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Fluoride in Drinking Water: A Review of Fluoridation and Regulation Issues

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Summary

According to the Centers for Disease Control and Prevention (CDC), in 2010, 73.9% of the people in the United States who receive their water from a public water system received fluoridated water (roughly 204.3 million people). One of CDC's national health goals is to increase the proportion of the U.S. population served by community water systems with "optimally" fluoridated drinking water to 79.6% by 2020. The decision to add fluoride to a water supply is made by local or state governments. The Department of Health and Human Services (HHS) had long recommended an optimal fluoridation level in the range of 0.7 to 1.2 milligrams per liter (mg/L) to prevent tooth decay.

The fluoridation of drinking water often generates both strong support and opposition within communities. This practice is controversial because fluoride has been found to have beneficial effects at low levels and is intentionally added to many public water supplies; however, at higher concentrations, it is known to have toxic effects. The Environmental Protection Agency (EPA) regulates the amount of fluoride that may be present in public water supplies to protect against fluoride's adverse health effects. Fluoridation opponents have expressed concern regarding potential adverse health effects of fluoride ingestion, and some view the practice as an unjustified infringement on individual freedom. The medical and public health communities generally have recommended water fluoridation, citing it as a safe, effective, and equitable way to provide dental health protection community-wide.

Because the use of fluoridated dental products and the consumption of food and beverages made with fluoridated water have increased since HHS recommended optimal levels for fluoridation, many people now may be exposed to more fluoride than had been anticipated. Consequently, questions have emerged as to whether current water fluoridation practices and levels offer the most appropriate ways to provide the expected beneficial effects of fluoride while avoiding adverse effects (most commonly, tooth mottling or pitting—dental fluorosis) that may result from ingestion of too much fluoride when teeth are developing. Also, scientific uncertainty regarding the health effects of exposure to higher levels of fluoride adds controversy to decisions regarding water fluoridation. In 2011, HHS proposed to reduce the recommended level to 0.7 mg/L.

Although fluoride is added to water to strengthen teeth, some communities must treat their water to remove excess amounts of fluoride that is present either naturally or from pollution. In 1986, EPA issued a drinking water regulation for fluoride that includes an enforceable standard—a maximum contaminant level (MCL)—and an MCL goal (MCLG) of 4 mg/L to protect against adverse effects on bone structure. EPA acknowledged that the standard did not protect infants and young children against dental fluorosis, which EPA considered a cosmetic effect rather than a health effect. To address this concern, EPA included in the regulation a secondary (advisory) standard of 2 mg/L to protect children against dental fluorosis and adverse health effects. As part of its current review of the fluoride regulation, EPA asked the National Research Council (NRC) to review the health risk data for fluoride and to assess the adequacy of EPA's standards. In March 2006, NRC released its study and concluded that EPA's 4 mg/L MCLG should be lowered.

In 2011, EPA released new risk and exposure assessments for fluoride. The agency announced its intent to use this science and additional research to review the primary and secondary drinking water standards for fluoride and to determine whether to revise them. To make a regulatory determination, EPA also must consider analytical methods for testing for fluoride at lower concentrations, treatment feasibility (including cost), occurrence, and exposure.

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Introduction

The fluoridation of drinking water often generates both strong support and opposition within communities. The practice is recommended by the U.S. Department of Health and Human Services (HHS) to prevent tooth decay. The decision to fluoridate a public water supply is made by the state or local municipality and is not mandated by any federal agency. Opponents have expressed concern regarding potential adverse health effects of exposure to fluoride, and some view the practice as an undemocratic infringement on individual freedom. The medical and public health communities generally have supported water fluoridation, citing it as a safe, effective, and equitable way to provide dental health protection community-wide.

With the increased use of products containing fluoride, such as toothpaste and rinses, questions have emerged as to whether current fluoridation practices and levels are necessary and offer the most appropriate way to provide the beneficial effects of fluoride while avoiding adverse effects (such as tooth mottling or dental fluorosis) that can result from exposure to too much fluoride. Moreover, research gaps regarding the potential health effects of exposure to increased amounts of fluoride and among different age groups continue to add controversy to decisions regarding water fluoridation.

Although many communities add fluoride to drinking water to strengthen teeth, others must treat their water to remove excess amounts of fluoride, which often is present naturally in water. The Environmental Protection Agency (EPA) regulates the maximum amount of fluoride that may be present in public drinking water supplies to protect against certain adverse health effects.

In 1986, EPA issued a drinking water regulation for fluoride that includes an enforceable standard (a maximum contaminant level, or MCL) and a non-enforceable health-based maximum contaminant level goal (MCLG) of 4 milligrams per liter (mg/L) to protect against adverse effects on bone structure. EPA acknowledged that the standard did not protect infants and young children against dental fluorosis, which EPA considered a cosmetic effect rather than a health effect. To address concerns, EPA included in the regulation a secondary (advisory) standard of 2 mg/L to protect children against dental fluorosis and adverse health effects. As part of its ongoing review of the fluoride regulation, EPA asked the National Research Council (NRC) of the National Academy of Sciences to review the health risk data for fluoride and to assess the adequacy of EPA's standards. On March 22, 2006, NRC released its study and concluded that EPA's 4 mg/L MCLG should be lowered.

This report discusses the potential benefits and adverse effects associated with the fluoridation of drinking water supplies. It also discusses the regulation of fluoride in drinking water to protect against adverse health effects from exposure to higher levels of fluoride, and it reviews the status of federal efforts to update the health risk assessment for fluoride and the primary drinking water standard for fluoride. The following review of issues related to fluoride in drinking water presents information from research published in peer-reviewed scientific journals, reports, and statements of federal agencies—including EPA and the Centers for Disease Control and Prevention (CDC) and the U.S. Public Health Service (PHS) within the Department of Health and Human Services (HHS)—and the World Health Organization, studies by the National Research Council, and other sources.

Background

Fluoride is a naturally occurring substance and is present in virtually all water, usually at very low levels. Higher concentrations of naturally occurring fluoride often are associated with well water, where fluoride has dissolved from the rock formations into the groundwater.[1] Community water fluoridation began in 1945, after scientists discovered that higher natural levels of fluoride in a community water supply were associated with fewer dental caries (cavities) among the residents.[2]

In 2010, CDC reported that more than 204.2 million (73.9%) of the people in the United States who received their water from public water systems received fluoridated water. Of the total U.S. population, 66.2% received fluoridated water.[3] In 2004, more than 170 million (67%) people served by public water systems received fluoridated water.[4]

Many public health agencies and professional health organizations have advocated the addition of a small amount of fluoride to drinking water to help strengthen teeth and prevent dental caries. Although this practice has been controversial in various communities, CDC, the American Medical Association, the American Dental Association (ADA), the American Academy of Pediatric Dentistry, and others have recommended fluoridation of public water supplies as an effective way to protect dental health. This approach has been advocated for its ability to provide community-wide benefits, particularly in poorer communities where children may be less likely to receive adequate dental care.[5]

CDC considers the reduction in tooth decay from fluoridation one of the top public health achievements of the 20th Century.[6] In 2002, CDC reported that "During the second half of the 20th century, a major decline in the prevalence and severity of dental caries resulted from the identification of fluoride as an effective method of preventing caries. Fluoridation of the public water supply is the most equitable, cost-effective, and cost-saving method of delivering fluoride to the community."[7]

One of CDC's national health goals is to increase the proportion of the U.S. population served by community water systems with "optimally" fluoridated drinking water to 79.6% by 2020.[8] The

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[1] Fluoride also occurs in many foods, including meat, potatoes, fish, sugar, milk, and legumes. The amount in brewed tea ranges from 1 to 6 milligrams per liter (mg/L), depending on brewing strength and time. Also, fluorides are used industrially and may be present in the environment as a result of inadequate pollution control.

[2] National Cancer Institute, *Cancer Facts: Fluoridated Water*, National Institutes of Health.

[3] Department of Health and Human Services, *Community Water Fluoridation*, Centers for Disease Control and Prevention, April 27, 2012, http://www.cdc.gov/fluoridation/index.htm.

[4] Dr. Richard Carmona, U.S. Surgeon General, *Surgeon General's Statement on Community Water Fluoridation*, Department of Health and Human Services, 2004.

[5] Centers for Disease Control and Prevention, "Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries," *Morbidity and Mortality Weekly Report*, vol. 48, no. 41, October 22, 1999, pp. 933-940, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm.

[6] Centers for Disease Control and Prevention, "Ten Great Public Health Achievements—United States, 1900-1999," *Morbidity and Mortality Weekly Report*, vol. 48, no. 12, April 2, 1999, pp. 241-243, http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm.

[7] Centers for Disease Control and Prevention, *Populations Receiving Optimally Fluoridated Public Drinking Water*, pp. 144.

[8] U.S. Department of Health and Human Services, *Healthy People 2020*, Oral Health Objective 13 (OH-13), http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=32.

optimal fluoridation level that has long been recommended by PHS for decay prevention is in the range of 0.7 to 1.2 milligrams per liter (mg/L).[9]

The World Health Organization (WHO) has identified dental caries (cavities) as a worldwide epidemic and recommends adding fluoride to drinking water where naturally occurring levels of fluoride are below optimal levels.[10] The WHO states that the goal of community-based public health programs "should be to implement the most appropriate means of maintaining a constant low level of fluoride in as many mouths as possible."[11] According to the WHO,

> [w]ater fluoridation in low fluoride-containing water supplies helps to maintain optimal dental tissue development and dental enamel resistance against caries attack during the entire life span.... People of all ages, including the elderly, benefit from community water fluoridation. For example, the prevalence of caries on root surfaces of teeth is inversely related to fluoride levels in the drinking water: in other words, within the non-toxic range for fluoride, the higher the level of fluoride in water, the lower the level of dental decay. This finding is important because with increasing tooth retention and an aging population, the prevalence of dental root caries would be expected to be higher in the absence of fluoridation.[12]

The recommended beneficial amount of fluoride can be obtained from a variety of sources other than water (e.g., fluoride toothpastes, rinses, and supplements). However, health officials historically have recommended fluoridation of community water supplies, citing socioeconomic reasons that may vary among countries and communities. The WHO explains this preference as follows:

> The consensus among dental experts is that fluoridation is the single most important intervention to reduce dental caries, not least because water is an essential part of the diet for everyone in the community, regardless of their motivation to maintain oral hygiene or their willingness to attend or pay for dental treatment. In some developed countries, the health and economic benefits of fluoridation may be small, but particularly important in deprived areas, where water fluoridation may be a key factor in reducing inequalities in dental health.[13]

Despite such recommendations, fluoridation remains far from universally practiced. Worldwide, an estimated 370 million people receive artificially fluoridated water, and another 50 million drink water that is naturally fluoridated at or near the optimal level.[14] Overall, some 30 countries practice water fluoridation, and the percentage of populations receiving artificially fluoridated water varies greatly. Countries where fluoridation is practiced (and the percentage of their

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[9] In 2011, HHS proposed a revised recommended level for community water fluoridation of 0.7 milligrams per liter, the lower end of the current range. HHS noted that exposure to fluoride from other sources (e.g., toothpaste and fluoridated rinses) has increased over the years. Department of Health and Human Services, "Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries," 76 *Federal Register* 2383, January 13, 2011.

[10] World Health Organization, Water Sanitation and Health, *World Water Day 2001: Oral Health: Dental Caries, a Worldwide Epidemic*, Health and Sanitation Unit and Oral Health Program.

[11] World Health Organization, *Risks to Oral Health and Intervention: Fluoride*. See http://www.who.int/oral_health/action/risks/en/index1.html.

[12] Ibid.

[13] World Health Organization, *Naturally Occurring Hazards*. Available at http://www.who.int/water_sanitation_health/naturalhazards.html#fluoride.

[14] British Fluoridation Society and the UK Public Health Association, *One in a Million: The Facts about Water Fluoridation*, 3rd ed., March 2012, Executive Summary, http://www.bfsweb.org/onemillion/onemillion2012.html.

populations receiving fluoridated water) include Argentina (21%), Australia (61%), Brazil (41%), Canada (43%), Chile (40%), Colombia (80%), Israel (75%), Malaysia (70%), New Zealand (61%), and Singapore (100%).[15] Of the Western European countries, the Republic of Ireland (73%), Spain (10%), and the United Kingdom (10%) fluoridate drinking water. Most other Western European countries have ceased, or never practiced, water fluoridation for various reasons, including the availability of other sources of fluoride (especially toothpaste), the availability of free school-based dental care programs in some countries, broader public skepticism about the safety and efficacy of fluoridation, and greater political opposition. In several Latin American countries, where centralized water supplies are often lacking, fluoridated salt is the chosen method of providing dental protection across disparate communities. Fluoridated salt also is available in some European countries, including Austria, France, Germany, Hungary, and Switzerland.[16]

Questions About the Safety and Benefits of Fluoridation

Water fluoridation has generated less opposition in the United States than in Europe. However, notwithstanding recommendations from many governmental and professional health organizations, this practice continues to generate controversy in some U.S. communities. Research gaps regarding the effects of long-term exposure to increased levels of fluoride fuel this debate, and decades into this practice, the safety and efficacy of water fluoridation continues to be questioned, debated, and studied.

Dental Fluorosis

Some oppose water fluoridation because of a concern that even recommended "optimal" levels of fluoridation may cause some dental fluorosis in children. Dental fluorosis is caused by excessive fluoride intake while teeth are developing, and it is during this period before teeth erupt that dental tissues are very sensitive to fluoride (typically during a child's first eight years).[17] Mild dental fluorosis is characterized by opaque white or stained patches in the dental enamel. More severe fluorosis is characterized by pitting of tooth enamel. In the 1960s, when PHS recommended an "optimal" fluoride concentration in water of 0.7 to 1.2 mg/L, this level was intended to "maximize prevention of caries while limiting the prevalence of dental fluorosis to about 10% of the population, virtually all of it mild to very mild."[18]

[15] Mullen, J. *History of Water Fluoridation*, British Dental Journal, 2005. p. 1-4

[16] Marthaler TM - "Salt fluoridation in Europe, comparisons with Latin America" 8th World Salt Symposium (2000); Volume 2: 1021-1026 (2000).

[17] Institute of Medicine. *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, National Academy Press, 1997, p. 298.

[18] National Research Council, *Health Effects of Ingested Fluoride*, Subcommittee on Health Effects of Ingested Fluoride, Committee on Toxicology, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Academy Press, 1993, p. 5.

Researchers determined that dental fluorosis had a clear dose-response relationship—increasing in severity and prevalence at higher concentrations. In 1993, NRC estimated that the effects generally ranged from mild or very mild, occurring at roughly 0.7 to 1.0 mg/L, to pronounced discoloration and pitting of teeth, occurring at 5 to 7 mg/L and (continued...)

Because of the increased use of fluoridated dental products and the tendency for young children to swallow these products, concern over dental fluorosis and other potential effects of fluoride ingestion has increased. Questions have arisen as to whether current fluoridation practices and levels offer the most appropriate ways to provide the expected beneficial effects of fluoride while avoiding adverse effects that can result from ingesting too much fluoride. As noted by NRC in 1997, "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."[19]

According to a 2002 study, fluorosis prevalence among schoolchildren in the 1980s ranged from 18% to 26%, depending on the analytical index used. The authors further estimated that approximately 2% of U.S. schoolchildren may experience "perceived esthetic problems" that could be attributable to currently recommended levels of fluoride in drinking water combined with fluoride toothpaste consumption.[20] However, the authors noted that data were not available for other potential fluoride exposures resulting from the ingestion of fluoridated toothpaste and diluted infant formula consumption, and that consequently, the risk of fluorosis attributable to fluoridation of public water supplies may be overestimated if fluoride consumption was higher in fluoridated areas.[21] The researchers concluded that in determining the optimal fluoridation policy, the prevalence of dental fluorosis

> should be weighed against fluoridation's lifetime benefits and the feasibility and associated costs of alternative solutions such as educating parents of preschoolers about appropriate toothpaste use and lowering the current fluoride content of children's toothpaste. Given that fluorosis results from fluoride exposure during a narrow age range and that the benefits accrue over the entire life span, educating parents as to the appropriate use of fluoride toothpaste or reducing the fluoride content of children's toothpaste as some have suggested may be more efficient than altering current fluoridation policy.[22]

In its 1993 fluoride health effects report, NRC agreed with this conclusion in principle, but determined that this approach may not be feasible in practice:

> The most effective approach to stabilizing the prevalence and severity of dental fluorosis, without jeopardizing the benefits to oral health, is likely to come from more judicious control of fluoride in foods, processed beverages, and dental products, rather than a reduction in the recommended concentrations of fluoride in drinking water. But applying such a policy would be formidable; reduction of fluoride concentrations in drinking water would be easier to administer, monitor, and evaluate.[23]

(...continued)

higher.

[19] Ibid.

[20] Griffin, Susan O., Eugenio D. Beltran, Stuart A. Lockwood, and Laurie K. Barker, *Esthetically Objectionable Fluorosis Attributable to Water Fluoridation*, Community Dental Oral Epidemiology, 2002, vol. 30, pp. 199-209. The prevalence of "perceived esthetic problems" was assessed by evaluating fluorosis in the teeth at the front of the mouth.

[21] Ibid., pp. 199, 208-209.

[22] Ibid., p. 209.

[23] National Research Council, *Health Effects of Ingested Fluoride*, 1993, pp. 47-48.

Although mild to moderate dental fluorosis had been considered by agencies to be a cosmetic effect, not a health effect, it may be objectionable to many and, if severe enough, may adversely affect tooth health. Therefore, this issue has factored in the fluoridation debate.[24]

In response to the widespread use of bottled waters and availability of a variety of fluoride-containing products, CDC issued new recommendations for fluoride use in 2001. The recommendations are intended to guide health-care providers and the public on the appropriate use of fluoride from various sources (such as tooth paste and baby formula made with fluoridated water). The recommendations specifically address fluoride intake among children aged younger than six years to decrease the risk for enamel fluorosis.[25] CDC also suggested areas for further research.

In 2006, the American Dental Association issued interim guidance on infant formula and fluoride. While affirming its support for fluoridation, the ADA recommended that infant formulas be mixed with water that is fluoride free or has very low levels of fluoride to decrease the risk of dental fluorosis.[26]

In 2011, responding to a 2006 NRC review of fluoride science and EPA's subsequent fluoride risk and exposure assessments (discussed below), HHS proposed a revised recommended level for community water fluoridation. Specifically, HHS proposed that community water systems use a fluoridation level of 0.7 milligrams per liter, which is the lower end of the current recommended range of 0.7 mg/L to 1.2 mg/L.[27]

Health Effects

Researchers continue to study the potential health effects associated with exposure to fluoride in drinking water. Many of the studies have focused on ingestion of higher, naturally occurring levels of fluoride rather than on artificial fluoridation levels. The studies generally have shown

[24] In setting a standard for fluoride in drinking water, EPA considered dental fluorosis to be a cosmetic effect, not an adverse health effect, and set the standard at a level that was not intended to protect against mild dental fluorosis. This issue is discussed below in the section on the federal regulation of fluoride in drinking water.

[25] Centers for Disease Control and Prevention, "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States," *Morbidity and Mortality Weekly Report*, vol. 50, no. 14, August 17, 2001, pp. 1-42. Available at http://www.cdc.gov/fluoridation/guidelines/tooth_decay.htm. The CDC recommendations included (1) using alternate water sources for children eight years and younger if the primary drinking water source has naturally occurring fluoride above 2 mg/L; (2) seeking professional advice on the use of fluoride toothpaste for children younger than two years; (3) supervising tooth brushing for children younger than age 6; (4) prescribing fluoride supplements judiciously; and (5) using fluoride mouth rinses appropriately.

[26] American Dental Association, *Interim Guidance on Fluoride Intake for Infants and Young Children*, November 2006, http://www.ada.org/1767.aspx.

[27] Department of Health and Human Services, "Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries," 76 *Federal Register* 2383, January 13, 2011. In this notice, HHS states that the proposed recommended optimal fluoride concentration of 0.7 mg/L was based on the following information: (1) community water fluoridation is the most cost-effective method of delivering fluoride for the prevention of tooth decay; (2) in addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence; (3) significant caries preventive benefits can be achieved and risk of fluorosis reduced at 0.7 mg/L, the lowest concentration in the range of the PHS recommendation; and (4) recent data do not show a convincing relationship between fluid intake and ambient air temperature; thus, there is no need for different recommendations for water fluoride concentrations in different temperature zones.

that fluoride ingestion at elevated levels primarily produces effects on skeletal tissues (skeletal fluorosis) and that these effects are more severe as exposure to fluoride increases above a threshold. Very mild, skeletal fluorosis is characterized by slight increases in bone mass. The most severe form of this condition, "crippling skeletal fluorosis," involves bone deformities, calcification of ligaments, pain, and immobility. In 1993, NRC reported that few cases of this condition had been reported in the United States and that it was not considered a public health concern.[28]

Bone Fracture Incidence

A related question that has been the subject of scientific research concerns whether artificial water fluoridation increases the risk of bone fracture in older women. A number of community-level studies conducted in the 1980s and 1990s compared rates of fracture, specific for age and gender, between fluoridated and nonfluoridated communities. Several of these studies indicated that exposure to fluoridated water increased the risk of fracture; a few studies indicated that water fluoridation reduced the risk of fracture; and several studies found no effect.[29] However, a weakness of these studies was that they were based on community-level data and lacked data on individuals.

To improve understanding of this issue, a 2000 study looked at the consumption of fluoridated water and fractures in individual women. The results of this study suggested that water fluoridation may reduce the risk of fractures of the hip and vertebrae in older white women (the subjects of the study).[30]

Cancer Studies

A possible link asserted in the 1970s between water fluoridation and increased cancer mortality raised health concerns and heightened controversy over the practice of fluoridation. Some researchers had reported that cancer mortality was higher in areas with fluoridated drinking water than in nonfluoridated areas.[31] These findings were refuted subsequently by other investigators who identified problems with the study's research methodology.[32] However, because of the importance of this question, researchers have continued to examine the possibility of an association between artificially fluoridated water and cancer in humans.

Independent expert panels conducted reviews of the available scientific studies in 1982 and 1985. The panels concluded that the studies provided "no credible evidence for an association between

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[28] National Research Council, *Health Effects of Ingested Fluoride*, 1993, p. 59. The severity of fluorosis varies among individuals and is complicated by factors such as malnutrition, calcium deficiency, and impaired kidney function (the kidneys clear much of the fluoride that is ingested). India has a high incidence of fluorosis because water supplies in large areas of the country contain high levels of naturally occurring fluoride. Fluorosis is also widely prevalent in China, the Middle East, North Africa, and other parts of Africa.

[29] National Research Council, *Health Effects of Ingested Fluoride*, pp. 60-61.

[30] Phipps, Kathy R., Eric S. Orwoll, Jill D. Mason, Jane A. Cauley, "Community Water Fluoridation, Bone Mineral Density, and Fractures: Prospective Study of Effects in Older Women," *British Medical Journal*, October 7, 2000, vol. 321, pp. 860-864.

[31] Yiamouyannis, J. and D. Burk, "Fluoridation and Cancer: Age Dependence of Cancer Mortality Related to Artificial Fluoridation," *Fluoride*, no. 10, 1977, pp. 102-123.

[32] National Research Council, *Health Effects of Ingested Fluoride*, 1993, p. 16.

fluoride in drinking water and risk of cancer."[33] However, according to the 1993 NRC fluoride review, all but one of these studies were ecological studies; that is, they were either geographic correlation or time-line studies that looked at exposures at the community level rather than individual exposures.[34] Consequently, the interpretation of the data was limited by an inability to measure *individual* fluoride exposures over long periods of time, or to measure exposure to other known risk factors such as smoking or other cancer-causing substances.[35]

In another examination of this issue, scientists at the National Cancer Institute (NCI) evaluated the relationship between drinking water fluoridation and the number of cancer deaths in the United States by county. After examining more than 2.2 million cancer death records, NCI researchers concluded that "there was no indication of increased cancer risk associated with fluoridated drinking water."[36] NRC concluded in 1993 that "[t]he large number of epidemiological studies [more than 50] combined with their lack of positive finding implies that if any link exists, it must be very weak."[37]

In 1990, the National Toxicology Program (NTP) published the results of studies on the potential carcinogenicity of fluoride in rats and mice.[38] The studies found no evidence of carcinogenic activity in female rats or mice at very high concentrations (100-175 mg/L) but found "equivocal evidence" of carcinogenicity in male rats. Osteosarcomas (bone cancers) were observed in 1 of 50 male rats receiving 100 mg/L sodium fluoride and 3 of 50 rats receiving 175 mg/L.[39] From this study, NTP researchers concluded that levels of sodium fluoride below 175 mg/L in drinking water over a two-year period would not be expected to cause any bone cancers in rats or mice. The result of the NTP study (i.e., equivocal evidence of carcinogenicity) was not confirmed in a 1992 study of rats using higher fluoride doses; however, rare, nonmalignant tumors were found in this study.[40] According to the Agency for Toxic Substances and Disease Registry, both studies had problems that limited their usefulness in showing whether fluoride can cause cancer in humans.[41]

In response to the concerns raised by the NTP 1990 study, EPA requested that NRC review the available toxicological and exposure data on fluoride to determine whether the current drinking water standard of 4 mg/L was sufficient to protect public health. In 1993, NRC completed an

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[33] Ibid., p. 110.

[34] Epidemiological studies look for associations between the occurrence of disease and exposure to known or suspected causes. In ecological studies, the unit of observation is the population or community; the specific exposures of individuals are not assessed.

[35] Department of Health and Human Services, Public Health Service, Ad-hoc Subcommittee on Fluoride, Committee to Coordinate Environmental Health and Related Programs, Review of Fluoride: Benefits and Risks, Executive Summary, February 1991, p. 9.

[36] National Cancer Institute, Cancer Facts: Fluoridated Water, 2000. Details discussed in National Research Council, *Health Effects of Ingested Fluoride, Carcinogenicity of Fluoride*. 1993, pp. 109-112.

[37] Ibid., p. 121.

[38] National Toxicology Program, *Toxicology and Carcinogenesis Studies of Sodium Fluoride in 344/N Rats and B6C3F1 Mice,* Department of Health and Human Services, National Institutes of Health, Technical Report 393, NIH Publ. No. 91-2848, 1990, p. 447.

[39] By NTP definition, equivocal evidence of carcinogenic activity is a category for uncertain findings by studies that are interpreted as showing a marginal increase in cancers that may be related to the administration of a chemical.

[40] National Toxicology Program, *NTP Supplemental 2-Year Study of Sodium Fluoride in Male F344 Rats*, CAS No. 7681-49-4, Study No. C55221D, National Institute of Environmental Health Sciences, Research Triangle Park, NC, 1992.

[41] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluorine*, U.S. Public Health Service, April 1993, p. 7.

extensive literature review concerning the association between fluoridated drinking water and increased cancer risk. Although NRC concluded that the data did not demonstrate an association between fluoridated drinking water and cancer, it did suggest that more research should be undertaken (especially research that examined individual, rather than population, exposures).[42]

Toward this end, a 1995 case-control analysis of bone cancer in Wisconsin controlled for several factors, including age at diagnosis. The researchers did not observe an association between fluoridation at the time of diagnosis and bone cancer. Although the study specifically examined young age groups (which some studies suggest may be more sensitive to fluoride exposure), exposure assignments were made without taking individual residence histories of the participants.[43] Therefore, the researchers did not account for duration or timing of exposure.

In 2002, EPA noted that additional studies regarding the effects of fluoride on bone had been published since the fluoride standard was promulgated in 1986, and that a new analysis of the data was warranted. EPA again requested NRC to review the toxicological and epidemiological data on fluoride, to update the fluoride risk assessment, and to evaluate the scientific basis and adequacy of EPA's drinking water standards for fluoride.[44]

In March 2006, NRC released *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*.[45] Because the NRC committee's charge was to evaluate the adequacy of EPA drinking water standards, NRC did not address questions regarding the benefits or risks of artificial fluoridation. However, after reviewing the available studies, 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 does not clearly indicate that fluoride either is or is not carcinogenic in humans." (The findings and recommendations of the NRC review are discussed further in the "Carcinogenicity" section below.)

Efficacy

The extent of the benefits of water fluoridation to oral health also has received some scrutiny and continues to do so. An overall reduction in caries has been observed in both fluoridated and nonfluoridated communities in the United States and Canada, and some more recent studies have suggested that water fluoridation has become less important and effective in preventing caries when compared with the findings of earlier studies. Some of this research has attributed the smaller differences in caries prevalence between fluoridated and nonfluoridated communities to the widespread use of fluoride toothpaste and other preventive dental care, and to better nutrition, including higher intake of vitamin D.[46]

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[42] National Research Council, *Health Effects of Ingested Fluoride*, pp. 121-123.

[43] National Research Council, Fluoride in Drinking Water: *A Scientific Review of EPA's Standards*, Committee on Fluoride in Drinking Water, Board on Environmental Studies and Toxicology, Division on Earth and Life Sciences, National Academies, March 2006.

[44] U.S. Environmental Protection Agency, "National Primary Drinking Water Regulations: EPA's Review of Existing Drinking Water Standards and Request for Public Comment," 67 *Federal Register* 19069, April 17, 2002.

[45] National Research Council, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*, Committee on Fluoride in Drinking Water, Board on Environmental Studies and Toxicology, Division on Earth and Life Sciences, National Academies, March 2006, p. 8.

[46] See, for example, Seppa, L., et al. "Caries Occurrence in a Fluoridated and a Nonfluoridated Town in Finland: A Retrospective Study Using Longitudinal Data from Public Dental Records," *Caries Research*, 2002, vol. 36, no. 5, pp. (continued...)

Several other studies have suggested that the traditional measure of the benefits of water fluoridation may understate its effectiveness. The authors of a 2001 study determined that the benefit of caries reduction from fluoridation is diffused to adjacent nonfluoridated communities through the export of bottled beverages and processed foods to those communities.[47] When this effect was accounted for, the authors found a beneficial effect from water fluoridation that was closer to the findings of studies conducted in the 1970s and earlier.[48] The results of a 1979-1980 survey found a 33% difference in the prevalence of dental caries among children in fluoridated and nonfluoridated regions in the United States, whereas a 1986-1987 national survey identified an 18% difference in caries prevalence. The National Institutes of Health (NIH) analyzed the 1986-1987 results and determined that when the effect of topical fluoride was controlled, the difference between fluoridated and nonfluoridated areas increased to 25%. According to the NIH researchers, the results suggested that fluoridation continued to play a major role in the decline in caries.[49]

In 2000, British researchers published the results of their systematic review of 214 studies on the safety and efficacy of water fluoridation. The researchers found that water fluoridation was associated with an increased proportion of children without caries and a reduction in the number of teeth with caries, but the overall reductions were smaller than had been reported in earlier studies.[50] The review also concluded that at a fluoride level of 1 mg/L, an estimated 12.5% of exposed individuals would have fluorosis that could be considered aesthetically concerning.[51] In reviewing the 214 studies, the authors found no other adverse effects associated with the fluoridation of drinking water. However, they noted that, overall, the studies were of low to moderate quality and recommended better research.[52]

Other Considerations

Aside from questions of safety and efficacy, social and political concerns may influence decisions about water fluoridation. A central issue for some who oppose fluoridation of the public water supply is lack of choice. Consumers who prefer not to drink fluoridated water generally are unable to exercise that choice without treating their tap water or buying bottled water. Some view a state or community fluoridation requirement as intrusive and object to receiving water that is not free of additives, other than those needed to make water safe. (In contrast, disinfectants, such as chlorine, generally have been accepted as necessary to protect public health by eliminating pathogens). In this view, decisions regarding dental health-care practices should be made by individuals and families and not imposed by government.

(...continued)

308-314.

[47] Griffin, Susan O., Barbara F. Gooch, Stuart A. Lockwood, and Scott Tomar. "Quantifying the Diffused Benefit from Water Fluoridation in the United States," *Community Dentistry and Oral Epidemiology*, 2001, vol. 29, pp. 120-129.

[48] Ibid., p. 128.

[49] Brunelle, J.A. and J.P. Carlos, "Recent Trends in Dental Caries in U.S. Children and the Effect of Water Fluoridation," National Institute of Dental Research National Institutes of Health, *Journal of Dental Research*, February 1990, vol. 69, pp. 723-727.

[50] McDonagh, Marian S., Penny F. Whiting, et al., "Systematic Review of Water Fluoridation," *British Medical Journal*, October 7, 2000, vol. 321, pp. 855-864.

[51] Ibid., p. 855.

[52] Ibid., p. 859.

To the extent that research gaps exist regarding potential adverse effects of increased exposures to fluoride because of its presence in multiple sources (e.g., water, beverages, toothpaste and rinses), the conflict between individual choice and public policy is likely to continue.

Regulation of Fluoride in Drinking Water

Fluoride poses challenges to regulators because many communities intentionally add it to their water supplies for a beneficial effect at low levels, whereas it has toxic effects and is regulated as a drinking water contaminant when it occurs in public water supplies at higher concentrations. Moreover, the range between the amounts that are considered beneficial and excessive is narrower for fluoride than for many trace minerals.[53]

This section discusses the federal regulation of fluoride in drinking water to protect against the potential adverse health effects associated with exposure to higher, typically naturally occurring fluoride levels (compared with levels recommended for artificial fluoridation to protect dental health). It reviews the current federal standards for fluoride in drinking water, EPA's steps to review and potentially revise the standards, and is followed by a review of NRC's updated assessment of the scientific basis and adequacy of EPA's standards, and the subsequent actions taken by the agency in response to the NRC findings and recommendations.

Standard Setting

The Safe Drinking Water Act (SDWA) requires EPA to promulgate national primary drinking water regulations for contaminants that may pose health risks and that are likely to be present in public water supplies. For each contaminant that EPA determines requires regulation, EPA sets a non-enforceable maximum contaminant level goal (MCLG) at a level at which no known or anticipated adverse health effects occur and that allows an adequate margin of safety. Amendments in 1996 (P.L. 104-182) added a requirement that EPA also must consider the exposure risks to sensitive subpopulations (e.g., children). Because MCLGs are based only on health effects and not on the availability or cost of monitoring and treatment technologies, they may be set at levels that are not feasible for water systems to meet. For example, EPA typically sets MCLGs for carcinogens at zero. EPA also considers the relative contribution that drinking water is expected to make to total human exposure to a contaminant. Under current policy, EPA assumes that 80% of exposure comes from other sources, such as the diet, and EPA sets a stricter MCLG to account for other sources of exposure.[54]

Using the MCLG as a starting point, EPA then sets an enforceable standard, the maximum contaminant level (MCL). The MCL generally must be set as close to the MCLG as is "feasible"

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[53] Many trace minerals share the property of having a health benefit at low levels but toxicity at higher levels (e.g., copper, chromium, manganese, selenium, and zinc). Although certain amounts of fluoride help make tooth enamel resistant to caries, fluoride has not been classified as an essential nutrient. In 1997, the National Academy of Sciences established Dietary Reference Intakes (DRI) for fluoride as a nutrient. The DRI included age- and gender-specific tolerable upper intake levels (UL) to indicate the highest average daily intake level likely to pose no risk of adverse effect to most individuals. NAS also established Adequate Intake (AI) values for fluoride. AI values are set when the data do not permit determination of a Recommended Dietary Allowance (RDA).

[54] For a discussion of EPA's standards revision approach, see U.S. EPA, *Six-Year Review Chemical Contaminants Health Effects Technical Support Document*, EPA 822-R-03-008, June 2003.

using the best technology or other means available, taking costs into consideration. The MCL is the legal limit of the amount of a substance that may be present in water provided by public water systems.

EPA also may issue *secondary* MCLs (SMCLs) that establish nonmandatory water quality standards for substances. These secondary standards are established as guidelines to help public water systems manage drinking water for aesthetic (e.g., taste and odor), cosmetic (e.g., tooth discoloration), and technical (e.g., corrosivity) effects.

Current Fluoride Standards

EPA issued the current national primary drinking water regulation for fluoride in 1986. This regulation included an MCLG and an enforceable drinking water standard MCL of 4 mg/L, which is intended to protect against fluoride's effects on the bone (specifically, crippling skeletal fluorosis).[55] The promulgation of the 4 mg/L standard was controversial, as it replaced a stricter, interim standard of 1.4 to 2.4 mg/L that was established in 1975 to protect against objectionable (moderate) dental fluorosis, which EPA previously had considered an adverse health effect.[56] (By comparison, the World Health Organization guideline for fluoride in drinking water is 1.5 mg/L.) When promulgating the new regulation, EPA estimated that, nationwide, 282 public water systems serving roughly 184,000 people had fluoride levels that exceeded the new standard of 4 mg/L. More recently, EPA has estimated that 220,000 people receive water from public water systems with fluoride levels that equal or exceed 4 mg/L.

When setting the fluoride MCL, EPA acknowledged that it would not protect infants and young children against moderate dental fluorosis, which EPA considered a cosmetic effect rather than an adverse health effect. Consequently, EPA established a secondary standard for fluoride at a level of 2 mg/L to protect children against dental fluorosis, as well as adverse health effects. (EPA standards for fluoride in drinking water are outlined in **Table 1**.) CDC has estimated that 850,000 people are served by water systems that contain more than 2 mg/L fluoride.[57]

Because of concerns regarding dental fluorosis, EPA does not recommend that infants consume water containing 4 mg/L fluoride. The fluoride regulation requires public water systems with water containing more than 2 mg/L fluoride to notify their customers and inform them that alternate sources of water should be used for infants and children (40 C.F.R. 143.5). However, EPA allows water systems one year to notify customers when the secondary standard is exceeded. This notification lag has been criticized because infants and children can have sustained exposure to elevated fluoride levels during a critical period of tooth development.

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[55] 51 *Federal Register* 11396, April 2, 1986. Note: In 1986, MCLGs were known as recommended MCLs (RMCLs) and EPA was required to issue RMCLs before setting MCLs. EPA promulgated the fluoride RMCL November 14, 1985 (50 *Fed. Reg.* 47142).

[56] Ibid., p. 11410. The Office of Management and Budget had opposed EPA's initial plan to reaffirm the stricter standard. Also, in 1981, the state of South Carolina had brought suit against EPA, arguing that the cost of complying with the stricter standard was prohibitive and not justified by the benefits. In 1987, the Natural Resources Defense Council sued EPA for relaxing the standard, but the Court of Appeals for the D.C. Circuit concluded that substantial evidence in the record supported EPA's determination that the MCLG provided an adequate margin of safety. (Source: Letter to Ralph Nader from Rebecca Hanmer, EPA's Office of Water, November 2, 1987.)

[57] Unpublished data as reported in National Research Council, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*, 2006, p. 21.

Table 1. EPA Standards for Fluoride in Drinking Water

Standard	Definition/Purpose
Maximum Contaminant Level Goal (MCLG): **4 mg/L**	The level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs allow for a margin of safety and are non-enforceable public health goals.
National Primary Drinking Water Standard (Maximum Contaminant Level (MCL)): **4 mg/L**	The highest level of a contaminant that is allowed in drinking water. MCLs are legally enforceable standards that apply to public water systems. They are set as close to MCLGs as feasible using the best treatment technology available (taking cost into consideration).
National Secondary Drinking Water Standard (SMCL): **2 mg/L**	SMCLs are non-enforceable guidelines for contaminants in drinking water that may cause cosmetic effects (e.g., tooth discoloration, as in the case of fluoride) or aesthetic effects (e.g., taste and odor). EPA recommends SMCLs to public water systems but does not require systems to comply. States may choose to adopt them as enforceable standards.

The Safe Drinking Water Act requires EPA to review and revise, as appropriate, each drinking water regulation at least every six years. Any revision must maintain or provide for greater protection of human health (SDWA §1412(b)(9)). EPA has initiated a review of the fluoride MCLG, MCL and SMCL to determine whether they are adequately protective of public health, based on the currently available scientific research.

EPA Fluoride Standards Review: 2002

Following increased concern regarding the potential carcinogenicity of fluoride related to the results of the 1990 NTP animal study, EPA asked NRC to review the available toxicological and exposure data on fluoride, and to assess the sufficiency of the current drinking water standard. NRC had concluded in 1993 that the national primary drinking water standard for fluoride (4 mg/L) was "appropriate as an interim standard" to protect public health. However, NRC noted that since EPA had promulgated the drinking water regulation for fluoride in 1986, the use of fluoride in dental products had increased and, as a result, many Americans might ingest more "incidental" fluoride than was anticipated by PHS and by EPA when recommending standards for drinking water.[58] Moreover, NRC found inconsistencies in the fluoride toxicity data base and gaps in knowledge, and it recommended further research in the areas of fluoride intake, dental fluorosis, bone strength, and carcinogenicity. NRC further recommended that EPA's fluoride standard should be reviewed and, if necessary, revised when results of new research become available.[59]

Toward that end, in 1998, EPA commissioned an evaluation of the exposure data for fluoride, including data on amounts in water, foods, and dental products. Moreover, in 2002, EPA published the results of its statutorily required review of existing drinking water standards and noted that new studies on fluoride's effects on bone had been published since the fluoride standard was established in 1986. EPA's literature search had identified various reports on the clinical, toxicological, and epidemiological data on fluoride and the skeletal system, and EPA concluded that a review of the new data was justified as part of the regulatory review process. Consequently, EPA asked NRC to conduct a review of the data, to update the fluoride health risk

[58] National Research Council, *Health Effects of Ingested Fluoride*, 1993, p. 2.

[59] Ibid., p. 11.

assessment, and to review EPA's relative source contribution assumptions for fluoride.[60] As discussed below, NRC agreed to evaluate the scientific basis for EPA's MCLG and secondary fluoride standard, and to advise EPA on the adequacy of its secondary standard to protect children and others from adverse effects.

2006 NRC Review of EPA's Fluoride Standards: Findings and Recommendations

In response to EPA's request for a new data review, the National Research Council convened the Committee on Fluoride in Drinking Water to evaluate toxicologic, epidemiologic, and clinical data on fluoride, with emphasis on data that had become available since NRC's 1993 report. EPA also asked the committee to evaluate the scientific basis and adequacy of EPA's maximum contaminant level goal (MCLG) and secondary standard for fluoride. [61]

In March 2006, the NRC committee issued *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*. The study concluded that EPA's MCLG of 4 mg/L should be lowered, and that information gaps regarding fluoride "prevented the committee from making some judgments about the safety or the risks of fluoride at concentrations of 2 to 4 mg/L."[62] (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 artificial fluoridation*.) The NRC committee's major findings are reviewed below.

Dental Fluorosis

When EPA promulgated the fluoride regulation in 1986, it did not differentiate between mild and severe dental fluorosis, and broadly considered fluorosis of the dental enamel to be a cosmetic effect. In contrast, 10 of the 12 NRC committee members concluded that *severe* enamel fluorosis is an *adverse health effect*, not simply a cosmetic effect. The committee members explained that severe enamel fluorosis involves enamel loss, and that loss compromises the function of tooth enamel, the purpose of which is to protect the tooth against decay and infection. Because severe enamel fluorosis occurs in roughly 10% of children in communities with water fluoride concentrations at or near the current standard of 4 mg/L, the committee unanimously agreed that the MCLG should be set to protect against this condition, and that EPA's standard of 4 mg/L is not adequately protective.[63]

[60] EPA based the current standard on the assumption that drinking water was the only source of fluoride exposure; thus, water's relative source contribution was considered to be 100%.

[61] Because primary drinking water standards, MCLs, are based on several factors, including health effects and toxicological data, monitoring and treatment technology capabilities, costs, and policy judgments, NRC focused its evaluation on the science-based MCLG rather than on the MCL. In the case of fluoride, the MCLG and MCL are identical.

[62] National Research Council, *Fluoride in Drinking Water*, 2006, pp. 8-9.

[63] Ibid, pp. 104-105. 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." (Summary, p. 3.)

Skeletal Fluorosis

As noted, EPA set the fluoride MCLG and MCL to protect against the adverse health effect of crippling skeletal fluorosis (*stage III* skeletal fluorosis). In this latest 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 constitutes an adverse health effect. Based on comparison of bone ash concentrations of fluoride and related evidence of skeletal fluorosis, the committee further found the data to suggest that

> Fluoride at 2 or 4 mg/L might not protect all individuals from the adverse stages of the condition. However, this comparison alone is not sufficient evidence to conclude that individuals exposed to fluoride at those concentrations are at risk of stage II skeletal fluorosis. There is little information in the epidemiologic literature on the occurrence of stage II skeletal fluorosis in U.S. residents, and stage III skeletal fluorosis appears to be a rare condition in the United States. Therefore, more research is needed to clarify the relationship between fluoride ingestion, fluoride concentrations in bone, and stage of skeletal fluorosis before any firm conclusions can be drawn.[64]

Bone Fractures

The committee also reviewed the few studies available for evaluating bone fracture risks from exposure to fluoride at 2 to 4 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 mg/L. The consensus of the committee was that, under certain conditions, fluoride can weaken bone and increase the risk of fractures. Moreover,

> The majority of the committee concluded that lifetime exposure to fluoride at drinking water concentrations of 4 mg/L or higher is likely to increase fracture rates in the population, compared with exposure at 1 mg/L, particularly in some susceptible demographic groups that are more prone to accumulate fluoride in their bones. However, three of the 12 members judged that the evidence only supported a conclusion that the MCLG *might not* be protective against bone fracture.... [T]he committee finds that the available epidemiologic data for assessing bone fracture risk in relation to fluoride exposure around 2 mg/L are inadequate for drawing firm conclusions about the risk or safety of exposures at that concentration.[65]

Carcinogenicity

In the 2006 report, NRC noted that the question of whether fluoride might be associated with bone cancer continues to be debated and analyzed, and that further research should be conducted. Most committee members held the view that the 1992 cancer bioassay that found no increase in osteosarcoma (a rare bone cancer) in male rats lacked sufficient power to counter the overall evidence of a positive dose-response trend found in the 1990 rat study.[66] After reviewing the studies available to date, 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,

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[64] National Research Council, *Fluoride in Drinking Water*, 2006, p. 146.

[65] Ibid.,

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

overall, the literature does not clearly indicate that fluoride either is or is not carcinogenic in humans.[67] NRC noted that the Harvard School of Public Health 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 males. The authors of this 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.[68] The 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.[69] The authors noted 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."[70]

Other Potential Effects

The NRC committee evaluated available scientific studies that assessed a range of other possible health effects related to fluoride exposure. This evaluation included a review of studies on fluoride's potential neurotoxicity and neurobehavioral effects, endocrine effects, and effects on the gastrointestinal system, kidneys, liver, and immune system. 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 their significance. Overall, the committee noted that more research was needed to determine what risks fluoride exposure at 4 mg/L might pose in these areas.[71]

Research Needs

Noting that research gaps prevented the NRC committee from making certain judgments regarding the safety or risk of fluoride, the committee made specific recommendations for further studies that the committee felt would help fill data gaps and facilitate EPA's revision of the fluoride standards. The recommendations covered a wide range of topics, including exposure assessment, pharmacokinetic studies, studies of enamel fluorosis, studies of stage II and stage III skeletal fluorosis, bone fracture studies, and studies on other health effects (e.g., endocrine effects and brain function).[72]

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[67] National Research Council, *Fluoride in Drinking Water*, 2006, p. 8, and pp. 274-284.

[68] Bassin, E.B., Wypij, D. Davis, R.B., Mittleman, M.A. *Age-specific Fluoride Exposure in Drinking Water and Osteosarcoma (United States)*, Cancer Causes and Control, 2006, v. 17, pp. 421-428. 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.

[69] F.M. Kim, C. Hayes, and P.L. Williams, et al., "An Assessment of Bone Fluoride and Osteosarcoma," *J. Dent. Res.*, vol. 90, no. 10 (1171-1176 2011).

[70] Ibid., p. 1175.

[71] National Research Council, *Fluoride in Drinking Water*, 2006, p. 7.

[72] Ibid., p. 9-10.

NRC Recommendations

Regarding the maximum contaminant level goal, NRC concluded that the MCLG of 4 mg/L should be lowered. The review committee specifically recommended that

> 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.[73]

For the cosmetic effects-based secondary maximum contaminant level, the committee noted that the current SMCL does not completely prevent the occurrence of moderate enamel fluorosis. In 1986, EPA set the standard to keep the occurrence of moderate enamel fluorosis to 15% or less of the exposed population. The committee noted that, although this goal is being met, the degree to which moderate enamel fluorosis might create an adverse psychological effect or an adverse effect on social functioning is not known. The committee recommended additional research on the prevalence and severity of enamel fluorosis in U.S. communities with fluoride concentrations greater than 1 mg/L. Specifically, "The studies should focus on moderate and severe enamel fluorosis in relation to caries and in relation to psychological, behavioral, and social effects among affected children, among their parents, and among affected children after they become adults."[74]

EPA's Review of Fluoride Standards

As noted, the Safe Drinking Water Act requires that, every six years, EPA must review and, if appropriate, revise each drinking water regulation. (See discussion under "Current Fluoride Standards.") In March 2010, EPA announced the results of its review of drinking water regulations for 71 contaminants, including fluoride.[75] The agency concluded that because of ongoing assessments recommended by NRC, a revision to the fluoride regulation was not appropriate at that time. Specifically, the agency's Office of Water was in the process of conducting a dose-response assessment of the noncancer impacts of fluoride on severe dental fluorosis and skeletal systems. The agency was also updating its evaluation of the relative contribution of drinking water to total fluoride exposure, considering contributions from dental products, foods, pesticide residues, and other potential sources.[76]

In December 2010, EPA published an analysis of exposure and relative source contribution for fluoride.[77] Responding to the NRC recommendation, EPA collected data to estimate the total fluoride exposure for children during the most sensitive period for severe dental fluorosis (ages

[73] Ibid., p. 299.

[74] National Research Council, *Fluoride in Drinking Water*, 2006, p. 299.

[75] U.S. Environmental Protection Agency, "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* 1550, March 29, 2010.

[76] Ibid., p. 15544.

[77] U.S. Environmental Protection Agency, *Fluoride: Exposure and Relative Source Contribution Analysis*, Office of Water, 820-R-10-015, December 2010, p. 210, http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm.

six months to 14 years). EPA also collected data to develop exposure estimates for adults. To develop estimates, EPA looked at concentrations of fluoride in foods and beverages, and estimated dietary exposures, concentrations in drinking water, and estimated fluoride intakes from toothpaste and pesticides, including sulfuryl fluoride.[78] (When setting the current standard for fluoride, EPA assumed that 100% of the exposure to fluoride came from drinking water.)

Based on the exposure and relative source analysis, EPA reported the following conclusions:

> - Some young children are being exposed to fluoride up to about age 7 at levels that increase the risk for severe dental fluorosis.
>
> - The contribution of residential tap water to total ingested fluoride is lower than it was in the past.
>
> - Use of fluoridated water for commercial beverage production has likely resulted in increased dietary fluoride in purchased beverages, adding to the risk for over-exposure.
>
> - The increase of fluoride in solid foods because of fluoridated commercial process water is more variable than that for beverages.
>
> - Incidental tooth paste ingestion is an important source of fluoride exposure in children up to about 4 years of age. However, use of fluoridated toothpaste is not recommended for children under age 2 according to FDA [Food and Drug Administration] guidance and package labeling[79] ...
>
> - Ambient air, soils, and sulfuryl fluoride[80] residues in foods are minor contributions to total fluoride exposure.[81]

EPA further concluded that "it is likely that most children, even those that live in fluoridated communities, can be over-exposed to fluoride at least occasionally."[82]

Also in December 2010, the agency completed a dose-response assessment for severe dental fluorosis.[83] This assessment provides a reference dose (RfD) based on the critical health effect of concern: pitting of the enamel in severe dental fluorosis. The estimated RfD for fluoride, 0.08 mg

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[78] Ibid., p. I.

[79] U.S. Food and Drug Administration, *Anticaries Drug Products for Over-the-Counter Use*, 2009, 21 C.F.R. Ch. 1, Part 355. pp. 302-397.

[80] According to EPA's pesticide office, sulfuryl fluoride "is an important replacement for several post-harvest uses of the stratospheric ozone-depleting pesticide, methyl bromide." This fumigant is used to control insects in harvested and processed foods including grains, prunes, and other dried fruits, coffee and cocoa beans, and nuts. Although EPA calculates that sulfuryl fluoride constitutes a minor portion of total fluoride exposure, the agency is phasing out use of this pesticide to reduce aggregate fluoride exposures and is working to identify potential alternatives. Source: U.S. Environmental Protection Agency, Pesticides: Registration Review, "EPA Proposes to Withdraw Sulfuryl Fluoride Tolerances," http://www.epa.gov/oppsrrd1/registration_review/sulfuryl-fluoride/evaluations.html. Background on EPA's actions on this pesticide and estimated exposure information are discussed in EPA's *Fluoride: Exposure and Relative Source Contribution Analysis*; see especially p. 27-29 and Appendix B.

[81] U.S. Environmental Protection Agency, *Fluoride: Exposure and Relative Source Contribution Analysis*, p. 108.

[82] Ibid., p. 109.

[83] U.S. Environmental Protection Agency, *Fluoride: Dose-Response Analysis for Non-cancer Effects*, Health and Ecological Criteria Division, Office of Water, 820-R-10-019, December 2010, 160 pp. http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm.

fluoride per kilogram per day (F/kg/day), is intended to protect children from enamel pitting during the critical period of enamel formation (between six months and 14 years of age). By protecting this sensitive subpopulation, EPA notes that the RfD would be protective for other potential risks as well.[84] The dose-response assessment and resulting reference dose are needed to support the development of a maximum contaminant level goal, and ultimately a drinking water standard (the maximum contaminant level).

EPA is reviewing the new fluoride risk assessment and relative source assessment documents to determine whether revisions to the MCLG, MCL, and/or SMCL would be appropriate.[85] To make a determination to revise the standard, EPA must not only review scientific information, but also must evaluate analytical methods for testing for fluoride at lower levels, treatment feasibility (including cost), occurrence, and exposure. Such analyses supporting regulatory efforts under the Safe Drinking Water Act can take EPA several years to complete.

Conclusion

Although NRC's new review of fluoride in drinking water did not address questions of artificial fluoridation, NRC did determine that EPA's maximum contaminant level goal for fluoride should be lowered. Assuming that a lower MCLG would lead to a lower enforceable MCL, NRC concluded that this would prevent children from developing severe enamel fluorosis and reduce the lifetime accumulation of fluoride in bone, which most committee members agreed "is likely to put individuals at greater risk of bone fracture and possibly skeletal fluorosis."[86]

Even if NRC had confirmed EPA's previous assessment of fluoride's health effects, the agency still might revise the health-based primary standard and the esthetics-based secondary standard. One reason for potential revisions is that when EPA developed the current standards, the agency considered drinking water to be the only source of exposure for fluoride. Since then, sources of potential fluoride exposure have increased, and now, when reviewing its standards, EPA would consider fluoride intake from sources other than drinking water. This consideration alone may lead to a lowering of the primary and secondary standards for fluoride. A second reason that EPA might revise the standard is that the 1996 SDWA amendments (P.L. 104-182) directed EPA to evaluate the effects of contaminants on groups within the general population, such as children, that might be at greater risk than the general population of adverse health effects due to exposure to contaminants in drinking water.[87]

Another possible revision to the fluoride regulation involves the public notification requirements for the secondary standard. Dental fluorosis occurs while tooth enamel is developing, and EPA has acknowledged that "waiting 12 months to provide public notification may result in young children being exposed to high levels of fluoride during the time at which they are most

[84] 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.

[85] U.S. Environmental Protection Agency, "Review of the Fluoride Drinking Water Regulation," http://water.epa.gov/lawsregs/rulesregs/regulatingcontaminants/sixyearreview/index.cfm#two.

[86] National Research Council, *Fluoride in Drinking Water*, 2006, p. 299.

[87] 42 U.S.C. 300g-1, SDWA Section 1412(b)(3).

vulnerable."[88] EPA has considered revising the public notification requirements, but has not yet done so.

The NRC committee conducted an extensive review of the available science, and EPA has used this significant foundation to support an update of its risk assessment for fluoride. EPA has also updated its exposure and relative source contribution analysis. These analyses potentially could become the basis for a new, more protective fluoride standard. However, in addition to health effects, EPA is required to consider compliance cost, risk reduction benefits, contaminant occurrence, technical feasibility, and other factors when setting standards. Consequently, it remains to be seen exactly how these factors, when taken together, might influence a new fluoride standard.

Although the purpose of the NRC study and subsequent analyses is to advise EPA on the adequacy of the fluoride drinking water standards, the evaluation of the available science and exposure led HHS to propose to change recommended levels for community water fluoridation. In 2011, HHS proposed that community water systems use a fluoridation level of 0.7 milligrams per liter, which is the lower end of the current recommended range of 0.7 mg/L to 1.2 mg/L. The new analyses may also be useful to states and communities that are assessing whether or not to fluoridate their public water supplies.

Opposition to water fluoridation often has been driven by concerns about the potential health risks of exposure to fluoride in drinking water; however, social and political concerns also influence decisions about water fluoridation. A central issue for some fluoridation opponents is lack of choice, and they oppose the addition of any chemicals to the water supply other than those needed to make water safe (e.g., chlorine). In contrast, many public health professionals and government officials have held the view that water fluoridation offers the most equitable and cost-effective way to protect dental health across socially and economically diverse communities. The conflict between individual liberty and social policy is one that is unlikely to be fully resolved by more research. Additional scientific evidence can help inform the decision to fluoridate a community's water, but such choices often are not made purely on the basis of science.

Because artificial fluoridation decisions have been made at the state and local levels, Congress has not been at the forefront of the water fluoridation debate. Nonetheless, Congress has expressed interest in water fluoridation issues in the past, particularly as questions have arisen regarding the benefits and risks of this practice. Since first enacted in 1974, the Safe Drinking Water Act (P.L. 93-523) has stated that "[n]o national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water."[89]

NRC's finding that EPA's drinking water standard for fluoride should be lowered to protect against adverse health effects (primarily dental fluorosis) may generate congressional oversight and legislative attention. Issues that might attract particular interest might include the health effects research gaps identified by NRC, subsequent research, and the status of EPA's review and potential revision of the fluoride regulation under the Safe Drinking Water Act.

[88] 67 *Federal Register* 19069, April 17, 2002.

[89] Safe Drinking Water Act, §1412(b)(11); 42 U.S.C. 300g-1.

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