Dear Public Water Providers of West Virginia:

The West Virginia Department of Health and Human Resources, Bureau for Public Health is committed to the fluoridation of community water systems. Fluoridation began nationally over seventy years ago. Strong support and active promotion of the measure as a safe, economical and effective means of reducing tooth decay has continued. Today, fluoridation is still the most cost-effective way to prevent dental cavities. It is an ideal public health measure where everyone benefits, whether rich or poor, no matter what age.

Beginning in Ohio County in 1950, West Virginia communities have embraced the concept of fluoridation for their citizens. Approximately 1.1 million people are currently benefiting from fluoridation in West Virginia. In 2010, the Centers for Disease Control and Prevention (CDC) estimated over 204 million people in the United States benefit from water containing fluoride at the recommended level for controlling dental decay.

National surveys of oral health, dating back several decades, document the continued benefit of fluoride in decreasing tooth decay in children and adults. It is doubtful that any other public health procedure has undergone more research, epidemiological study and intense public scrutiny than water fluoridation. In 1999, the CDC recognized water fluoridation as one of the ten great public health achievements of the 20th century. In the last few years, systematic reviews of community water fluoridation studies through the Surgeon General’s Report on Oral Health in America, CDC’s Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States, and the Oral Health Report, issued by the Task Force on Community Preventive Services, have all reinforced safety and efficacy of fluoridation in preventing dental decay in both children and adults.

Along with the overwhelming majority of the world’s health care organizations and leaders within the scientific community, the West Virginia Department of Health and Human Resources, Bureau for Public Health firmly supports and continues to recommend water fluoridation as the most economical and effective means to control the major public health problem of dental caries.

Sincerely,

Rahul Gupta, MD, MPH, FACP
Commissioner and State Health Officer

RG:wi:alf
STATEMENT ON COMMUNITY WATER FLUORIDATION

Over the past 70 years, community water fluoridation has contributed to dramatic declines in both the prevalence and severity of tooth decay, leading the Centers for Disease Control and Prevention to name it as one of 10 great public health achievements of the 20th century, alongside immunizations, family planning, tobacco control, and motor vehicle safety.

Water fluoridation is the best method for delivering fluoride to all members of the community, regardless of age, education, income level or access to routine dental care. Fluoride’s effectiveness in preventing tooth decay extends throughout one’s life, resulting in fewer – and less severe – cavities. In fact, each generation born over the past 70 years has enjoyed better dental health than the one before it. That’s the very essence of the American promise.

Our progress on this issue over the past 70 years has been undeniable.

But we still have work to do. Because we know that so much of our health is determined by zip code rather than genetic code. That’s why creating a culture of disease prevention through community efforts – and ensuring health equity for all – is one of my highest priorities.

Community water fluoridation helps us meet these goals; as it is one of the most cost-effective, equitable, and safe measures communities can take to prevent tooth decay and improve oral health. Advocates and community leaders have fought to make water fluoridation a reality in communities throughout our country.

Today, we applaud their efforts. But our work is far from finished, and we will not rest until every community is equipped with the many tools they need to help their residents live healthy, happy lives.

Sincerely yours,

Vivek H. Murthy, M.D., M.B.A.
United States Surgeon General
STATEMENT ON THE EVIDENCE SUPPORTING THE SAFETY AND EFFECTIVENESS OF COMMUNITY WATER FLUORIDATION

On behalf of the Centers for Disease Control and Prevention (CDC), I am pleased to provide a statement on the evidence regarding the safety and benefits of community water fluoridation. For the record, this statement is not testimony for or against any specific legislative proposal.

Good oral health is an important part of good overall health and an essential part of our everyday lives. Diet, sleep, psychological status, social interaction, school, and work are all affected by impaired oral health. Over the past several decades, there have been major improvements in the nation’s oral health that have benefitted most Americans.¹

However, profound disparities in oral health status remain for some population subgroups, such as the poor, the elderly, and many members of racial and ethnic minority groups.¹ Tooth decay is one of the most common chronic diseases among American children with 1 of 4 children living below the federal poverty level experiencing untreated tooth decay.² Untreated decay can cause pain, school absences, difficulty concentrating, and poor appearance—all contributing to decreased quality of life and ability to succeed.³

Tooth decay and its complications are preventable, and several preventive and early treatment options are safe, effective, and economical. The CDC leads national efforts to improve oral health by using proven strategies such as community water fluoridation and school-based dental sealant programs that prevent oral diseases.

An Effective Intervention

Community water fluoridation is “the controlled addition of a fluoride compound to a public water supply to achieve a concentration optimal for dental caries prevention.”¹ The process of adding fluoride to public water systems in the United States began in 1945 in Grand Rapids, Michigan. Soon after, dramatic declines in dental caries were noted among school children in Grand Rapids compared with school children from surrounding areas. Since then, community water fluoridation has been adopted by communities across the country, providing the cornerstone of caries prevention in the United States.¹ In 2012, more than 210 million people, or 74.6% of the U.S. population served by public water supplies, drank water with optimal fluoride levels to prevent tooth decay.⁴

Water fluoridation is beneficial for reducing and controlling tooth decay and promoting oral health across the lifespan. Evidence shows that water fluoridation prevents tooth decay by providing frequent and consistent contact with low levels of fluoride, ultimately reducing tooth decay by 25% in children and adults.⁵⁻⁸ Additional evidence shows that schoolchildren living in communities
where water is fluoridated have, on average, 2.25 fewer decayed teeth compared to similar children not living in fluoridated communities.9

The safety and benefits of fluoride are well documented and have been reviewed comprehensively by several scientific and public health organizations. The U.S. Public Health Service; the United Kingdom’s National Institute for Health Research, Centre for Reviews and Dissemination, at the University of York; and the National Health and Medical Research Council, Australia have all conducted scientific reviews by expert panels and concluded that community water fluoridation is a safe and effective way to promote good oral health and prevent decay.10–12 The U.S. Community Preventive Services Task Force, on the basis of systematic reviews of scientific literature, issued a strong recommendation in 2001 and again in 2013, for community water fluoridation for the prevention and control of tooth decay.9,13

**A Cost-saving Intervention**

Although other fluoride-containing products such as toothpaste, mouth rinses, and dietary supplements are available and contribute to the prevention and control of dental caries, community water fluoridation has been identified as the most cost-effective method of delivering fluoride to all members of the community regardless of age, educational attainment, or income level.14,15 Analyses have also shown that water fluoridation provides additional benefits across the lifespan beyond what is gained from using other fluoride-containing products.8,11,16

By preventing tooth decay, community water fluoridation has been shown to save money, both for families and the health care system.7,17 The return on investment (ROI) for community water fluoridation varies with size of the community, increasing as community size increases, but, as noted by the U.S. Community Preventive Services Task Force, community water fluoridation is cost-saving even for small communities.17,18 The estimated annual ROI for community water fluoridation, including productivity losses, ranged from $4.32 in small communities of 5,000 people or less, to $27.41 in large communities of 20,000 or more people.7 The estimated ROI for community water fluoridation excluding productivity losses was $3.24 in small communities and $20.52 in large communities.19

A study of a community water fluoridation program in Colorado used an economic model to compare the program costs associated with community water fluoridation with treatment savings achieved through reduced tooth decay. The analysis, which included 172 public water systems, each serving populations of 1,000 individuals or more, found that 1 year of exposure to fluoridated water yielded an average savings of $60 per person when the lifetime costs of maintaining a restoration were included.20 Analyses of Medicaid claims data in 3 other states (Louisiana, New York, and Texas), have also found that children living in fluoridated communities have lower caries related treatment costs than do similar children living in non-fluoridated communities; the difference in annual per child treatment costs ranged from $28 to $67.21–23

**A Safe Intervention**

Expert panels consisting of scientists from the United States and other countries, with expertise in various health and scientific disciplines, have considered the available evidence in peer-reviewed literature and have not found convincing scientific evidence linking community water fluoridation with any potential adverse health effect or systemic disorder such as an increased risk for cancer,
Down syndrome, heart disease, osteoporosis and bone fracture, immune disorders, low intelligence, renal disorders, Alzheimer disease, or allergic reactions.9,11

Documented risks of community water fluoridation are limited to dental fluorosis, a change in dental enamel that is cosmetic in its most common form. Changes range from barely visible lacy white markings in milder cases to pitting of the teeth in the rare, severe form. In the United States, most dental fluorosis seen today is of the mildest form, affecting neither aesthetics nor dental function.24 Fluorosis can occur when young children—typically less than 8 years of age, whose permanent teeth are still forming under the gums—take in fluoride from any source.9,11 Recommendations provided by the U.S. Public Health Service for the optimal level of fluoride in public water systems take into account levels of water consumption as well as the availability of other fluoride products.25

Conclusion

In the seminal report, Oral Health in America: A Report of the Surgeon General, Surgeon General David Satcher observed a “silent epidemic’ of dental and oral diseases [...] with those suffering the most found among the poor of all ages.”1 The report affirms that community water fluoridation is “an inexpensive means of improving oral health that benefits all residents of a community, young and old, rich and poor alike.” Because of its contribution to the dramatic decline in tooth decay over the past 70 years, CDC named community water fluoridation 1 of 10 great public health achievements of the 20th century.14

Katherine Weno, DDS, JD
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National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

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COMMUNITY WATER FLUORIDATION: ONE OF CDC’S “10 GREAT PUBLIC HEALTH ACHIEVEMENTS OF THE 20TH CENTURY”

VIVEK H. MURTHY, MD, MBA

Seventy years ago, nearly everyone in the United States had tooth decay. No one knew how to prevent it. It was not uncommon for 13-year-olds to have lost one or more permanent teeth to decay.1 As recently as the late 1950s, about half of Americans older than 65 years of age lost all their natural teeth, which many replaced with dentures.2

In some areas of the United States, dentists observed that the enamel on many of their patients’ teeth looked stained or mottled. However, these same teeth appeared to be protected from tooth decay. After some sleuthing, it was determined that fluoride in the local water supply was the reason for both phenomena. In 1945, as one of the first in a series of landmark studies, the city of Grand Rapids, Michigan, added low amounts of fluoride (i.e., much lower than the levels determined to cause the staining and mottling, which later became known as “dental fluorosis”) to its community water system.3 This study and others like it4–6 ultimately demonstrated that people living in communities with fluoridated water had fewer cavities and healthier teeth than those living in communities where the water was not fluoridated.

These findings led the U.S. Public Health Service (PHS), in 1962, to recommend that community water systems add fluoride to drinking water to prevent tooth decay.7 After the recommendations were published, more and more state and local governments implemented this public health measure. As a result, more than 210 million people across the country—about 75% of all people served by community water systems—currently benefit from this safe and effective intervention.8,9

Community water fluoridation, which celebrates its 70th anniversary this year, has been so successful—leading to dramatic declines in both the prevalence and severity of tooth decay—that the Centers for Disease Control and Prevention identified it as one of 10 great public health achievements of the 20th century.9,10

As Surgeon General, I encourage all Americans to make choices that enable them to prevent illness and promote well-being. Community water fluoridation is one of the most practical, cost-effective, equitable, and safe measures communities can take to prevent tooth decay and improve oral health.9

Water fluoridation’s biggest advantage is that it is the best method for delivering fluoride to all members of the community regardless of age, education, income level, or access to routine dental care. Fluoride’s effectiveness in preventing tooth decay extends throughout life, resulting in fewer and less severe cavities. In fact, each generation born since the implementation of water fluoridation has enjoyed better dental health than the preceding generation.9,10

Based on further research, we have concluded that it is time to update the original 1962 PHS recommendations on fluoridation. Americans now have access to more sources of fluoride, such as toothpaste and mouth rinses, than they did when water fluoridation was first introduced in the United States. The result has been an increase in dental fluorosis, which, in most cases, manifests as barely visible lacy white markings or spots on the tooth enamel11,12. A severe form of dental fluorosis, with staining and pitting of the tooth surface, is rare in the United States.11 Dental fluorosis can occur when children younger than 8 years of age, whose permanent teeth are still forming, regularly ingest fluoride.13
The panel considered:

- The scientific evidence related to the effectiveness of community water fluoridation in the prevention and control of dental caries across all age groups,
- Fluoride in drinking water as one of several available sources of fluoride,
- Trends in the prevalence and severity of dental fluorosis,
- Current evidence regarding children’s water intake at various outdoor air temperatures,
- An extensive review by the National Research Council (NRC) of potential adverse effects of naturally occurring fluoride in drinking water at 2–4 milligrams per liter (mg/L)—a level much higher than the 1962 recommendation of 0.7–1.2 mg/L of fluoride in drinking water,14
- Public comments submitted in response to a January 2011 Federal Register notice15 of the panel’s proposed recommendation that community water systems use a fluoride concentration of 0.7 mg/L (the low end of the previously recommended range of 0.7–1.2 mg/L) to maintain caries prevention benefits and reduce the risk of dental fluorosis, and
- Independent peer review of the draft recommendation document, including summary and response to public comment, by experts in toxicology, environmental health, and epidemiology. This peer review demonstrated compliance with the specific requirements of the Information Quality Act (2000)16 and of peer review standards developed by the Office of Management and Budget17 and HHS.18

The panel carefully considered public comments concerning fluoride in drinking water, including possible adverse health effects. As described in the updated guideline,19 the panel reviewed and accepted the scientific evidence in the 2006 NRC report on fluoride.14 Even at higher concentrations (i.e., 2–4 mg/L), the NRC found no evidence substantial enough to support claims of unwanted health effects, other than severe dental fluorosis. The NRC review noted that prevalence of severe dental fluorosis is nearly zero at fluoride concentrations <2 mg/L.

The panel’s assessment of the best available science concluded that community water fluoridation remains an effective public health strategy for delivering fluoride to prevent tooth decay and is the most feasible and cost-effective strategy for reaching entire communities. It agreed that community water fluoridation continues to offer substantial protection against tooth decay beyond that provided by other fluoride products. In studies conducted after other fluoride products (e.g., toothpaste) became widely available, scientists found up to 25% reductions in tooth decay among people in communities with water fluoridation as compared with those without fluoridation.20–22

The panel also decided that reductions in tooth decay can be maintained with a lower concentration of fluoride in drinking water, given the increase in other sources of fluoride during the past several decades, and that one universal target concentration for community water fluoridation can be used in all U.S. temperature zones.

Based on this comprehensive, multiyear assessment, PHS now recommends that community water systems use a single concentration of 0.7 mg/L of fluoride in drinking water to maintain cavity prevention benefits and reduce the risk of dental fluorosis. This new recommendation revises and replaces the previously recommended range of 0.7–1.2 mg/L.

We urge you to review our updated guideline and adopt it in your communities.

REFERENCES


Water Fluoridation Additives

On this Page

- Types of Fluoride Additives
- Sources of Fluoride Additives
- Regulatory Scope on Additives
- EPA Regulatory Criteria for Fluoride Additives
- AWWA Standards
- NSF/ANSI Standards for Drinking Water Additives
- Measured Levels of Impurities
- FDA Regulatory Criteria for Fluoride
- United States Pharmacopeia (USP) Grade Fluoride Products
- Fluoride Additives Are Not Different From Natural Fluoride

Types of Fluoride Additives

Community water systems in the United States use one of three additives for water fluoridation. Decisions on which additive to use are based on cost of product, product-handling requirements, space availability, and equipment.

The three additives are:

- Fluorosilicic acid: a water-based solution used by most water systems in the United States. Fluorosilicic acid is also referred to as hydrofluorosilicate, FSA, or HFS.
- Sodium fluorosilicate: a dry salt additive, dissolved into a solution before being added to water.
- Sodium fluoride: a dry salt additive, typically used in small water systems, dissolved into a solution before being added to water.

Sources of Fluoride Additives

Most fluoride additives used in the United States are produced from phosphorite rock. Phosphorite contains calcium phosphate mixed with limestone (calcium carbonates) minerals and apatite—a mineral with high phosphate and fluoride content. It is refluxed (heated) with sulfuric acid to produce a phosphoric acid-gypsum (calcium sulfate-CaSO4) slurry. The phosphoric and fluoride gases that are released in the process are then separated. The fluoride gas is captured and used to create fluorosilicic acid.

According to the American Water Works Association Standards Committee on Fluorides, the

https://www.cdc.gov/fluoridation/engineering/wfadditives.htm

1/4/2017
sources of fluoride products used for water fluoridation in the United States are as follows:

- Approximately 90% are produced during the process of extracting phosphate from phosphoric ore.
- Approximately 5% come from the production of hydrogen fluoride or sodium fluoride.
- Approximately 5% come from the purification of high-quality quartz.

Since the early 1950s, FSA has been the main additive used for water fluoridation in the United States. The favorable cost and high purity of FSA make it a popular additive. Sodium fluorosilicate and sodium fluoride come from processing FSA, or from processing hydrogen fluoride. FSA can be partially neutralized by either table salt (sodium chloride) or caustic soda to get sodium fluorosilicate. If enough caustic soda is added to completely neutralize the fluorosilicate, the result is sodium fluoride. About 90% of the sodium fluoride used in the United States comes from FSA.

**Regulatory Scope on Additives**

The U.S. Environmental Protection Agency (EPA) has authority over safe community drinking water, as specified in the Safe Drinking Water Act. On the basis of the scientific study of potential harmful health effects from contaminated water, the EPA sets a Maximum Contaminant Level (MCL) concentration allowed for various organisms or substances.

Although the EPA does not specifically regulate levels of "direct additives," which are additives added to water in the course of treatment, it does specify that the addition of chemicals as part of the treatment process should not be more than the MCL concentration for regulated substances. This MCL limit includes the levels naturally occurring in the source water, plus the contribution from direct additives. In 1979, EPA executed a Memorandum of Understanding with the U.S. Food and Drug Administration (FDA) to establish and clarify areas of authority in controlling additives in drinking water. FDA has regulatory oversight for food additives, which includes bottled water, and EPA has regulatory oversight of direct additives in public drinking water supplies.

Because of the decision to transfer the additives program to the private sector, EPA declared a moratorium in 1980 on issuing new advisory opinions on additives. EPA awarded a cooperative agreement to a group of nonprofit, nongovernmental organizations led by the National Sanitation Foundation (NSF) in 1985 (now NSF International) to develop a new additives program. Three years later, EPA announced that the new National Sanitation Foundation/American National Standards Institute (NSF/ANSI) Standard 60 was in operation.

Information on drinking water treatment quality assurance practices of governmental authorities in various countries can be found in the *Overview of National and International Guidelines and Recommendations on the Assessment and Approval of Chemicals Used in the Treatment of*

https://www.cdc.gov/fluoridation/engineering/wfadditives.htm
Drinking Water [PDF-476K] (https://www.nhmrc.gov.au/guidelines/publications/eh37) . This document discusses the American Water Works Association (AWWA) and NSF/ANSI standards and practices, which apply to water fluoridation in the United States.

EPA Regulatory Criteria for Fluoride Additives

All additives used by water treatment plants, including fluoride additives, must meet strict quality standards that assure the public's safety. These additives are subject to a stringent system of standards, testing, and certificates by AWWA and NSF International. Both of these organizations are nonprofit, nongovernmental organizations.

Fluoridated community water systems adjust fluoride to approximately 0.7 milligrams per Liter (mg/L). Because in some rare locations fluoride is naturally present in water at much higher levels, the EPA established a Maximum Contaminant Level (MCL) for fluoride of 4.0 mg/L (parts per million).

The EPA has not established an MCL for silicates, the second most prevalent substance in FSA, because there are no known health concerns. NSF/ANSI Standard 60, however, has a Maximum Allowable Level of 16 mg/L for sodium silicates as corrosion control agents. This is mainly to control turbidity—a measure of water clarity or how much the material suspended in water decreases light passing through the water.

Studies have shown that silicofluorides achieve virtually complete dissolution and ionic disassociation at the concentrations used when they are added to the drinking water. The equilibrium reached at the pH, temperature, and fluoride concentration used in water fluoridation account for this. One study reported that no intermediates or other products were observed at pH levels as low as 3.5. (Finney WF, Wilson E, Callender A, Morris MD, Beck LW. Reexamination of hexafluorosilicate hydrolysis by fluoride NMR and pH measurement (http://www.ncbi.nlm.nih.gov/pubmed/16683594) . Environ Sci Technol 2006;40:8:2572).

The studies that examined potential health effects from sodium fluoride additives in drinking water should also apply to FSA because they have the same results for ionic disassociation.

AWWA Standards

The AWWA sets the minimum requirements for the design, installation, performance, and manufacturing of fluoride products used for adjusting water content. The AWWA standards for fluoride additives are ANSI/AWWA B701 (sodium fluoride), ANSI/AWWA B702 (sodium fluorosilicate), and ANSI/AWWA B703 (FSA). AWWA's standards are prepared by its Fluoride
Standards Committee, with oversight by the Standards Council, concurrence by the AWWA Board of Directors, and concurrence by ANSI. AWWA standards are reviewed and updated at least every 5 years. AWWA standards stipulate product quality testing requirements and verification.

NSF/ANSI Standards for Drinking Water Additives

The NSF/ANSI Standard 60 limits a chemical or product's contribution of contaminants to drinking water applications. Standard 60 provides for product purity and safety assurance that aim to prevent adding harmful levels of contaminants from chemicals and water treatment additives. It includes a detailed audit of the production of the additive products, validation testing of quality, and auditing of all locations for logistic handling. There are also specific criteria for imported products from other countries, and in conjunction with NSF/ANSI Standard 223, there is conformity in quality controls regardless of where certification occurs or which entity performs the certification.

Forty-seven states have laws or regulations requiring product compliance with Standard 60. NSF/ANSI standards 60 and 61 (a related standard that applies to products that come in contact with water) were developed by a consortium of associations, including NSF, AWWA, ANSI, the Association of State Drinking Water Administrators, and the Conference of State Health and Environmental Managers. Standards 60 and 61 are accepted by the EPA as the requirements for controlling potential harmful effects from products added to water for its treatment. These standards replaced the former EPA Additives Advisory Program. More information on Standard 60 is posted on NSF's website (http://www.ncbi.nlm.nih.gov/pubmed/16683594).

Independent organizations, including NSF International and Underwriters Laboratories, verify that fluoride additives meet the NSF/ANSI standards. These organizations test fluoride additives for regulated metal compounds and other substances that have an EPA MCL. For a fluoride additive product to meet certification standards, regulated metal compounds added by the water treatment process must have a concentration less than 10% of the MCL.

A comprehensive assessment of the ANSI/NSF Standard 60 for more than 50 additives was published in 2004. This peer-reviewed assessment concluded that the process successfully met the stated goals of preventing problems with trace contaminants in U.S. water treatment additives. More information is available in the following article: Brown, Cornwell, MacPhee. Trace contaminants in water treatment chemicals (http://www.awwa.org/publications/journal-awwa/abstract/articleid/15160.aspx) (Journal of the American Water Works Association 2004;96:12:111–125.)

Measured Levels of Impurities
Fluoride additives are analyzed for potential impurities including arsenic, lead, and radionuclides. Verification of compliance with NSF/ANSI Standard 60 must also be certified. NSF hosts a detailed fact sheet on the documented quality of fluoride additives, including impurities [PDF-142KB](http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf). The fact sheet is based on separate product samples analyzed from 2000 to 2011.

Consumers may raise concerns about arsenic in drinking water and that fluoride additives may contain some arsenic. The EPA allowable amount for arsenic in drinking water is 10 parts per billion. NSF quality testing has found that most fluoride additive samples do not have detectable levels of arsenic. For those samples that do have some amount of arsenic, the arsenic level that an average consumer would experience over an entire year of drinking water at a concentration of 1.2 mg/L fluoride is extremely small -- only about 1.2% of the EPA allowable amount.

Other impurities in the NSF International-certified fluoride product testing were found to be even lower than the arsenic levels, with only 1%-3% of fluoride products containing detectable levels of metals. The average exposure to a typical consumer would be less than 0.1% of the EPA allowable levels.

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FDA Regulatory Criteria for Fluoride

The U.S. Food and Drug Administration (FDA) does not regulate additives used for community drinking water (i.e., tap water), because its regulatory reach concerns the safety and efficacy of food, drugs, or cosmetic-related products. However, because the FDA has authority over bottled water as a consumer beverage (Federal Register, Volume 44, No. 141, July 20, 1979), they do regulate the intentional addition of fluoride to bottled water and require labeling identifying the additive used. Bottlers typically use NSF/ANSI Standard 60-certified fluoride product.

In 2006, FDA announced that bottled water with fluoride levels greater than 0.6 and up to 1.0 mg/L could be labeled with the following statement: "Drinking fluoridated water may reduce the risk of tooth decay." CDC’s fact sheet, Bottled Water and Fluoride, provides additional information on FDA requirements.

FDA also regulates fluoride in over-the-counter drug products, such as toothpaste and mouthwash, and in prescription items, such as pediatric fluoride tablets and professional-strength gels and foams. FDA does not have criteria on allowable impurities in sodium fluoride or fluorosilicate products.

United States Pharmacopeia (USP) Grade Fluoride Products
Some have suggested that pharmaceutical grade fluoride additives should be used for water fluoridation. Pharmaceutical grading standards used in formulating prescription drugs are not appropriate for water fluoridation additives. If applied, those standards could actually exceed the amount of impurities allowed by AWWA and NSF/ANSI in drinking water.

The U.S. Pharmacopeia-National Formulary (USP-NF) publishes monographs on tests and acceptance criteria for substances and ingredients by manufacturers for pharmaceuticals. The USP 29 NF–24 monograph on sodium fluoride provides no independent monitoring or quality assurance testing. The USP does not include acceptance criteria for fluorosilicic acid or sodium fluorosilicate. As a result, the manufacturer is responsible for quality assurance and reporting. The USP does not provide specific protection levels for individual contaminants, but establishes a relative maximum exposure level for a group of related contaminants. Some potential impurities have no restrictions by the USP, including arsenic, some heavy metals regulated by the U.S. EPA, and radionuclides. Given the volumes of chemicals used in water fluoridation, a pharmaceutical grade of sodium fluoride for fluoridation could potentially contain much higher levels of arsenic, radionuclides, and regulated heavy metals than an NSF/ANSI Standard 60-certified product.

In addition, AWWA-grade sodium fluoride is preferred over USP-grade sodium fluoride for use in water treatment facilities because the granular AWWA product is less likely to result in exposure to fluoride dust by water plant operators than the more powder-like USP-grade sodium fluoride.

Fluoride Additives Are Not Different From Natural Fluoride

Some consumers have questioned whether fluoride from natural groundwater sources, such as calcium fluoride, is better than fluorides added "artificially," such as FSA or sodium fluoride. Two recent scientific studies, listed below, demonstrate that the same fluoride ion is present in naturally occurring fluoride or in fluoride drinking water additives and that no intermediates or other products were observed at pH levels as low as 3.5. In addition, the metabolism of fluoride does not differ depending on the chemical compound used or whether the fluoride is present naturally or added to the water supply.


Additional Resources

https://www.cdc.gov/fluoridation/engineering/wfadditives.htm
Community Water Fluoridation: Questions and Answers

Temporary Shortages of Fluoridation Additives: FAQs


File Formats Help:

How do I view different file formats (PDF, DOC, PPT, MPEG) on this site? (https://www.cdc.gov/Other/plugins/)

(https://www.cdc.gov/Other/plugins/#pdf)

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