). Each Academy is composed of members who are elected by their peers for their contributions to their particular field of study. The National Research Council (NRC) was formed in 1918 and functioned as the operational and principal programmatic arm of NAE and NAS. Concurrent with the shift from IOM to NAM, the name of the NRC was supplanted by NASEM.[58] This report uses "NRC" when referring to studies conducted prior to this 2015 name change.

NASEM conducts a range of activities such as researching and publishing congressionally mandated reports (i.e., studies that originated out of direction in congressional legislation), convening roundtables and other proceedings, providing testimony or briefings before Congress, and other public engagement programs. NASEM provides a list of recent public laws directing studies for NASEM on its website.[59] NASEM may also provide review of scientific works. For example, because of the public interest in water fluoridation, NTP asked NASEM to provide an independent review and evaluation of the draft NTP monograph on fluoride exposure and neurodevelopmental and cognitive health effects. As a result, NASEM reviewed both the 2019 and 2020 drafts of the NTP monograph.[60]

Broadly, the final monograph (published in August 2024) found with "moderate confidence"[61] that exposure to higher levels of fluoride (i.e., fluoride levels above the World Health Organization's [WHO's] drinking water guideline of 1.5 mg/L) are associated with a lower IQ in children. This WHO guideline value is above the PHS optimal fluoride concentration of 0.7 mg/L.[62] The evidence examining the relationship between fluoride exposure and children's IQ was from countries other than the United States where some pregnant women, infants, and children were exposed to fluoride levels higher than the WHO 1.5 mg/L guideline; according to the monograph, no high-quality studies examining the association between fluoride exposure and neurodevelopmental effects in adults or children have been conducted in the United States.[63]

A limited number of studies have examined the relationship between children's IQ and lower fluoride exposure (i.e., lower than 1.5 mg/L);[64] the monograph was not able to measure whether water fluoridation levels such as 0.7 mg/L in the United States are associated with a decrease in IQ.[65] The review also stated that there is "some evidence" to suggest that fluoride exposure is associated with other adverse neurodevelopmental and cognitive effects in children, while also noting that there is low confidence from the literature about these effects since the studies

[58] NASEM, *A History of the National Academy of Medicine*: *50 Years of Transformational Leadership*, Washington, DC, 2022, https://doi.org/10.17226/26708.

[59] NASEM, Office of Congressional and Government Affairs, "Public Laws Containing Studies for the Academies," https://www.nationalacademies.org/ocga/public-laws.

[60] Committee to Review the Revised NTP Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects, *Review of the Revised NTP Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects—National Academies of Sciences, Engineering, and Medicine: A Letter Report*, Washington, DC, 2021, http://nap.nationalacademies.org/26030.

[61] "Moderate confidence" is the second highest of four confidence ratings within the "Grading of Recommendations, Assessment, Development, and Evaluation" or GRADE system, which characterizes the strength of the scientific evidence that examines a particular health outcome and an exposure. More information about how each rating was determined can be found in the NTP Protocol; see NTP, "Data and Protocol for Systematic Review of Fluoride Exposure and Neurodevelopment and Cognition," https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/completed/fluoride/data, accessed March 6, 2025.

[62] The World Health Organization (WHO) guideline value of 1.5 mg/L for fluoridated drinking water was first established in 1984 and reaffirmed in 1993 and 2011. The guideline reflects the WHO's recommendation for the protection from skeletal fluorosis. For more information, see WHO, *Guidelines for Drinking-Water Quality: Fourth Edition Incorporating First Addendum*, 4th edition; 1st addendum, Geneva, 2017, https://iris.who.int/handle/10665/254637.

[63] *NTP Monograph*, August 2024, p. 80.

[64] *NTP Monograph*, August 2024, p. 80.

[65] *NTP Monograph*, August 2024, p. xii.

included in the review examined a wide range of outcomes (e.g., IQ versus other cognitive measures), which makes drawing comprehensive conclusions and understanding the biological plausibility challenging.[66] The monograph also states that the studies examined in the review did not result in "increased understanding of how fluoride may affect children's cognitive neurodevelopment" and called for more research to better understand the potential relationship between lower levels of fluoride exposure and neurodevelopmental outcomes in children, including potential mechanisms and the dose-response relationship.

In January 2025, the results from the meta-analysis were published independently from the NTP monograph in a peer-reviewed journal.[67] Results from the meta-analysis demonstrated an inverse relationship (i.e., a relationship wherein one variable decreases as another variable increases) between children's IQ scores and fluoride exposure across fluoride concentrations of 1.5 mg/L or higher. However, the meta-analysis indicated that the majority (52 of 74) of included studies had a "high risk of bias," and that there were "limited data and uncertainty" when examining the relationship between children's IQ and fluoridated drinking water concentrations at concentrations less than 1.5 mg/L.[68] Accompanying editorial publications have critiqued the meta-analysis, arguing that it did not provide "increase[d] transparency" on the included articles or on the origin of the meta-analysis, which was originally part of the NTP monograph.[69] Others have suggested that the results of the meta-analysis indicate a "need to reassess the potential risks of fluoride during early brain development."[70]

U.S. Department of Health and Human Services (HHS)

The following section outlines agencies and initiatives within HHS that have a role in community water fluoridation. This section is not intended to be exhaustive, but rather summarizes ongoing programs or guidelines administered by the HHS agencies that are most commonly referred to with regard to community water fluoridation. As mentioned earlier, on March 27, 2025, HHS issued a press release and fact sheet announcing that HHS is being restructured. At the time of this report's publication, the potential effect of this restructuring on the fluoride-related activities discussed below is unknown.[71] The following sections discuss HHS activities, roles, and organization as they were implemented prior to the restructuring announcement.

Aside from recommendations, programs, or other initiatives, many HHS agencies are involved in the funding, development, implementation, and/or dissemination of research related to fluoride. The full breadth of federally funded research on water fluoridation is expansive and not covered

[66] *NTP Monograph*, August 2024, p. xix.

[67] K.W. Taylor et al., "Fluoride Exposure and Children's IQ Scores: A Systematic Review and Meta-Analysis," *JAMA Pediatrics*, published online January 6, 2025, https://doi.org/10.1001/jamapediatrics.2024.5542.

[68] The NTP Monograph assessed the degree of bias in each research study using standardized questions and assessments depending on each individual study's design (e.g., observational versus experimental studies.) For more information about how study bias was assessed, see *NTP Monograph*, August 2024, p. 14.

[69] Steven M. Levy, "Caution Needed in Interpreting the Evidence Base on Fluoride and IQ," *JAMA Pediatrics*, published online January 6, 2025, https://doi.org/10.1001/jamapediatrics.2024.5539.

[70] Bruce P. Lanphear et al., "Time to Reassess Systemic Fluoride Exposure, Again," *JAMA Pediatrics*, published online January 6, 2025, https://doi.org/10.1001/jamapediatrics.2024.5549.

[71] HHS, "HHS Announces Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/press-room/hhs-restructuring-doge.html.

in detail within this report; however, studies and reviews as they relate to community water fluoridation are discussed throughout this report.

U.S. Public Health Service (PHS)

The PHS has long carried out HHS's public health functions. It has undergone several changes since its inception; at the time of the March 2025 restructuring announcement, PHS was composed of the nine health-related agencies within HHS and is overseen by the Assistant Secretary for Health.[72] Whereas each individual health agency operates under specific authorities and within a particular scope, the PHS may issue cross-agency recommendations, guidelines, and policies developed by interdepartmental, interagency experts and with public input. PHS recommendations are not regulatory and therefore not considered enforceable standards.[73]

The PHS published its first set of recommendations regarding fluoride levels as part of the 1962 Drinking Water Standards.[74] With a goal of reducing dental caries while also minimizing the risk of dental fluorosis, the PHS recommended a range of community water fluoride concentrations (0.7-1.2 mg/L) and stated that the fluoride concentration should depend on the outdoor temperature in the area.[75] The rationale for this variable fluoride level was based on the assumption that children's tap water intake would increase as outdoor air temperature increased—therefore, a lower fluoride concentration would be appropriate in warmer climates, and vice versa. However, updated scientific evidence, alongside social and environmental changes (e.g., indoor air conditioning), refuted this idea, as research demonstrated that outdoor temperature had little to no impact on children's total water intake. In 2015, PHS published the "U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries"—effectively replacing the 1962 Drinking Water Standards recommendations related to community water fluoride concentrations.[76]

The revised PHS recommendations were based on an updated evaluation of systematic reviews examining the effectiveness of fluoride in preventing dental caries, the effectiveness of community water fluoridation, and a National Research Council review focusing on hazardous levels of naturally occurring fluoride. The panel's conclusions and proposed recommended concentration of 0.7 mg/L were summarized in the *Federal Register* in 2011 and followed by a four-month public comment period. Public comments included those that deemed the proposed recommendation too high, those that thought the recommendation was too low, and those that

[72] Most recently, the PHS includes the NIH, the CDC, the FDA, the Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Indian Health Service (IHS), the Administration for Strategic Preparedness and Response (ASPR), and the Agency for Toxic Substances and Disease Registry (ATSDR). For further information, see CRS Report R48060, Department of Health and Human Services: FY2025 Budget Request, by Jessica Tollestrup, Karen E. Lynch, and Ada S. Cornell.

[73] The PHS has undergone many reorganizations throughout its history and previously included many environmental health functions and programs, most of which were transferred to EPA when the agency was established in 1970. The PHS has retained its role in issuing guidance related to community water fluoridation; however, the primarily regulatory authority over drinking water was transferred to EPA.

[74] U.S. Department of Health, Education, and Welfare, *Public Health Service Drinking Water Standards, Revised 1962*, PHS Publication No. 956, Washington, DC, August 1962.

[75] *PHS Recommendations for Fluoride Concentration*, 2015, pp. 322.

[76] The 2015 PHS recommendations were authored by the HHS Federal Panel on Community Water Fluoridation, which was composed of panel members from CDC, FDA, HRSA, NIH, AHRQ, HHS Office of the Assistant Secretary for Health (OASH), EPA, the U.S. Department of Agriculture (USDA), and advisors and consultants within the PHS.

supported the recommendation.[77] In response to comments that opposed the proposed fluoride concentration level as too high and comments that cited specific adverse health outcomes, the PHS panel undertook a second review of the scientific evidence and summarized findings across the health outcomes cited in the public comment period; these included dental fluorosis, bone fractures and skeletal fluorosis, carcinogenicity, neurologic effects (including IQ effects), endocrine disruption, and the prevention of dental caries.[78] The panel also summarized literature examining the cost-effectiveness, safety, and ethics of community water fluoridation.

Following the panel's second review and consideration of the public comments alongside the "best available science," the panel did not alter the proposed level of 0.7 mg/L. In the final 2015 PHS recommendations, the PHS recommends an optimal fluoride concentration of 0.7 mg/L for community water systems that add fluoride to drinking water or may choose to initiate water fluoridation in the future.[79] The PHS stated that this optimal fluoride concentration is based on updated scientific evidence regarding the prevalence of dental fluorosis (see "Research on Health Effects of Fluoride"), the contribution of fluoridated drinking water in relation to other sources of fluoride (e.g., fluoridated toothpaste), and an updated understanding of the relationship between children's water intake and outdoor temperatures. Further, the PHS continued to recommend community water fluoridation as "an effective public health strategy ... and … the most feasible and cost-effective strategy" with the understanding that water supply fluoridation decisions are made at the state and/or local levels.[80] The 2015 PHS recommendation remains the most current PHS recommendation related to water fluoridation.

Community Preventive Services Task Force (CPSTF)

The Community Preventive Services Task Force (CPSTF) is an independent panel of public health experts tasked with developing guidance on community-based health promotion and disease prevention interventions.[81] CPSTF recommendations are intended to guide the decisionmaking processes for federal, state, and local health departments, as well as other stakeholders, including other government agencies, communities, health care providers, and more. Members are appointed by the CDC Director. The CPSTF "uses scientifically rigorous" methods to conduct systematic reviews of the scientific evidence.[82] The CPSTF was established by HHS in 1996 and complements the work of the U.S. Preventive Services Task Force (USPSTF).[83] Whereas USPSTF focuses on medical and clinical recommendations for individual patients geared toward health providers and health systems, the CPSTF employs a public health perspective and examines interventions and public policies focused on communities.[84]

[77] HHS, "Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries," 76 *Federal Register* 9, January 13, 2011.

[78] *PHS Recommendations for Fluoride Concentration*, 2015, pp. 323-327.

[79] *PHS Recommendations for Fluoride Concentration*, 2015.

[80] *PHS Recommendations for Fluoride Concentration*, 2015, p. 328.

[81] 42 U.S.C. §280g-10.

[82] The Community Guide, "About the Community Preventive Services Task Force," https://www.thecommunityguide.org/pages/about-community-preventive-services-task-force.html.

[83] The Community Guide, "Community Preventive Services Task Force and United States Preventive Services Task Force," https://www.thecommunityguide.org/pages/guide-clinical-preventive-services.html.

[84] For more information on the USPSTF, see https://www.uspreventiveservicestaskforce.org/uspstf/.

The CPSTF first published recommendations for community water fluoridation in 2000 based on a review of scientific evidence published between 1966 and 1999.[85] In 2013, the CPSTF reaffirmed its recommendation on community water fluoridation following an updated review of scientific studies published between 1999 and 2012.[86] Both the 2000 and 2013 recommendations state that the scientific evidence links community water fluoridation with a decrease in tooth decay in children across all socioeconomic groups; notably, all included studies examined the effectiveness of community water fluoridation with respect to children, exclusively. The 2013 recommendations also noted areas where evidence was lacking at the time of publication; this included knowledge about the contribution of alternative fluoride sources (e.g., toothpaste), the effectiveness of community water fluoridation for adults, and other potential positive or negative health effects.[87] The CPSTF also references the 2011 "Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries," which, following a public comment period, was finalized as the 2015 PHS recommendations; CPSTF references the proposed (and later finalized) 0.7 mg/L as the "optimal concentration" to prevent dental caries.[88] The 2013 CPSTF recommendations remain the most current CPSTF recommendation related to water fluoridation.

Centers for Disease Control and Prevention (CDC)

Broadly, CDC works to protect public health by providing information and scientific expertise to prevent and respond to diseases and other health threats.[89] CDC does not publish mandates or enforce standards related to water fluoridation; as mentioned in the "Background" section, state and/or local governments decide whether to implement community water fluoridation initiatives. However, CDC's Division of Oral Health (DOH), located within the National Center for Chronic Disease Prevention and Health Promotion, promotes community water fluoridation as a safe, effective, and cost-saving public health intervention,[90] and in 1999, CDC named it as "1 of the 10 great public health achievements of the 20th century"[91] and a "cornerstone strategy for the prevention of tooth decay in the United States."[92] DOH supports states and territories with the implementation of programs to reduce cavity and oral disease rates. DOH programs specifically related to community water fluoridation are summarized below; these summaries reflect CDC

[85] The Community Guide, *Preventing Dental Caries: Community Water Fluoridation (2000 Archived Review)*, https://www.thecommunityguide.org/media/pdf/Oral-Health-Fluoridation-Archive.pdf.

[86] CPSTF, *Oral Health: Preventing Dental Caries, Community Water Fluoridation*, Task Force Finding and Rationale Statement, April 2013, https://www.thecommunityguide.org/media/pdf/Oral-Health-Caries-Community-Water-Fluoridation_2.pdf.

[87] CPSTF, *Oral Health: Preventing Dental Caries, Community Water Fluoridation*, p. 5.

[88] HHS, "Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries," 76 *Federal Register* 9, January 13, 2011.

[89] For more background information about CDC, see CRS Report R47981, *Centers for Disease Control and Prevention (CDC): History, Overview of Domestic Programs, and Selected Issues*.

[90] CDC, "CDC Scientific Statement on Community Water Fluoridation," May 15, 2024, https://www.cdc.gov/fluoridation/about/statement-on-the-evidence-supporting-the-safety-and-effectiveness-of-community-water-fluoridation.html.

[91] CDC, "Fluoridation of Drinking Water to Prevent Dental Caries," *Morbidity and Mortality Weekly Report*, vol. 48, no. 41 (October 20, 1999), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm. The Division of Oral Health (DOH) is within CDC's National Center for Chronic Disease Prevention and Health Promotion.

[92] CDC, "Community Water Fluoridation Recommendations," May 15, 2024, https://www.cdc.gov/fluoridation/about/community-water-fluoridation-recommendations.html.

activities, roles, and structures prior to the March 27, 2025, announcement indicating HHS is being restructured.[93]

Water Fluoridation Reporting System

CDC's DOH manages the "Water Fluoridation Reporting System (WFRS)," an online data management tool where state officials (e.g., drinking water engineers, health department staff) can collect and enter data on fluoride levels in water systems.[94] Although CDC recommends that fluoride levels are measured daily within state and local water systems, reporting in WFRS is voluntary.[95] WFRS collects information including average fluoride concentrations, daily testing results, and data related to water facility inspections.[96] CDC uses these datasets as the basis for national reports and analyses on community fluoridation levels; state fluoridation officials may use the data reported in WFRS for various program quality reports.[97]

CDC also operates a public-facing side of WFRS, known as "My Water's Fluoride (MWF)."[98] Approximately 40 states choose to share public-facing data through MWF.[99] Users can access county-specific water fluoridation information within participating states, such as whether a county's water is fluoridated, the most recent water fluoride concentration, and the total population served by a water source. CDC also publishes summative reports with data available in MWF, where users can examine status reports such as the average fluoride level by month in a given county. Not all information may be available across all participating states, and may not be reported consistently due to the voluntary nature of water fluoridation reporting. CDC notes that MWF contains general information on fluoridated water systems and clarified that users should access the most up-to-date information on fluoride levels in community water systems from their local water providers or utility companies.[100]

Generally on a biennial basis, CDC has summarized the state-reported data compiled in WFRS and MWF. These "Water Fluoridation Statistics" are national surveillance reports, which include information on the proportion of the U.S. population receiving fluoridated water on a national level and within each state.

Based on the 2022 report (the latest data available), over 289 million people out of the U.S. population (333 million, per the 2020 Census) are served by a community water system, meaning that the remaining approximately 44 million are not served by a community water system and may operate their own private residential well.[101] Out of the 289 million people who receive

[93] As mentioned earlier in this report, on March 27, 2025, HHS issued a press release and fact sheet announcing that HHS is being restructured. The fact sheet indicated that this restructuring would include a reduction of approximately 1,400 employees from CDC's workforce. At the time of this report's publication, the potential effect of this restructuring on the fluoride-related activities discussed below is unknown.

[94] The data collected and used in the WFRS are provided and owned by the states or tribes. See CDC, "Water Fluoridation Reporting System," Data and Public Health, https://www.cdc.gov/oral-health-data-systems/about/index.html. Hereinafter CDC, "Water Fluoridation Reporting System," July 17, 2024.

[95] CDC, "Water Fluoridation Reporting System," July 17, 2024.

[96] CDC, "Water Fluoridation Reporting System," July 17, 2024.

[97] CDC, "Water Fluoridation Reporting System," July 17, 2024.

[98] CDC, "My Water's Fluoride," https://nccd.cdc.gov/DOH_MWF/Default/Default.aspx, accessed January 8, 2025.

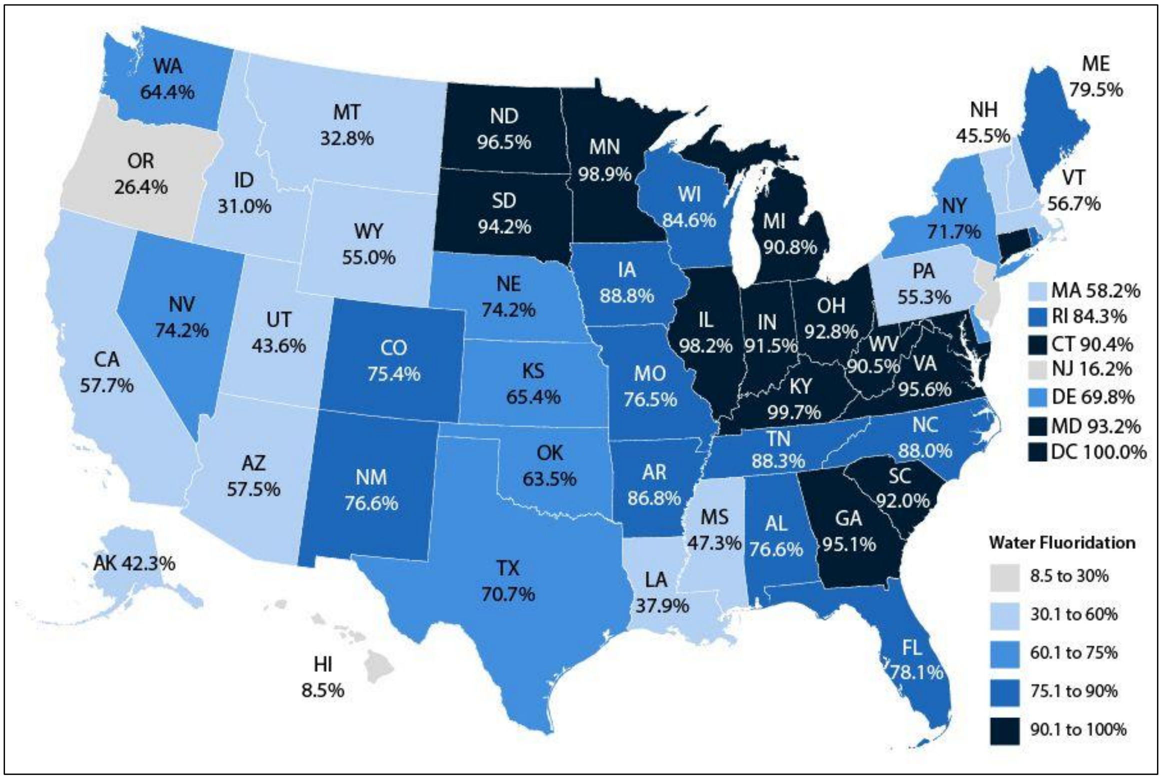
[99] CDC, "My Water's Fluoride," accessed March 6, 2025. See also CDC, "Water Fluoridation Reporting System," July 17, 2024, https://www.cdc.gov/oral-health-data-systems/about/index.html. Hereinafter CDC, "My Water's Fluoride," accessed March 6, 2025.

[100] CDC, "My Water's Fluoride," accessed March 6, 2025.

[101] Depending on the geologic conditions in the specific area, groundwater sources may have naturally occurring levels (continued...)

water from a community water system, 72.3% received fluoridated water through such community water systems (approximately 209.1 million people); see **Figure 1**.[102] When comparing this total (209.1 million) against the entire U.S. population (333 million), the proportion of individuals receiving fluoridated water was 62.8% in 2022.[103] Data from WFRS and MWF are also used to track progress toward health goals, including the Healthy People 2030 objective of "increasing the proportion of people whose water systems have the recommended amount of fluoride" to a target of 77.1%.[104]

Figure 1. Percentage of Population in Each State (and DC) Served by Community Water Systems Receiving Fluoridated Water in 2022



Source: CRS, using data from Centers for Disease Control and Prevention, *2022 Water Fluoridation Statistics*, https://www.cdc.gov/fluoridation/php/statistics/2022-water-fluoridation-statistics.html.

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of fluoride, meaning that individuals with private residential wells may be ingesting water with some level of naturally occurring fluoride.

[102] As discussed, no federal requirement exists to fluoridate community water supplies. CDC, *2022 Water Fluoridation Statistics*, June 6, 2024, https://www.cdc.gov/fluoridation/php/statistics/2022-water-fluoridation-statistics.html.

[103] Water systems that do not regularly serve at least 25 individuals year-round may opt to fluoridate their water supplies. Data on such fluoridation practices are limited.

[104] Healthy People 2030 is a set of 10-year public health objectives with the goal of improving health and well-being and is coordinated by the Office of Disease Prevention and Health Promotion within the HHS Office of the Assistant Secretary for Health (OASH). Objective OH-11 measures the number of persons served by public community water systems with optimally fluoridated water systems as compared to the total number of persons served by public community water systems. Other Healthy People 2030 objectives under the "Oral Conditions" topic may also directly or indirectly relate to water fluoridation. For more information, see HHS Office of Disease Prevention and Health Promotion, "Oral Conditions—Healthy People 2030," https://odphp.health.gov/healthypeople/objectives-and-data/browse-objectives/oral-conditions.

Notes: These statistics were prepared by CDC and reflect water system data as reported to CDC's Water Fluoridation Reporting System (WFRS) by December 31, 2022; U.S. Census state population estimates as of July 1, 2022; and estimates of populations served by public water supply as of 2015 published by the U.S. Geological Survey (USGS) as of June 19, 2018. These statistics are for water systems that have fluoridated their water supplies; that is, the statistics do not account for naturally occurring fluoride in community water systems' source water. Fluoride concentrations in groundwater vary depending on geology. For more information about source water concentrations, see the following publication authored by USGS staff: Peter B. McMahon et al., "Fluoride Occurrence in United States Groundwater," *Science of the Total Environment,* vol. 732 (August 2020), p. 139217, https://doi.org/10.1016/j.scitotenv.2020.139217.

Technical Assistance and Training

CDC's DOH has developed and promoted tools, resources, and trainings related to community water fluoridation. These include online trainings such as "Fluoridation Learning Online,"[105] which aims to build the capacity of state fluoridation program staff by increasing knowledge and refining skills relevant to community water fluoridation programs, and "Fluoridation Resources Online,"[106] which is geared toward water operators, engineers, and fluoride program managers and aims to ensure fluoridated water systems provide optimal oral health benefits. Both of these free trainings are publicly available through CDC's website. CDC has also supported 13 states with technical assistance through continuing education/training units to incentivize completion of the online training.[107]

CDC may also provide technical assistance to other federal agencies, state programs, professional organizations, and the general public in other forms, such as by participating in panels, including those organized by PHS, or through other knowledge dissemination activities, including the "Frequently Asked Questions" or "Community Water Fluoridation Facts" pages within the DOH website.[108]

CDC also has awarded some grants to support community water fluoridation. In collaboration with the Small Business Administration, CDC awarded Small Business Innovation Research (SBIR) grants related to water fluoridation in 2014 and 2015.[109] According to CDC estimates, of the approximately 40,000 water systems without optimally fluoridated water, about 32,000 are small public utilities often in rural communities.[110] These small and/or rural water systems may face additional challenges and costs associated with applying traditional water fluoridation technologies. The SBIR grants focused on exploring the development of a tablet or pill (similar to those used for swimming water chlorination) that could support water systems to provide fluoridated water.[111] The DOH also provides grant funding to states and national partner

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[105] CDC, "Fluoridation Learning Online," May 15, 2024, https://www.cdc.gov/fluoridation-engineering/trainings/fluoridation-learning-online.html. Hereinafter CDC, "Fluoridation Learning Online," May 15, 2024.

[106] CDC, "Fluoridation Learning Online," May 15, 2024.

[107] CDC, "Fluoridation Learning Online," May 15, 2024.

[108] CDC, "Community Water Fluoridation: What CDC Is Doing," May 15, 2024, https://www.cdc.gov/fluoridation/about/what-cdc-is-doing.html.

[109] Eleven federal agencies (including HHS) operate Small Business Innovation Research (SBIR) programs. For more information on the SBIR program, see CRS In Focus IF12874, *Small Business Research Programs: Overview and Issues for Reauthorization in the 119th Congress*.

[110] CDC, "CDC Initiative Creates New Water Fluoridation Technology to Support Rural Health Needs," press release, March 18, 2021, https://archive.cdc.gov/www_cdc_gov/media/releases/2021/p0318-Fluoridation.html. For more information about small water system challenges, see CRS Report R47315, *Small Water Systems: Selected Safe Drinking Water Act (SDWA) Provisions*.

[111] CDC, *Justification of Estimates for Appropriation Committees*, *Fiscal Year 2025*, March 15, 2024, pp. 391-395, https://www.cdc.gov/budget/documents/fy2025/FY-2025-CDC-congressional-justification.pdf; and CDC, "Innovation (continued...)

organizations to conduct a range of activities related to oral health. Some of these programs, such as the State Promotion of Strategies to Promote Oral Health, may fund activities that inform or support community water fluoridation efforts, among others.[112]

Agency for Toxic Substances and Disease Registry (ATSDR)

The ATSDR is a separate operating division under HHS and is overseen by the CDC Director.[113] As authorized by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), ATSDR is tasked with investigating, determining, and mitigating the public health effects of environmental exposures and hazardous substances.[114] ATSDR is a nonregulatory agency and serves as the lead agency within the PHS in responding to releases of hazardous substances, pollutants, and contaminants under CERCLA in collaboration with other federal partners, such as EPA.

Regarding water fluoridation, ATSDR's primary role is to maintain toxicological profiles for fluoride in various forms. Broadly, ATSDR profiles summarize the toxicologic information and epidemiological evaluations of potentially hazardous substances, determine levels of exposure that present significant risks, and identify the types of toxicologic testing that may be necessary to identify types or levels of exposure. ATSDR's toxicological profile for fluorides, hydrogen fluoride, and fluorine was last updated in 2003.[115] Within the "Public Health Statement" section of the toxicological profile, ATSDR discusses the evidence regarding the public health benefits and risks of fluoride exposure across many exposure routes including, but not limited to, water fluoridation.[116] ATSDR also identified that higher levels of fluoride, "nearly 30 times" the concentrations found in fluoridated water, can result in skeletal fluorosis, but stated that insufficient evidence existed about other health effects (e.g., reproductive or carcinogenic effects) of fluoride exposure.[117]

National Toxicology Program (NTP)

The NTP is an interagency program composed of, and supported by, three HHS agencies: the National Center for Toxicological Research (NCTR) within the Food and Drug Administration (FDA); the National Institute of Environmental Health Sciences (NIEHS) within the National Institutes of Health; and the National Institute for Occupational Safety and Health (NIOSH)

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in Fluoridation Technology Promises Improvements in Oral Health," March 12, 2021, https://www.cdc.gov/os/technology/innovation/sbir/successstories/fluoridation.htm.

112 CDC, *Current Oral Health Program Funding*, https://www.cdc.gov/oral-health-funded-programs/funding/oral-health-program-funding.html.

113 HHS initially established ATSDR to be headed by an Administrator who reported directly to the Assistant Secretary for Health on April 25, 1983 (HHS, "Statement of Organization, Functions, and Delegation of Authority," 48 *Federal Register* 17652, April 25, 1983). On May 12, 1983, the then-CDC Director became the first Administrator of ATSDR following litigation that compelled the federal government to carry out certain provisions of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (42 U.S.C. §9601 et seq.). See Richard G. Stoll, Jr., "Resolution of EDF/CMA Suit to Promote Government Health Studies," *Natural Resources Law Newsletter*, vol. 15, no. 4 (1983), pp. 3-4.

114 42 U.S.C §9604(i). ATSDR, "About the Agency for Toxic Substances and Disease Registry," November 12, 2024, https://www.atsdr.cdc.gov/about/index.html.

115 ATSDR, *Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluorine*, September 2003, https://www.atsdr.cdc.gov/toxprofiles/tp11.pdf. Hereinafter ATSDR, *Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluorine*, September 2003.

116 ATSDR, *Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluorine*, September 2003, pp. 1-13.

117 ATSDR, *Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluorine*, September 2003, p. 7.

within CDC. The NIEHS Director serves as the director of NTP. NTP was founded in 1978 and is tasked with testing chemicals of public health concern, developing and validating new testing methods, providing information to regulatory and research agencies, and strengthening the toxicological science base.[118] The NTP has published multiple reports on fluoride exposure over the years. The NTP's research, including the latest monograph, is further discussed elsewhere in this report; see "Research on Health Effects of Fluoride" and "Toxic Substances Control Act (TSCA) Citizen Petition, Litigation, and Court Order."

U.S. Environmental Protection Agency (EPA)

EPA's role in assessing and addressing the potential health risks of fluoride exposure has primarily involved the agency's authority under the Safe Drinking Water Act (SDWA). SDWA authorizes EPA to establish drinking water regulations to limit (i.e., provide an upper threshold for) the amount of a contaminant that may be present in water provided by public water systems.[119] SDWA drinking water regulations apply to community water systems, including those that choose to implement the 0.7 mg/L PHS recommendation for community water fluoridation, as well as those that may use water sources with naturally occurring fluoride. This section discusses the health effects information that EPA used to develop the fluoride drinking water regulation, and the agency's ongoing activities under SDWA with regard to the drinking water regulation for fluoride.

In addition, TSCA provides EPA separate but complementary authorities to regulate the production and use of certain chemical substances that it finds pose a risk to human health or the environment.[120] TSCA creates a framework that differentiates between chemical substances newly introduced to the market (or introduced for a new purpose) and existing chemical substances. For existing chemical substances, TSCA establishes a system for prioritizing risk assessments.[121] As discussed further below, recent litigation in federal court resulted in an order requiring EPA to initiate a rulemaking authorized by TSCA.

On May 2, 2025, EPA's press release announced a reorganization of the agency's functions.[122] It remains to be seen whether EPA's reorganization would have an effect on the agency's priorities regarding scientific research or funding.

EPA's Safe Drinking Water Act (SDWA) Regulation

To protect against adverse health effects, EPA established a national primary drinking water regulation with a health-based standard for fluoride in 1986.[123] EPA's regulation for fluoride

[118] NTP, "History & Milestones," accessed March 6, 2025, https://ntp.niehs.nih.gov/whoweare/history.

[119] 42 U.S.C. §300g-1.

[120] 15 U.S.C. §2601 et seq.

[121] For an overview of the TSCA framework, see CRS Report R45149, *Title I of the Toxic Substances Control Act (TSCA): A Summary of the Statute*, by Jerry H. Yen and Kate R. Bowers.

[122] EPA, "EPA Announces Next Phase of Organizational Improvements to Better Integrate Science into Agency Offices, Deliver Clean Air, Land, and Water to All Americans," press release, May 2, 2025, https://www.epa.gov/newsreleases/epa-announces-next-phase-organizational-improvements-better-integrate-science-agency.

[123] EPA, "National Primary and Secondary Drinking Water Regulations: Fluoride," 51 *Federal Register* 11396-11412, April 2, 1986. At the time of promulgation, EPA reported that 282 water systems reported concentrations of fluoride above 4 mg/L. In 1975, EPA established an interim drinking water regulation for fluoride that included enforceable levels ranging from 1.4 mg/L to 2.4 mg/L, depending on the average annual ambient air temperature (i.e., 1.4 mg/L in areas where the annual average maximum temperature is above 79.3 degrees Fahrenheit to 2.4 mg/L in areas where (continued...)

includes an enforceable standard—called a maximum contaminant level (MCL)—of 4.0 mg/L, specifically to protect against crippling skeletal fluorosis. The MCL is based off the maximum contaminant level goal (MCLG), which EPA sets at a level where no adverse health effects are anticipated, with a margin of safety. In addition, EPA established a national secondary drinking water regulation for fluoride that includes a nonenforceable secondary MCL of 2.0 mg/L to protect against dental fluorosis. These levels, and their derivation, are further detailed below.

Maximum Contaminant Level Goals (MCLG)

In addition to the enforceable MCL, national primary drinking water regulations specify a level that is now known as the Maximum Contaminant Level Goal (MCLG). An MCLG is set at a level where no adverse health effects are anticipated, with a margin of safety. An MCLG is to be based solely on health effects data.[124] The nonenforceable MCLG provides the basis for calculating the enforceable MCL. Unlike the MCL, the MCLG does not reflect cost or technical feasibility considerations.[125] Because the MCLG is based only on health effects and not on the availability or cost of monitoring and treatment technologies, an MCLG may be set at levels that are not feasible for some water systems to meet. EPA derives the MCLG based on a reference dose, which is an estimate of the amount of a contaminant that a person can be exposed to daily over a lifetime that is not anticipated to cause adverse health effects for meaningful populations (e.g., infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other sensitive subpopulations).[126] This amount incorporates uncertainty factors to provide a margin of protection for sensitive subpopulations and to account for uncertainties in the data.[127]

When developing the MCLG, EPA estimates the general population's exposure to a contaminant from drinking water and other sources (e.g., food, dust, soil, and air).[128] After considering other exposure routes, EPA estimates the proportion of exposure attributable to drinking water (i.e., the relative source contribution [RSC]).[129] EPA applies the RSC, which is intended to ensure that an individual's total exposure from all sources remains below the estimated protective level.[130]

Fluoride MCLG and Maximum Contaminant Level (MCL)

For the 1986 fluoride MCLG, EPA determined that the agency did not anticipate adverse health effects at 4.0 mg/L of fluoride or below in drinking water.[131] To develop the MCLG, EPA

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temperatures are below 53.7 degrees Fahrenheit). At the time, EPA considered these levels to be twice the "optimum" level of fluoride, with "optimum" defined as a balance between both dental caries and "objectionable" dental fluorosis. Subsequently, the U.S. Court of Appeals for the District of Columbia Circuit questioned whether mottling could be regarded as an adverse health effect, in response to litigation brought by the Environmental Defense Fund in 1977 (*75-2224*, F.2d 578 337 (United States Court of Appeals, District of Columbia Circuit 1977).

[124] 42 U.S.C. §300g-1(b)(4)(A).

[125] For contaminants with carcinogenic effects and for microbial contaminants, EPA typically sets this level at zero. For more information, see EPA, "How EPA Regulates Drinking Water Contaminants," October 21, 2024, https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants#standards.

[126] EPA, "Once EPA Decides to Regulate a Contaminant, How Does the Agency Develop a Regulation?" October 21, 2024, https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants#standards. Hereinafter EPA, "Once EPA Decides to Regulate a Contaminant, How Does the Agency Develop a Regulation?"

[127] EPA, "Once EPA Decides to Regulate a Contaminant, How Does the Agency Develop a Regulation?"

[128] EPA, "Once EPA Decides to Regulate a Contaminant, How Does the Agency Develop a Regulation?"

[129] EPA, "Once EPA Decides to Regulate a Contaminant, How Does the Agency Develop a Regulation?"

[130] EPA, "Once EPA Decides to Regulate a Contaminant, How Does the Agency Develop a Regulation?"

[131] At the time of promulgation, SDWA referred to this value as the "recommended maximum contaminant level." (continued...)

reviewed the existing health effects literature and solicited input from the National Drinking Water Advisory Council (NDWAC), the U.S. Surgeon General, the American Medical Association, the American Dental Association, and the National Academy of Sciences.[132]

In the 1980s, a topic of debate pertained to whether dental fluorosis constituted an adverse health effect. EPA solicited input regarding this question from the U.S. Surgeon General and NDWAC. In 1982, the Surgeon General replied to EPA that he concurred with findings from the prior Surgeon General that neither dental fluorosis nor changes in bone density were an adverse health effect.[133] NDWAC identified that although osteosclerosis and other adverse health effects constitute a sufficient basis for a drinking water regulation, dental fluorosis did not constitute an adverse health effect.[134] In subsequent meetings, the council changed its determination, stating that moderate to severe dental fluorosis could constitute an adverse health effect, as dental fluorosis at these stages corresponded to cosmetic deformity, dental dysfunction, and possible social and behavioral effects.[135]

To develop the 1986 SDWA regulation's MCLG, EPA evaluated research on fluorosis—both dental and skeletal—as well as other health effects. In its assessment, EPA identified several studies that assessed the incidence of dental fluorosis among children from communities with varying fluoride rates, among other studies. The agency summarized the studies' findings that no moderate to severe dental fluorosis was observed at levels of 0.6 mg/L or less, while severe dental fluorosis was consistently observed at levels of 2.5 mg/L or higher.[136] EPA also noted the variation among incidence rates of dental fluorosis observed in different cities varied with "essentially the same level of fluoride."[137] EPA did not characterize why the incidence rates varied. In addition, EPA identified that the development of skeletal fluorosis, which EPA identified as the deposition of irregular bone deposits that in extreme cases can result in crippling deformities, required the daily consumption of 20.0 mg/day or more of fluoride over 20 or more years.[138] After considering a daily consumption rate of 2 liters, EPA stated that this would correspond to a drinking water concentration of 10.0 mg/L.[139] EPA also reviewed studies on acute fluoride toxicity, and found that consumption of fluoride at levels found in U.S. drinking water at the time was not associated with other health effects such as Down syndrome, cancer, decreases in longevity, or a variety of other toxic effects.[140]

Subsequent SDWA amendments changed the term to "maximum contaminant level goal." For more information on SDWA's regulatory development provisions, see CRS Report R46652, *Regulating Contaminants Under the Safe Drinking Water Act (SDWA)*, by Elena H. Humphreys.

132 EPA, "National Primary Drinking Water Regulations; Fluoride," 50 *Federal Register* 20164-20175, May 14, 1985.

133 Letter from C. Everett Koop, Surgeon General, to John W. Hernandez, Jr., EPA Deputy Administrator, July 30, 1982. The Surgeon General also concurred with findings from a committee headed by the Chief Dental Officer of the PHS that no sound evidence supported a finding that drinking water at naturally occurring levels of fluoride had an adverse health effect, and similarly that no sound evidence supported a finding that drinking water at naturally occurring levels of fluoride had an adverse effect on dental health, as measured by loss of function and tooth mortality.

134 National Drinking Water Advisory Council (NDWAC), "Minutes of Meeting, October 26, 1982," October 1982.

135 NDWAC, "Minutes of Meeting, August 2 and 3, 1984," August 1984. NDWAC, "Minutes of Meeting, December 6 and 7, 1984," January 1985.

136 50 *Federal Register* 20170.

137 50 *Federal Register* 20170.

138 50 *Federal Register* 47144. At the time, EPA stated that two cases of water-related crippling skeletal fluorosis had been observed in the United States.

139 50 *Federal Register* 47144.

140 50 *Federal Register* 20171.

To protect against crippling skeletal fluorosis, EPA used the level of 10.0 mg/L for fluoride and added a margin of safety to establish the MCL of 4.0 mg/L in 1986.[141] EPA stated that less than a 10-fold margin of safety was appropriate given that studies used to derive the level of 10.0 mg/L were based on "human data."[142] EPA noted that the agency used a smaller safety factor, as the scientific uncertainty about the levels at which fluoride may present risks was relatively small.[143] Further, EPA identified that, when determining the levels for its fluoride drinking water regulation, it was unnecessary to adjust the level based on exposure to fluoride from food or other sources.[144] EPA stated that the epidemiology studies used to develop this level implicitly incorporated dietary exposure to fluoride, as they were based on observational data in which participants were exposed to fluoride from other sources in their everyday lives.[145] EPA did not adjust the 4.0 mg/L level based on other sources of an individual's exposure to fluoride.

SDWA requires EPA to set the MCL as close to the MCLG as is feasible.[146] EPA set the enforceable level at 4.0 mg/L after determining that meeting this level was "feasible" for water systems.[147] When setting the fluoride MCL, EPA acknowledged that it would not protect infants and young children against moderate dental fluorosis, which was considered a cosmetic effect rather than an adverse health effect.[148] Consequently, EPA established a national secondary drinking water regulation with a nonenforceable secondary MCL (SMCL) for fluoride at a level of 2.0 mg/L to protect children against dental fluorosis, as well as adverse health effects.[149] While the secondary MCLs are nonenforceable, systems are required to notify customers of the risk of dental fluorosis in children when the SMCL is exceeded.[150]

Reviews of the Fluoride Regulation and Its Scientific Basis

SDWA requires EPA to review drinking water regulations periodically.[151] After the 1986 promulgation of the fluoride regulation, EPA reviewed this, and other, regulations to determine if revisions were warranted. In support of its review, EPA at various times requested that the National Research Council evaluate the scientific basis of the fluoride drinking water regulation to determine if the regulation's MCL of 4.0 mg/L remains "appropriate."[152]

1993 National Research Council (NRC) Study

In response to a request from EPA to evaluate its fluoride regulation, in 1993, the NRC's Subcommittee on Health Effects of Ingested Fluoride concluded that the fluoride MCL was

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141 EPA proposed the MCL in 1985 (50 *Federal Register* 20172), and finalized the MCL in 1986 (51 *Federal Register* 11396-11412).

142 50 *Federal Register* 47142-47155.

143 50 *Federal Register* 47144.

144 50 *Federal Register* 20168.

145 50 *Federal Register* 20168.

146 42 U.S.C. §300g-1(b)(4)(B).

147 50 *Federal Register* 47162. For this regulation, EPA determined that 4.0 mg/L of fluoride was feasible for water systems since there were sufficient analytical methods to measure fluoride to this level and there were technologies generally available to reduce naturally occurring fluoride concentrations to this level.

148 51 *Federal Register* 11396-11412.

149 51 *Federal Register* 11396-11412.

150 51 *Federal Register* 11396-11412. See also 40 C.F.R. 143.5.

151 42 U.S.C. §300g-1(b)(9).

152 NRC's Committee on Toxicology, Subcommittee on Health Effects of Ingested Fluoride, *Health Effects of Ingested Fluoride* (Washington, DC: National Academies Press, March 1993).

appropriate as an interim standard, but recommended that the standard should continue to be reviewed (and, if necessary, revised) as new research becomes available, particularly given NRC-identified fluoride toxicity knowledge gaps and data inconsistencies.[153] In this 1993 review, the NRC subcommittee noted that, since EPA promulgated the drinking water regulation for fluoride, the use of fluoride in dental products has increased:

> In addition to fluoride in drinking water, people also can ingest fluoride in toothpaste, mouth rinse, and dietary fluoride supplements or in beverages and foods prepared with fluoridated water. As a result, many Americans might ingest more "incidental" fluoride than was anticipated by the PHS and by EPA in recommending standards for drinking water.[154]

EPA's First Six-Year Review

In 2002, EPA published in the *Federal Register* the results of its review of existing drinking water regulations and standards, including fluoride.[155] The agency noted that new studies on fluoride's effects on bone had been published since EPA issued the fluoride standard in 1986, and that new data warranted review by EPA; given this, EPA stated that the agency would defer selecting the fluoride regulation as a candidate for revision.[156] EPA conducted a literature search to identify reports of the clinical and epidemiological data on fluoride and the skeletal system. Subsequently, EPA requested that the NRC conduct a review of these data to update the fluoride health risk assessment and review EPA's relative source contribution assumptions.[157]

2006 NRC Study

As requested by EPA, in March 2006, the NRC issued a study that reviewed the health risk data for fluoride. NRC concluded that EPA's MCLG of 4.0 mg/L should be lowered based on the consideration of severe dental fluorosis as an adverse health effect as well as new information identified in studies published since the 1990s.[158] In addition, NRC concluded that information gaps regarding fluoride "prevented the committee from making some judgments about the safety or the risks of fluoride at concentrations of 2.0 to 4.0 mg/L."[159] The NRC's major findings related to health effect research are discussed below, accompanied by information on related subsequent studies.

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[153] NRC, *Health Effects of Ingested Fluoride*, March 1993.

[154] NRC, *Health Effects of Ingested Fluoride*, March 1993. In 1998, EPA commissioned an evaluation of the exposure data for fluoride, including data on amounts in water, foods, and dental products.

[155] EPA, "National Primary Drinking Water Regulations: Announcement of the Results of EPA's Review of Existing National Drinking Water Standards and Request for Public Comment," 67 *Federal Register* 19030-19060, April 17, 2002.

[156] EPA, "National Primary Drinking Water Regulations; Announcement of Completion of EPA's Review of Existing Drinking Water Standards; Notice," 68 *Federal Register* 42908-42929, July 18, 2003.

[157] NRC's Committee on Fluoride in Drinking Water, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards* (Washington, DC: National Academies Press, 2006), https://nap.nationalacademies.org/catalog/11571/fluoride-in-drinking-water-a-scientific-review-of-epas-standards. Hereinafter NRC, *Fluoride in Drinking Water*, 2006.

[158] As mentioned earlier, the NRC is the operating research arm of the National Academies of Sciences, Engineering, and Medicine (NASEM).

[159] NRC, *Fluoride in Drinking Water*, 2006. Because NRC's charge was to evaluate the scientific basis and adequacy of EPA's drinking water standards for fluoride, the committee did not address questions concerning the risks or benefits of fluoridation.

Dental Fluorosis

At the time of EPA's 1986 fluoride standard, fluorosis of the dental enamel was considered to be a cosmetic effect, and EPA's evaluation of health research did not differentiate between moderate and severe fluorosis. In contrast, 10 of the 12 NRC committee members for the 2006 NRC study concluded that *severe* enamel fluorosis is an adverse health effect, not simply a cosmetic effect, as it involves enamel loss that compromises the function of tooth enamel.[160] The purpose of tooth enamel is to protect the tooth against decay and infection. Because the committee identified that severe enamel fluorosis occurs in roughly 10% of children in communities with water fluoride concentrations at or near the standard of 4.0 mg/L, it unanimously agreed that the MCLG should be set to protect against this condition, and that EPA's standard of 4.0 mg/L was not adequately protective.[161]

Skeletal Fluorosis

As discussed above, EPA set the fluoride MCLG and MCL to protect against the adverse health effect of crippling skeletal fluorosis (*stage III* skeletal fluorosis). In the 2006 review, the NRC committee concluded that *stage II* skeletal fluorosis, the symptoms of which include sporadic pain, joint stiffness, and abnormal thickening (osteosclerosis) of the pelvis and spine, also constituted an adverse health effect. Based on comparison of concentrations of fluoride in bone and related evidence of skeletal fluorosis, the committee further found the data to suggest that not all individuals may be protected from adverse stages of skeletal fluorosis under EPA's 1986 regulation. NRC stated that additional research was needed "before any firm conclusions could be drawn."[162]

Bone Fractures

The committee also reviewed the few studies available for evaluating bone fracture risks from exposure to fluoride at 2.0 mg/L to 4.0 mg/L or more. NRC reported that clinical studies indicated an increased risk of nonvertebral bone fracture and a slightly decreased risk of vertebral fractures in populations exposed to fluoride at 4.0 mg/L.[163] The consensus of the committee was that, under certain conditions, fluoride can weaken bone and increase the risk of fractures.[164] A majority of the committee found that a lifetime of exposure to fluoride in drinking water at 4.0 mg/L or higher is likely to increase fracture rates as compared to those exposed to 1.0 mg/L, but also found that available epidemiologic data was inadequate for drawing conclusions about fracture risk related to exposure to fluoride at 2.0 mg/L.[165]

Carcinogenicity

In the 2006 report, NRC noted that the question of whether fluoride might be associated with bone cancer continued to be debated and analyzed, and that further research should be

[160] NRC, *Fluoride in Drinking Water*, 2006, p. 4.

[161] NRC, *Fluoride in Drinking Water*, 2006. The NRC fluoride committee concluded that "damage to teeth caused by severe dental fluorosis is a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effects."

[162] NRC, *Fluoride in Drinking Water*, 2006, p. 146.

[163] NRC, *Fluoride in Drinking Water*, 2006, p. 158.

[164] NRC, *Fluoride in Drinking Water*, 2006, p. 7.

[165] NRC, *Fluoride in Drinking Water*, 2006, p. 146.

conducted.[166] Most committee members held the view that a 1992 cancer bioassay study, which found no increase in osteosarcoma in male rats, lacked sufficient power (e.g., sample size was too small) to counter the overall evidence of a positive dose-response trend found in a similar 1990 rat study.[167] After reviewing the studies available at the time in 2006, the NRC committee concluded that "the evidence on the potential of fluoride to initiate or promote cancers, particularly of the bone, is tentative and mixed," and that, overall, the literature did not clearly indicate that fluoride either was or was not carcinogenic in humans.[168] NRC stated that the Harvard School of Dental Medicine was expected to publish a large, hospital-based case-control study of osteosarcoma and fluoride exposure in 2006, and that the results of that study might help to identify research needs. The NRC review did include an assessment of pre-publication data from an exploratory analysis of a subset of the Harvard data that found an association between exposure to fluoride in drinking water and the incidence of osteosarcoma in young human males.[169]

After the 2006 NRC study, the authors of the Harvard School of Dental Medicine research noted several limitations with the analysis (e.g., relying on estimated fluoride exposure from drinking water) and concluded that further research was needed to confirm or refute the results.[170] A subsequent study evaluated whether bone fluoride levels were higher in individuals with osteosarcoma. In this study, reported in 2011, researchers detected no significant association between bone fluoride levels and osteosarcoma risk.[171] The authors stated that "the major advantage of this study is the use of bone fluoride concentrations as the measure of fluoride exposure, rather than estimated fluoride exposure in drinking water."[172]

Endocrine Effects

As a part of the 2006 study, the NRC committee evaluated potential linkages between fluoride exposure and endocrine system disruption in both human and animal studies. The NRC committee's report stated that many of the available studies had significant methodological flaws (e.g., did not assess hormone concentrations or other confounding variables).[173] The report called for additional research to better understand associations between fluoride exposure and effects on the endocrine system.[174]

[166] NRC, *Fluoride in Drinking Water*, 2006, pp. 9-10 and p. 338.

[167] Lack of statistical power generally is due to an insufficient number of observations (i.e., in this case, the number of rats).

[168] NRC, *Fluoride in Drinking Water*, 2006, p. 8 and pp. 274-284.

[169] NRC, *Fluoride in Drinking Water*, 2006, p. 112.

[170] Elise B. Bassin et al., "Age-Specific Fluoride Exposure in Drinking Water and Osteosarcoma (United States)," *Cancer Causes & Control*, vol. 17 (May 17, 2006), pp. 421-428, https://pubmed.ncbi.nlm.nih.gov/16596294/. Hereinafter Elise B. Bassin et al., "An Assessment of Bone Fluoride and Osteosarcoma. In a letter to the editor in this same issue, the principal investigator of the larger 15-year Harvard research project, Dr. C. W. Douglass, cautioned readers not to overinterpret the results of the Bassin study, and to wait for the results of the full study.

[171] F. M. Kim et al., "An Assessment of Bone Fluoride and Osteosarcoma," *Journal of Dental Research*, vol. 90, no. 10 (October 2021), pp. 1171-1176.

[172] Elise B. Bassin et al., "An Assessment of Bone Fluoride and Osteosarcoma," p. 1175.

[173] NRC, *Fluoride in Drinking Water*, 2006, pp. 264-266.

[174] CRS scanned studies published from 2013 through 2024. Some systematic reviews identified a potential relationship between high fluoride exposure and the prevalence of thyroid diseases; however, there was little data about the specific fluoride concentration levels individuals were exposed to and their individual levels of fluoride measured in their blood serum, particularly given that some studies looked at high, naturally occurring fluoride levels as compared to supplementally fluoridated systems. See, for example, Inga Iamandii et al., "Does Fluoride Exposure Affect Thyroid (continued...)

Other Potential Effects

The NRC committee evaluated available scientific studies that assessed a range of other possible health effects related to fluoride exposure.[175] This evaluation included a review of studies on fluoride's potential neurotoxicity and neurobehavioral effects, and effects on the gastrointestinal system, kidneys, liver, and immune system.[176] Although various studies in these areas suggested an association between fluoride exposure and adverse effects, the committee generally concluded that the research on these topics was insufficient to assess the significance of the relationships.[177] Overall, the committee concluded that more research was needed to determine what health risks fluoride exposure at 4.0 mg/L might pose.[178]

NRC 2006 Recommendations

Regarding the maximum contaminant level goal, the NRC committee concluded that the MCLG of 4.0 mg/L should be lowered, and that EPA should update the risk assessment for fluoride to identify an updated MCLG protective of severe enamel fluorosis. The review committee specifically recommended the following:

> To develop an MCLG that is protective of severe enamel fluorosis, clinical stage II skeletal fluorosis, and bone fractures, EPA should update the risk assessment of fluoride to include new data on health risks and better estimates of total exposure (relative source contribution) in individuals and to use current approaches to quantifying risk, considering susceptible subpopulations, and characterizing uncertainties and variability.[179]

The NRC committee recommended that EPA develop a dose-response assessment for severe dental fluorosis as the critical effect and update an assessment of fluoride exposure from all sources.[180]

EPA's Second Six-Year Review

After the 2006 NRC report, EPA published in 2010 the results of its review of drinking water regulations, including the 1986 fluoride regulation.[181] The agency concluded that, because of ongoing assessments recommended by NRC, a revision to the fluoride regulation was not appropriate at that time. Specifically, as recommended by the NRC committee, the agency was conducting a dose-response assessment of the noncancer impacts of fluoride on severe dental fluorosis and skeletal systems, and was in the process of updating its evaluation of the relative

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Function? A Systematic Review and Dose-Response Meta-Analysis," *Environmental Research*, vol. 242 (February 2024), pp. 11759, https://doi.org/10.1016/j.envres.2023.117759. See also Nallan Chaitanya et al., "A Systematic Analysis on Possibility of Water Fluoridation Causing Hypothyroidism," *Indian Journal of Dental Research*, vol. 29, no. 3 (May-June 2018), pp. 358-363, https://doi.org/10.4103/ijdr.ijdr_505_16. These studies also describe a need for more rigorously conducted research to evaluate potential linkages.

[175] NRC, *Fluoride in Drinking Water*, 2006.

[176] NRC, *Fluoride in Drinking Water*, 2006, pp. 5-10.

[177] NRC, *Fluoride in Drinking Water*, 2006, p. 223 and pp. 302-303.

[178] NRC, *Fluoride in Drinking Water*, 2006, p. 7.

[179] NRC, *Fluoride in Drinking Water*, 2006, p. 10. In this NRC report, the committee gave an example of "susceptible subpopulations" as individuals with renal impairments who retain more fluoride than healthy people do (p. 9 of *Fluoride in Drinking Water*).

[180] NRC, *Fluoride in Drinking Water*, 2006, p. 352.

[181] EPA, "National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues," 75 *Federal Register* 15500-15572, March 29, 2010.

contribution of drinking water to total fluoride exposure, considering contributions from dental products, foods, pesticide residues, and other potential sources.[182]

Also in 2010, EPA published the findings of its dose-response assessment related to noncancer health effects, and the updated relative source contribution values for fluoride from drinking water.[183] EPA determined that, at a reference dose of 0.08 mg per kilogram of bodyweight per day, the most sensitive subpopulation—children between 6 months to 14 years—was not anticipated to experience severe dental fluorosis.[184] By protecting this sensitive subpopulation, EPA noted that this reference dose would be protective for other potential risks as well.[185] EPA found that drinking water represents 40% to 70% of an individual's exposure to fluoride, rather than the 100% assumed in EPA's 1986 regulation,[186] meaning that the 1986 regulation's MCL of 4.0 mg/L may be lowered to account for an individual's other sources of fluoride exposure.[187]

EPA's Third Six-Year Review

In 2017, EPA published another review of its drinking water regulations and again determined that the fluoride regulation was not a candidate for revision.[188] EPA acknowledged the new health effects data and updated assumptions regarding an individual's exposure to fluoride, but noted that the agency had identified several other regulations that were selected for revision. The agency stated that a revision of fluoride was a lower priority, and that its selection would "divert significant resources from the higher priority candidates for revision," as EPA identified that the contaminants selected for this review had potential adverse health effects ranging from bladder cancer to giardiasis, cryptosporidiosis, legionellosis, hepatitis, meningitis, and encephalitis.[189] In the same *Federal Register* notice, EPA provided occurrence data on naturally occurring fluoride levels in water supplies. EPA reported that between 2006 and 2011 approximately 130 U.S. systems serving in total roughly 60,000 individuals recorded fluoride levels that exceeded the MCL of 4.0 mg/L, while more than 900 systems serving roughly 1.5 million people recorded fluoride levels above the SMCL of 2.0 mg/L.[190]

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[182] 75 *Federal Register* 15544.

[183] EPA, *Fluoride: Dose-Response Analysis for Non-cancer Effects*, 820-R-10-019, December 2010, https://www.epa.gov/sites/default/files/2019-03/documents/fluoride-dose-response-noncancer-effects.pdf. Hereinafter EPA, *Fluoride: Dose-Response Analysis for Non-cancer Effects*, December 2010. EPA, *Fluoride: Exposure and Relative Source Contribution Analysis*, 820-R-10-015, December 2010, https://www.epa.gov/sites/default/files/2019-03/documents/fluoride-exposure-relative-report.pdf. Hereinafter EPA, *Fluoride: Exposure and Relative Source Contribution Analysis*, December 2010.

[184] EPA, *Fluoride: Dose-Response Analysis for Non-cancer Effects*, December 2010.

[185] EPA notes that further research would be needed to obtain dose-response data for conducting a risk assessment for skeletal fluorosis and skeletal fractures; however, the reference dose for severe dental fluorosis would protect against the potential bone effects because severe dental fluorosis appears to occur at a lower dose than bone effects.

[186] EPA, *Fluoride: Exposure and Relative Source Contribution Analysis*, December 2010.

[187] In EPA's fourth six-year review published in 2024, the agency uses the reference dose from the dose-response assessment of 0.08 mg/kg/day and accounts for other sources of exposure to calculate a potential MCL for fluoride of 0.9 mg/L in water. EPA, *Results of the Health Effects Assessment for the Fourth Six-Year Review of Existing Chemical and Radionuclide National Primary Drinking Water Standards*, 815-R-24-020, February 2024.

[188] EPA, "National Primary Drinking Water Regulation; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues," 82 *Federal Register* 3518-3552, January 11, 2017.

[189] 82 *Federal Register* 3531-3532.

[190] 82 *Federal Register* 3533.

EPA's Fourth Six-Year Review

In February 2024, EPA published its latest review of drinking water regulations, and did not select fluoride as a candidate for revision.[191] In its publication, EPA categorized fluoride as a contaminant with an updated health assessment that could support a change in the MCLG, potentially to 0.9 mg/L,[192] though the agency stated that, due to the pending monograph from the NTP on developmental neurotoxicity after fluoride exposure, as well as competing workloads, it did not select fluoride for revision.[193] For more information about the NTP report, see "National Toxicology Program (NTP)."

Out-of-Cycle Review

In April 2025, EPA announced that it would review "new" scientific evidence on fluoride to inform the agency's statutory obligations under SDWA.[194] In EPA's announcement, the agency specifically identified the NTP and the results from the meta-analysis that were published independently from the NTP monograph in a peer-reviewed journal.[195] EPA also stated that it would look at other peer-reviewed studies to prepare an updated health risk assessment for fluoride, which could inform a potential revision to the regulation.[196]

Recommended and Regulatory Levels for Fluoride

To summarize, the various levels identified in this report for fluoride in community water systems include a nonenforceable optimal concentration and enforceable upper thresholds to prevent against adverse health effects.

Optimal Fluoride Concentration in the United States for Community Water Systems

- PHS recommends an optimal fluoride concentration of 0.7 mg/L for community water systems that currently add fluoride to drinking water or may choose to initiate water fluoridation in the future. This level is intended to maintain the prevention of dental caries and reduce the risk of dental fluorosis. This is a nonenforceable recommendation.

Fluoride Maximum Levels for U.S. Community Water Systems

- EPA's MCL of 4.0 mg/L, established under SDWA, is the enforceable maximum allowable concentration of fluoride in water provided by community water systems, and is intended to protect against adverse health effects associated with fluoride.
- EPA's SMCL of 2.0 mg/L is a nonenforceable level that is intended to prevent against cosmetic effects associated with fluoride.

World Health Organization's Fluoride Guideline Value for Drinking Water

- The World Health Organization's Guidelines for Drinking Water set a limit of 1.5 mg/L for fluoride in drinking water.

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191 EPA, "National Primary Drinking Water Regulations; Announcement of Results of EPA's Fourth Review of Existing Drinking Water Standards," 89 *Federal Register* 59623-59645, July 23, 2024.

192 This potential MCLG uses the updated reference dose published by EPA in 2010 and reflects updated assumptions about the relative contribution of an individual's exposure to fluoride.

193 89 *Federal Register* 59637.

194 EPA, "EPA Will Expeditiously Review New Science on Fluoride in Drinking Water," press release, April 7, 2025, https://www.epa.gov/newsreleases/epa-will-expeditiously-review-new-science-fluoride-drinking-water. Hereinafter EPA, "EPA Will Expeditiously Review New Science on Fluoride in Drinking Water."

195 K. W. Taylor et al., "Fluoride Exposure and Children's IQ Scores: A Systematic Review and Meta-Analysis," *JAMA Pediatrics*, published online January 6, 2025, https://doi.org/10.1001/jamapediatrics.2024.5542.

196 EPA, "EPA Will Expeditiously Review New Science on Fluoride in Drinking Water."

Toxic Substances Control Act (TSCA) Citizen Petition, Litigation, and Court Order

TSCA gives EPA a broad range of authorities over certain chemical substances, which could include fluoridation chemicals.[197] TSCA Section 6(a) requires EPA to promulgate rules applying certain requirements, defined in the statute, to uses of a chemical substance or mixture that the agency determines "presents an unreasonable risk of injury to health or the environment."[198] TSCA Section 21 establishes a process by which citizens can petition EPA to issue, amend, or repeal certain TSCA rules or orders.[199] EPA must either grant or deny a citizen petition within 90 days after the petition is filed, and the agency's denial or failure to grant a citizen petition is subject to judicial review.[200]

On September 24, 2024, a federal district court found that, based on a preponderance of the evidence presented at trial, "water fluoridation at the level of 0.7 mg/L—the prescribed optimal level of fluoridation in the United States" constituted "an unreasonable risk of injury to health or the environment" under TSCA and ordered EPA to initiate a rulemaking pursuant to TSCA Section 6(a).[201] The court entered judgment on November 20, 2024.[202] The order followed years of agency proceedings and litigation, beginning in November 2016, when EPA received a citizen petition under TSCA Section 21 seeking the issuance of a rule under TSCA Section 6(a) to "prohibit the purposeful addition of fluoridation chemicals to U.S. water supplies."[203] EPA has appealed the district court's ruling.[204]

The court's decision in the water fluoridation case marks the first time that a judicial challenge to a denial of a Section 21 petition has resulted in an order to initiate a new rulemaking. The November 2016 petition and the legal and regulatory developments that followed it are discussed below.

Section 21 Petition

The November 2016 citizen petition asserted that "a large body of animal, cellular, and human research shows that fluoride is neurotoxic at doses within the range now seen in fluoridated communities."[205] The petition proposed various Reference Doses that generally were an order of magnitude lower than the estimated exposure to fluoride by those who reside in areas where

[197] 15 U.S.C. §2601 et seq.

[198] 15 U.S.C. §2605(a).

[199] 15 U.S.C. §2620.

[200] 15 U.S.C. §2620(b)(3), (b)(4).

[201] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc. v. EPA, No. 17-cv-02162 EMC (N.D. Cal., Sept. 24, 2024), ECF No. 445.

[202] Judgment, Food & Water Watch, Inc. Nov. 20, 2024, ECF No. 452.

[203] Michael Connett, Fluoride Action Network, *Citizen Petition Under Section 21 of TSCA Regarding the Neurotoxic Risks Posed by Fluoride Chemicals in Drinking Water*, November 2016, https://www.epa.gov/sites/default/files/2017-02/documents/tsca_fluoride_petition.pdf. Hereinafter Connett, *Citizen Petition.*

[204] Notice of Appeal to the 9th Circuit Court of Appeals, Food & Water Watch, Jan. 17, 2025, ECF No. 455; Food & Water Watch v. EPA, No. 25-384 (9th Cir.).

[205] Connett, *Citizen Petition*, p. 29.

fluoride is added to drinking water.[206] In February 2017, EPA denied the citizen petition.[207] In denying the petition, EPA stated that the petitioners had not scientifically justified their request due to their reliance on several human studies that had "basic data quality issues" or were not considered a suitable basis on which to make causal inferences between exposure to fluoride and specific adverse health outcomes.[208] EPA also explained that the calculation of reference doses was premature without first considering the weight of the evidence provided by the available database of scientific literature.[209]

TSCA Section 21 provides that if EPA denies a petition, the petitioner may file a civil action in federal district court to compel the agency to undertake the requested action.[210] This court proceeding is de novo, meaning that the court makes independent findings of fact and conclusions of law without deference to the earlier agency decision.[211] To prevail in a TSCA Section 21 proceeding seeking to compel EPA to issue a rule under Section 6(a), the petitioner must show by a preponderance of the evidence that the chemical substance or mixture to be subject to the rule "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors ... under the conditions of use."[212] "Preponderance of the evidence" means that, to prevail, the petitioner must demonstrate to the court that the evidence shows its position is more likely to be true than not.[213]

Civil Action and Bench Trials

In April 2017, the petitioners filed a lawsuit to compel EPA to use its authority under TSCA Section 6(a) to prohibit the addition of fluoridation chemicals to water supplies.[214] In their complaint, the plaintiffs alleged fluoridated water harmed them in a number of ways, including causing them to experience stained teeth, headaches, pain, gastrointestinal problems, and other physical symptoms, and to incur the cost of removing fluoride from their water.[215]

Following substantial motion practice,[216] the court held a bench trial in June 2020.[217] After that bench trial, however, the court stayed the proceeding.[218] In its order, the court noted "serious questions" about whether the plaintiffs had standing to pursue their case.[219] *Standing* is a

[206] Connett, *Citizen Petition*, pp. 19-21. Estimated exposure levels included average total daily dose of fluoride, and fluoride concentrations in drinking water or blood serum.

[207] Letter from Wendy Cleland-Hammett, EPA Acting Assistant Administrator, to Michael Connett, Fluoride Action Network, February 17, 2017, https://www.epa.gov/sites/default/files/2017-02/documents/fluoridetsca21_response_letter_signed_2017-02-17.pdf.

[208] EPA, "Fluoride Chemicals in Drinking Water; TSCA Section 21 Petition; Reasons for Agency Response," 82 *Federal Register* 11878-11890, February 27, 2017.

[209] 82 *Federal Register* 11885.

[210] 15 U.S.C. §2620(b)(4).

[211] See Environmental Defense Fund v. Reilly, 909 F.2d 1497, 1506 (D.C. Cir. 1990) (explaining that "the Section 21 court, proceeding de novo, is free to disregard EPA's reasoning and decision.").

[212] 15 U.S.C. §2620(b)(4)(B)(ii).

[213] See, for example, Barhoumi v. Obama, 609 F.3d 416, 424 (D.C. Cir. 2010).

[214] Complaint, Food & Water Watch, Inc., Apr. 18, 2017, ECF No. 1.

[215] Complaint, Food & Water Watch, Inc. Apr. 18, 2017, ECF No. 1, pp. 5-10.

[216] See Order Denying Defendant's Motion to Dismiss, Food & Water Watch, Inc. Dec. 21, 2017, ECF No. 422; Order Denying Plaintiffs' Motion for Summary Judgment and Denying Defendants' Motion for Summary Judgment, Food & Water Watch, Inc., Dec. 30, 2019, ECF No. 156.

[217] Clerk's Notice Setting Zoom Hearing; Food & Water Watch, Inc., June 5, 2020, ECF No. 219.

[218] Order Holding Proceedings in Abeyance, Food & Water Watch, Inc., Aug. 10, 2020, ECF No. 262.

[219] Order Holding Proceedings in Abeyance at 1-3, Food & Water Watch, Inc. Aug. 10, 2020, ECF No. 262.

jurisdictional requirement arising from the U.S. Constitution; where a plaintiff is unable to demonstrate standing, a court has no authority to hear the plaintiff's case.[220] To demonstrate standing, plaintiff must show that he or she suffered an "injury in fact," which is "fairly traceable to the challenged action of the defendant" rather than some other action, and which is "likely [to be] redressed by a favorable decision" of the court.[221] The court observed that the plaintiffs' evidence at trial "focused overwhelmingly, if not exclusively" on alleged risks of neurodevelopmental harm posed by fluoride, particularly during gestational and neonatal periods, but none of the plaintiffs alleged that they were "pregnant, planning to become pregnant, or caring for infants."[222] The court further observed that evidence pertaining to the harms the plaintiffs had alleged in their complaint was "practically non-existent at trial."[223] Because of the scarcity of evidence linking their alleged harms to fluoride, and because no decision relating to neurodevelopmental harm would be likely to address the harms actually pled in their complaint, the court stated that the plaintiffs likely failed to establish standing.[224] The court directed plaintiffs to file a new TSCA Section 21 petition with EPA, and ordered that the plaintiffs would be permitted to amend their complaint in the event that EPA denied that second petition.[225]

The court also noted two other reasons for staying the proceeding, both relating to developments in scientific research. First, the court observed that the plaintiffs' trial evidence was not the same evidence that accompanied their original petition.[226] Among this evidence, the court pointed in particular to studies of birth cohorts in Mexico and Canada published after EPA denied the plaintiffs' petition that "even EPA acknowledge[d] ... are the highest quality, most reliable studies to date" on the subject.[227] Second, the court noted that publication of a systematic review by the NTP was "imminent" and "likely to add substantially to the body of scientific analysis relevant to the precise questions" at issue.[228] The NTP released a draft of this review—the draft NTP monograph[229]—on September 16, 2020.[230]

In November 2020, the plaintiffs filed a supplemental TSCA Section 21 petition, requesting that the "EPA prohibit the addition of fluoridation chemicals to drinking water in order to protect the public, including susceptible subpopulations, from fluoride's neurotoxic risks."[231] The supplemental petition noted that the draft NTP monograph estimated a hazard level of 1.5 mg/L of fluoride in drinking water.[232] After the plaintiffs applied a default uncertainty factor of 10 to this estimated hazard level (i.e., reduced the estimated hazard level by an order of magnitude), the plaintiffs argued that a reference dose of 0.15 mg/L of fluoride in drinking water suggests that EPA should find that community water fluoridation presents an unreasonable risk at the

[220] *See* Simon v. E. Ky. Welfare Rts. Org., 426 U.S. 26, 38 (1976). Also, see Congressional Research Service, "ArtIII.S2.C1.6.1 Overview of Standing," *Constitution Annotated*, https://constitution.congress.gov/browse/essay/artIII-S2-C1-6-1/ALDE_00012992/ (last visited March 5, 2025).

[221] Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992) (internal citations omitted).

[222] Order Holding Proceedings in Abeyance, Food & Water Watch, Inc., Aug. 10, 2020, ECF No. 262, pp. 1-2.

[223] Order Holding Proceedings in Abeyance, Food & Water Watch, Inc. Aug. 10, 2020), ECF No. 262, pp. 3.

[224] Order Holding Proceedings in Abeyance, Food & Water Watch, Inc., Aug. 10, 2020, ECF No. 262, pp. 1-3.

[225] Order Holding Proceedings in Abeyance, Food & Water Watch, Inc., Aug. 10, 2020, ECF No. 262, pp. 4-5.

[226] Order Holding Proceedings in Abeyance, Food & Water Watch, Inc., Aug. 10, 2020, ECF No. 262, p. 4.

[227] Order Holding Proceedings in Abeyance, Food & Water Watch, Inc., Aug. 10, 2020, ECF No. 262, p. 4.

[228] Order Holding Proceedings in Abeyance, Food & Water Watch, Inc. Aug. 10, 2020, ECF No. 262, p. 4.

[229] NTP produced a number of drafts of the Monograph. This report distinguishes these drafts by date where relevant to the litigation.

[230] Letter from Michael Connett, Food & Water Watch, Inc., Nov. 4, 2020, ECF No. 270-1, p. 4.

[231] Letter from Michael Connett, Food & Water Watch, Inc., Nov. 4, 2020, ECF No. 270-1.

[232] Letter from Michael Connett, Food & Water Watch, Inc., Nov. 4, 2020), ECF No. 270-1, pp. 4 and 10.

recommended level of 0.7 mg/L of fluoride.[233] The plaintiffs stated that a default uncertainty factor of 10 is generally applied by EPA to protect susceptible populations and is considered to be appropriate in the absence of convincing data to the contrary.[234] Additionally, the supplemental petition noted that an unpublished dose-response modeling analysis identified maternal urinary fluoride levels that were associated with the loss of one IQ point among four-year-old children across two different cohorts.[235] The supplemental petition argued that this analysis justified reconsidering EPA's petition denial, because the identified maternal urinary fluoride levels associated with the loss of one IQ point were lower when compared to maternal urinary fluoride levels measured among pregnant women living in areas where fluoride is added to drinking water.[236] On January 19, 2021, EPA declined to exercise its discretion to reopen the administrative record and reconsider the 2017 citizen petition.[237] EPA noted that the newly submitted information, including the draft NTP monograph, an unpublished dose-response modeling analysis, and an op-ed, did not provide "sufficient scientific or administrative justification to reopen and reconsider the November 2016 petition."[238]

Following EPA's denial, the plaintiffs filed an amended complaint in federal court on February 19, 2021.[239] The amended complaint included an allegation that one of the named plaintiffs had become pregnant, as well as "[a]llegations conforming to the evidence introduced at trial regarding the findings of the National Institute[s] of Health's recent prospective studies on the impact of early life fluoride exposure on neurodevelopment, and the vulnerability of the fetal brain to fluoride exposure."[240] In an October 2022 order, the court lifted the stay in the case, noting that the allegation of pregnancy "appear[ed]" to have cured the standing defect identified in its earlier order.[241] The court also rejected an argument from EPA that scientific developments arising after the end of the June 2020 bench trial should be excluded from consideration, and instead "permit[ted] commencement of expert review of the new scientific evidence."[242] Following additional discovery, the court held a second bench trial beginning on January 31, 2024.[243] During this trial, the court examined, under seal, a May 2022 iteration of the draft NTP monograph.[244]

[233] Letter from Michael Connett, Food & Water Watch, Inc., Nov. 4, 2020), ECF No. 270-1, p. 10.

[234] Letter from Michael Connett, Food & Water Watch, Inc., Nov. 4, 2020), ECF No. 270-1, p. 10.

[235] Letter from Michael Connett, Food & Water Watch, Inc., Nov. 4, 2020), ECF No. 270-1, p. 11.

[236] Letter from Michael Connett, Food & Water Watch, Inc., Nov. 4, 2020, ECF No. 270-1, p. 11.

[237] Letter from Yvette T. Collazo, Director of EPA Office of Pollution Prevention and Toxics, to Michael Connett, Food & Water Watch, Inc., Jan. 19, 2021, ECF No. 278-1.

[238] Letter from Yvette T. Collazo, Food & Water Watch, Inc., Jan. 19, 2021, ECF No. 278-1, p. 6.

[239] First Motion to Amend/Correct Complaint to Add Supplemental Pleadings, Exhibit A, Food & Water Watch, Inc., Feb. 19, 2021, ECF No. 279-1. The court granted that motion on May 11, 2021, and plaintiffs filed their amended complaint as a separate document on December 15, 2023. Plaintiffs' Notice of Filing Supplemental Complaint, Food & Water Watch, Inc., Dec. 15, 2023, ECF No. 372.

[240] First Motion to Amend/Correct Complaint to Add Supplemental Pleadings, Food & Water Watch, Inc., Feb. 19, 2021, ECF No. 279, p. 8.

[241] Order Granting Plaintiff's Motion to Lift the Stay and Take Case Out of Abeyance, Food & Water Watch, Inc., Oct. 28, 2022, ECF No. 306, p. 3.

[242] Order Granting Plaintiff's Motion to Lift the Stay, Food & Water Watch, Inc., Oct. 28, 2022, ECF No. 306, p. 5.

[243] Transcript of Proceedings Trial Vol. 1 held on 1/31/2024, Food & Water Watch, Inc., Feb. 4, 2024, ECF No. 395.

[244] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 15. In this iteration, the Draft NTP Monograph was retitled *NTP Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects: A Systematic Review*; NTP published a final version in August 2024, as discussed in "Neurodevelopmental Effects."

The Court's Order

On September 24, 2024, the court ruled in favor of the plaintiffs.[245] The court held that the plaintiffs had proven, by a preponderance of the evidence, that water fluoridation at the level of 0.7 mg/L presents an "unreasonable risk of injury to health or the environment" under TSCA.[246] The court noted that EPA's own expert recognized that "fluoride is hazardous," and it rejected EPA's argument that the hazard level and the relationship between dosage and response at lower exposure levels was not clear.[247]

To support its ruling, the court noted two approaches to deriving reference doses to compare with estimated exposure levels: one for maternal urinary concentrations and the other for drinking water concentrations.[248] For an exposure level measured by maternal urinary fluoride concentrations, the court identified three potential maternal urinary fluoride reference doses (0.028 mg/L, 0.077 mg/L, and 0.154 mg/L) based on data from three study cohorts.[249] Although the studies varied in the strength of the association, the court found that these reference doses for maternal urinary fluoride would be expected to protect children up to the age of four from the loss of one IQ point.[250] By comparison the estimated median urinary fluoride levels for pregnant mothers who live in communities that receive fluoridated drinking water is 0.8 mg/L, and the 95th percentile urinary fluoride levels for pregnant mothers who live in communities that receive fluoridated drinking water is 1.89 mg/L.[251] The court noted that the three maternal fluoride urinary reference doses were substantially lower than the two estimated maternal urinary fluoride exposure levels.[252]

For drinking water concentrations, the court identified a potential reference dose of 0.04 mg/L of fluoride in water.[253] The court calculated this potential reference dose of fluoride in water by applying a 100-fold uncertainty factor,[254] to 4.0 mg/L of fluoride, which was determined to be the lowest observed adverse effect level for IQ loss from ingesting fluoride through water consumption.[255] The court explained that the 100-fold uncertainty factor was warranted due to a 10-fold uncertainty factor to account for interspecies variability and another 10-fold uncertainty factor for using the lowest observed adverse effect level rather than a no observed adverse effect level.[256] The court compared the potential reference dose for drinking water concentrations to the estimated fluoride level in water due to optimal community water fluoridation (i.e., 0.7 mg/L) and noted how the potential reference dose was significantly lower than the estimated fluoride level from community water fluoridation.[257]

[245] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445.

[246] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445.

[247] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 4.

[248] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 40-41.

[249] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 71-72.

[250] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 42-51 and 70-72.

[251] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 70-72.

[252] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 4-5, 71-72.

[253] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 72-73.

[254] The court noted that an uncertainty factor "account[s] for assumptions or uncertainty" in data. Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 56.

[255] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 52 and 72-73.

[256] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 73.

[257] Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 73.

Given how both approaches in deriving reference doses resulted in values that were lower than estimated exposure levels, the court found that community water fluoridation at 0.7 mg/L of fluoride presented an unreasonable risk.[258] Before deriving these potential reference doses, the court noted that the findings of the draft NTP monograph are "properly afforded substantial weight" as part of the "weight-of-the-scientific-evidence analysis" that precedes the dose-response assessment.[259] While the findings of the draft NTP monograph were not used to derive potential reference doses, the court explained that the findings justified conducting a dose-response assessment using data from other studies.[260] The court acknowledged various uncertainties with its evaluation of risks but noted that the uncertainties do not undermine the finding of an unreasonable risk.[261]

The court explicitly ordered EPA to initiate a rulemaking under TSCA Section 6(a).[262] The court, however, was clear that its order did not prescribe the outcome of this rulemaking, and it did not specify a date by which EPA must take further regulatory action.[263] EPA is entitled to appeal the ruling, including the court's decision on standing.[264] On January 17, 2025, EPA filed a notice of appeal of the court's order with the U.S. Court of Appeals for the Ninth Circuit.[265]

In light of the pending appeal, EPA's path forward is unclear. If the agency proceeds with a rulemaking, it may consider additional evidence, including the NTP materials published after the conclusion of the trial.[266] Under TSCA Section 6(a), EPA could apply a range of requirements from requiring warnings to an outright ban.[267] Further, TSCA Section 9 requires EPA to assess whether another authority that EPA administers or another federal agency may be appropriate to address the identified unreasonable risk.[268] Therefore, EPA could conclude that another statutory authority, such as a revision to the fluoride MCLG and MCL under SDWA,[269] is better suited than TSCA's range of remedies to address the identified unreasonable risk and take action under that authority.

Policy Considerations

Recent federal agency announcements and state actions related to fluoride and drinking water raise a number of considerations. It remains to be seen whether EPA or HHS will take specific

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258 Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 74.

259 Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 34-40. The parties agreed that the Draft NTP Monograph that was the subject of testimony and argument at trial did not differ materially from the version of the monograph published after trial, though plaintiffs asserted that certain aspects of that version might have provided additional support for their case. Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 15.

260 Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 40.

261 Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 77-79.

262 Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, pp. 79.

263 Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 6.

264 Fed. R. App. P. 4(a)(1)(B).

265 Notice of Appeal to the 9th Circuit Court of Appeals, Food & Water Watch, Jan. 17, 2025, ECF No. 455; Food & Water Watch v. EPA, No. 25-384 (9th Cir.).

266 Findings of Fact and Conclusions of Law, Food & Water Watch, Inc., Sept. 24, 2024, ECF No. 445, p. 67.

267 15 U.S.C. §2605(a).

268 15 U.S.C. §2608.

269 42 U.S.C. §§300f et seq.

actions regarding fluoride, though several considerations may arise in light of these announcements.

Regarding health effects research, federal agencies rely on existing scientific research to establish guidance or set regulatory levels, including guidance for community water fluoridation and for the SDWA fluoride drinking water regulation. As discussed in "Research on Health Effects of Fluoride," the scientific evidence demonstrating that fluoride levels of 0.7 mg/L can prevent dental caries is generally well-accepted in the scientific community, as is the evidence that links crippling skeletal fluorosis to prolonged exposure (i.e., more than 20 years) to 10.0 mg/L of fluoride. However, some ongoing debates pertaining to fluoridation cite challenges related to understanding how different sources of fluoride exposure at different levels may contribute to a range of health benefits or risks. Others highlight specific gaps in the research on the connection between fluoride and other health outcomes (see "Overview of Research Challenges").

Future oversight and legislative efforts may consider whether, and if so how, additional federally funded research or monitoring could address such questions and gaps in understanding. Such data could inform federal action related to community water fluoridation or revisions to the fluoride drinking water regulation, or could also lead to the identification of additional research gaps and priorities. Additional support for federally directed research may also be weighed in relation to competing uses of federal funding and other congressional or agency priorities, particularly as changes to some federal agencies, including cuts, maintenance, or increases to their research and regulatory programs, are proposed and considered.

Other considerations pertain to EPA's April 7, 2025, announcement that the agency would review the scientific evidence related to fluoride to inform a potential revision to the drinking water regulation. The outcome of this review may depend on the strength of evidence from the research on certain health effects. Under SDWA, EPA is required to use the best available, peer-reviewed science to assess health risks.[270] If EPA finds, as an outcome of its review, that the scientific information it reviewed does not meet this standard, use of that scientific information would be inconsistent with SDWA's regulatory development provisions.[271] Using the best-available, peer-reviewed science also raises considerations in the context of revisions to SDWA regulations. A potential revision of the regulation raises questions regarding where EPA would set the MCL, and what effect a revised MCL may have on communities that have higher levels of naturally occurring fluoride. SDWA's so-called "anti-backsliding" provision requires that any revision of a drinking water regulation maintain or provide greater health protection than the existing regulation.[272] This constraint on EPA's ability to subsequently revise a regulation heightens the need to use scientifically sound research to support a revision. Accordingly, the relative strength of the evidence regarding certain health effects in existing research might be a contributing reason for waiting to revise the regulation as further research is conducted—that is, the agency may continue to review the regulation every six years (expected in 2030) as required by SDWA.

Amid ongoing changes to agency structures, priorities, and guidance, another consideration is oversight and observation of fluoride-related health outcomes and programs. Regarding oversight, one question involves the extent to which mechanisms to monitor impact of these structural changes on public health programs or certain health outcomes (e.g., dental caries) are or may become available, particularly if there are changes to federal fluoridation- and fluoride-related activities and guidance. Some mechanisms for oversight may require congressional direction; for instance, such impacts could be assessed through external evaluation mechanisms (e.g.,

[270] 42 U.S.C. §300g-1(b)(3)(A)(i).

[271] Under SDWA, EPA could also issue a nonenforceable health advisory for fluoride.

[272] 42 U.S.C. §300g-1(b)(9).

Government Accountability Office reports or NASEM). Other mechanisms for oversight may involve congressional hearings with scientific experts, agency leaders, or other key stakeholders. Alternatively, policymakers and stakeholders may also employ an observational approach to see how specific health outcomes related to fluoride or fluoridation that are monitored may change over time. Regarding this approach, the reliability and continuity of data collection efforts also raises considerations regarding data confidence. Under both approaches, information gathered could inform future legislative action. The implementation of either approach may be affected by the time needed to observe changes in certain health outcomes and the availability of data, among other factors.

It remains to be seen how ongoing HHS restructuring may affect certain HHS agencies' work related to fluoridation.[273] For example, the March 27, 2025, HHS restructuring fact sheet indicated that this effort would include a reduction of approximately 1,400 employees from CDC's workforce.[274] Similarly, EPA's May 2, 2025, press release announcing a reorganization of the agency's functions may raise questions of whether EPA's reorganization would affect the agency's priorities for scientific research or funding. [275] At the time of this report's publication, it is unclear if or how these restructurings may affect the various federal activities or programs related to water fluoridation or fluoride regulation.

[273] HHS, "HHS Announces Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/press-room/hhs-restructuring-doge.html. See also CRS Legal Sidebar LSB11311, *The Reorganization of the U.S. Department of Health and Human Services: Selected Legal Issues*.

[274] HHS, "HHS Announces Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/press-room/hhs-restructuring-doge.html.

[275] EPA, "EPA Announces Next Phase of Organizational Improvements to Better Integrate Science into Agency Offices, Deliver Clean Air, Land, and Water to All Americans," press release, May 2, 2025, https://www.epa.gov/newsreleases/epa-announces-next-phase-organizational-improvements-better-integrate-science-agency.

Appendix. Abbreviations

Table A-1. Abbreviations Used in This Report

AHRQ	Agency for Healthcare Research and Quality
ASPE	Assistant Secretary for Planning and Evaluation
ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CPSTF	Community Preventive Services Task Force
DOH	Division of Oral Health
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
IQ	Intelligence Quotient
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MWF	My Water's Fluoride
NASEM	National Academies of Sciences, Engineering, and Medicine
NCTR	National Center for Toxicological Research
NDWAC	National Drinking Water Advisory Council
NHANES	National Health and Nutrition Examination Survey
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NRC	National Research Council
NTP	National Toxicology Program
PHS	U.S. Public Health Service
RSC	Relative Source Contribution
SDWA	Safe Drinking Water Act
SMCL	Secondary Maximum Contaminant Level
TSCA	Toxic Substances Control Act

Author Information

Elena H. Humphreys, Coordinator
Analyst in Environmental Policy

Jerry H. Yen
Analyst in Environmental Policy

Alexandria K. Mickler
Analyst in Health Policy

Jason O. Heflin
Legislative Attorney

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