BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	R15-
AMENDMENTS TO PRIMARY	)	(Rulemaking - Public Water Supply)
DRINKING WATER STANDARDS:	)	
35 ILL. ADM. CODE 611	)	

NOTICE OF FILING

PLEASE TAKE NOTICE that I have filed today with the Illinois Pollution Control Board Illinois EPA's APPEARANCE; STATEMENT OF REASONS; MOTION FOR ACCEPTANCE; MOTION FOR EXPEDITED REVIEW; CERTIFICATE OF ORIGINATION; and PROPOSED AMENDMENTS TO 35 ILL. ADM. CODE PART 611, a copy of which is herewith served upon you.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

By: /s/Joanne M. Olson
Joanne M. Olson
Assistant Counsel
Division of Legal Counsel

DATED: May 20, 2015

Joanne M. Olson #6293500
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1021 N. Grand Ave. East
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(217) 782-5544

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APPEARANCE

The undersigned hereby enters her appearance as an attorney on behalf of the Illinois Environmental Protection Agency.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

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STATEMENT OF REASONS

NOW COMES the Illinois Environmental Protection Agency ("Illinois EPA" or "Agency"), by and through its counsel, and hereby submits this Statement of Reasons to the Illinois Pollution Control Board ("Board") pursuant to Sections 17, 27, and 28 of the Environmental Protection Act ("Act") (415 ILCS 5/17, 27, and 28) and 35 Ill. Adm. Code 102.202 in support of the attached proposed regulations.

I. INTRODUCTION

Under Section 611.125 of the Board's regulations, all community water supplies (CWS) must maintain a fluoride ion concentration of 0.9 to 1.2 milligrams per liter (mg/l) in the CWS' distribution system. 35 Ill. Adm. Code 611.125. This state requirement was based in a statutory fluoridation requirement found in the Public Water Supply Regulation Act, 415 ILCS 40. In 2011, this fluoridation range was removed from the statute and replaced with a reference to the optimal fluoridation levels recommended by the United States Department of Health and Human Services (HHS). Recently, HHS adopted a recommended fluoridation ion concentration of 0.7 mg/L. To bring the Board's rules in line with the current HHS recommendation, and to reduce CWS' cost of having to meet higher fluoridation levels, the Agency recommends the Board amend it rules to reflect a fluoridation ion concentration of 0.7 mg/L. The Agency also proposes

that the Board reinstate a secondary fluoride standard in Section 611.858 that appears to have been inadvertently repealed in 2001. Order and Opinion, R2001-07 (January 4, 2001).

II. BACKGROUND

A. Fluoridation Requirement

On April 5, 1962, the United States Department of Health, Education, and Welfare[1] adopted Drinking Water Standards. See Exhibit A, Public Health Service Publication No. 956. These Drinking Water Standards contained recommended optimal control limits for fluoride concentrations. The recommend limits were based on the annual average of maximum daily air temperatures. For example, where the annual average of maximum daily air temperatures was 63.9 to 70.6 ºF, the optimum fluoridation concentration was 0.9 mg/l. Id. at 8.

Beginning on July 17, 1967, public water supplies in Illinois were required to add fluoride to drinking water to maintain a fluoride content between 0.9 and 1.2 mg/l. Laws 1967 p. 1769, S.B. No. 516; Illinois Revised Statutes Ch. 111 ½ ¶ 121g1. The 1967 law required the Illinois Department of Public Health ("IDPH") to promulgate rules to require the addition of fluoride. Id. In August 1967, IDPH promulgated rules and regulations requiring the addition of fluoride to maintain a fluoride ion concentration of 0.9 to 1.2 mg/l. See Exhibit B, IDPH Fluoridation of Public Water Supplies, Technical Release 10-3.

The Illinois EPA was created in 1970 with the adoption of the Act. Public Act 76-2429. The General Assembly found that "state supervision of public water supplies is necessary in order to protect the public from disease and to assure an adequate supply of pure water for all beneficial uses." 415 ILCS 5/14 (2012). Under Title IV of the Act, the Illinois EPA and the

[1] In 1979, the United States Department of Health, Education and Welfare was divided into two departments: Department of Education and the Department of Health and Human Services.

Board began regulating public water supplies.[2] The Agency initially operated the public water supply program under the rules developed by the IDPH. See Exhibit C, Letter to Jacob D. Dumelle, Subject: Proposed Public Water Supply Rules, October 24, 1973; *In the Matter of Public Water Supplies*, R1973-13, Opinion of the Board at 2 (January 3, 1975). In 1975, the Board adopted rules governing public water supplies. R1973-13. The Board added a fluoridation requirement in Rule 306, stating "This rule reinforces the existing law requiring fluoridation of public water supplies. The Environmental Protection Agency will by this rule cooperate with the Public Health Department, and by its field personnel insure proper operation of equipment and enforcement of the rule." R1973-13, Opinion of the Board at 38 (January 3, 1975).

The fluoridation requirement in Rule 306 was re-codified at 35 Ill. Adm. Code 604.405 pursuant to the Illinois Administrative Procedure Act. In 1990, the fluoridation requirement was again moved to Section 611.125 when the Board adopted regulations implementing the Safe Drinking Water Act to Section 611.125. In its Proposed Order, the Board stated, "The Board has moved the mandatory fluoridation requirement from 35 Ill. Adm. Code 604.405. This is an additional state requirement. Since mandatory fluoridation is enforced by the Department of Public Health, the Board solicits comment as to whether it should retain this provision in the regulations." R88-26, Proposed Order at 20 (October 5, 1989). The Board did not receive any comments, and retained the mandatory fluoridation in Part 611. R88-26, Final Order, 59 (August 9, 1990).

[2] On September 4, 1981, the General Assembly bifurcated public water supplies into community water supplies and non-community water supplies. P.A. 82-393; PCB Docket R 81-6/R81-28. Non-community water supplies were no longer regulated by the Board. *In the Matter of: Proposal for Rulemaking for Ch. 6: Public Water Supply Regulations of the Illinois Pollution Control Board*, Final Opinion of the Board, R81-6/R81-28, 2 (September 2, 1982) ("Therefore, the Board no longer has jurisdiction over non-community water supplies for the purpose of the Certified Operators Act or the [Environmental Protection] Act. Accordingly, Section 601.102, Applicability, has been added to Chapter 6. This section makes clear that Chapter 6 does not apply to those public water supplies classified as non-community water supplies.")

The law in Illinois regarding mandatory fluoridation remained unchanged until June 28, 2011. P.A. 97-43; 415 ILCS 40/7a (2012). Public Act 97-43 amended the Public Water Supply Regulation Act, Section 7a, by removing the required range of fluoride content. Instead of requiring the fluoride content to be between 0.9 and 1.2 mg/l, the statute now requires the IDPH to promulgate rules requiring the addition of fluoride based on the recommendation on optimal fluoridation for community water levels as proposed and adopted by the United States Department of Health and Human Services (HHS). 415 ILCS40/7(a)(2012).

When the Public Water Supply Regulation Act was amended in 2011, the only adopted recommendation from HHS was from 1962, when HHS was the Department of Health, Education, and Welfare. See Exhibit A. On January 13, 2011, HHS proposed a new recommendation for fluoride concentration in drinking water: "HHS proposes that community water systems adjust their fluoride content to 0.7 mg/l." See Exhibit D, 76 Fed. Reg. 2383-2388. HHS accepted comments on the proposed fluoride recommendation until April 15, 2011. 76 Fed. Reg. 10899 (February 29, 2011). On May 1, 2105, HHS issued its recommendation for fluoride concentration in drinking water:

> For community water systems that add fluoride to their water, PHS recommends a fluoride concentration of 0.7 mg/L (parts per million [ppm]) to maintain caries prevention benefits and reduce the risk of dental fluorosis.

See Exhibit E, 80 Fed. Reg. 24936-24947 (May 1, 2015).

B. Fluoride Secondary Standard

In a final order[3], issued January 4, 2001, the Board repealed Section 611.858. R01-07, Order of the Board at 117; 25 Ill. Reg. 1329. The Board's final opinion struck the text of Section

[3] The Notice of Adopted Amendments which appeared in the Illinois Register on January 26, 2001 also contained the repeal of Section 611.858.

611.858[4], but did not provide any discussion of its repeal. R01-07, Opinion of the Board (January 4, 2001). Instead, the Board stated that it intended to repeal Sections 611.832, 611.851 through 611.856, and existing Appendix A to Part 611. *Id*. at 12. Moreover, Sections 611.901, 611.904, 611.908 were added in the same final order repealing Section 611.858, but each of these sections contained a cross reference to Section 611.858. R01-07, Order of the Board at 131, 137, 143. The Code of Federal Regulations published in July 2001 still contained the secondary standard for fluoride of 2.0 mg/lm. See Exhibit F; 40 C.F.R. §143.3 (July 2001). Based on the forgoing, the repeal of Section 611.858 appears to be an inadvertent error and the Agency proposes that the Section be reinstated.

III. THE ILLINOIS EPA'S PROPOSAL

A. Section 611.125

The Agency proposes that the Board amend Section 611.125 to reflect HHS's 2015 Recommendation. As noted above, HHS recommends that CWSs that add fluoride to their water should maintain a fluoride concentration of 0.7 mg/l. The Agency proposes amending Section 652.125 as follows:

> **Section 611.125 Fluoridation Requirement**
>
> All CWSs that are required to add fluoride to the water must maintain a fluoride ion concentration, reported as F, of 0.7~~0.9 to 1.2~~ mg/ℓ in its distribution system~~, as required by Section 7a of the Public Water Supply Regulation Act [415 ILCS 40/7a]~~.

[4] Before its repeal, Section 611.858 provided:

> If a CWS exceeds the secondary standard for fluoride of 2.0 mg/L, as determined by the last single sample taken in accordance with Section 611.603, but does not exceed the MCL in Section 611.301(b), the supplier shall provide the fluoride notice in Section 611.Appendix A (9) to:
>
> a) All billing units annually;
>
> b) All billing units at the time service begins; and
>
> c) The local public health department.
>
> BOARD NOTE: Derived from 40 CFR 143.3 and 143.5 (1994).

BOARD NOTE: This is an additional State requirement.

B. **Section 611.858**

As the Agency believes Section 611.858 was inadvertently repealed, the Agency proposes the following language:

Section 611.858 Fluoride Secondary Standard

The secondary standard for fluoride is 2.0 mg/L.

BOARD NOTE: Derived from 40 CFR 143.3 (2014).

IV. TECHNICAL FEASIBILITY AND ECONOMIC REASONABLENESS

Section 27 of the Act requires the Board to consider the technical feasibility and economic reasonableness of all rulemaking proposals. Illinois EPA's proposed amendment would not require facilities to implement additional treatment technologies. Instead, the converse is true. A CWS may be able to stop or reduce fluoride addition to meet the proposed fluoridation requirement. CWSs will not have to spend additional money to comply with this proposed change. For these reasons, the Agency's proposed changes are technically feasible and economically reasonable.

V. AFFECTED FACILITIES AND ECONOMIC IMPACT

The Illinois EPA regulates 1,744 CWSs. These CWSs obtain water from groundwater and surface water sources. Approximately, 1,006 CWSs use groundwater sources, and 98 use surface water sources or groundwater sources under the direct influence of surface water. Seven CWSs use both groundwater and surface water sources, and 652 CWSs purchase water from other CWSs. Approximately 12, 000,000 persons are served by these systems in Illinois. Water delivery can vary greatly. A very small community water system such as Stratford West

Apartments near Macomb, Illinois produces on average 2,500 gallons per day. The City Chicago is capable of delivering over two billion gallons of water per day and routinely produces on average 510 million gallons per day.

The Illinois EPA anticipates that any CWS that adds fluoride will be affected by these proposed rules. The Agency believes the impact will be positive. This proposal will reduce or eliminate costs associated with fluoride addition because it proposes to lower the fluoride requirement. The Illinois EPA projects water systems that add fluoride could see a reduction of 20% to 30% in the cost of their chemical addition for fluoride. A moderately sized surface water treatment plant that currently adds fluoride could save $8,000 to $10,000 per year. A large private utility estimates that revising the standard will save them approximately $150,000 per year. The City Chicago estimates a cost savings of almost $1,000,000 a year.

VI. SYNOPSIS OF TESTIMONY

The Illinois EPA will present one witness, David McMillian, Manager of the Agency's Division of Public Water Supplies. Mr. McMillan has a Bachelor of Science Degree in Geological Sciences from Bradley University, and is an Illinois licensed professional geologist. He has worked in the Division of Public Water Supplies at Illinois EPA for 29 years, and has been the manager of the Division since December of 2010. In 1985, Mr. McMillan began his career in the Peoria Regional office as a member of the Groundwater Section. He advance into a Unit Manager position in 1992 and moved to the Central Office in Springfield. In 2004, he became the interim Manager of the Field Operations Section, a position that later became permanent. In Mr. McMillan's current position, he leads a collaborative program of four sections staffed by environmental engineers, geologists and specialists. The Permit, Compliance Assurance, Groundwater and Field Operations Sections ensure the safety of the Illinois' drinking

water supplies. Together the staff of the Division of Public Water Supplies oversees inspections of CWSs, evaluates source water protection programs, issues permits, and ensures the safety and compliance of community water systems. Mr. McMillan will be present at the Board's hearing to testify regarding the necessity, purpose and effect of this regulatory proposal.

VII. PUBLISHED STUDY OR RESEARCH REPORT

Section 102.202(e) of Title 35 of the Illinois Administrative Code requires the regulatory proposal to include "[a] descriptive title or other description of any published study or research report used in developing the rule." Neither a research report nor a published study was used in developing this rule. Therefore, the requirement of Section 102.202(e) is inapplicable.

VIII. CONCLUSION

WHEREFORE, the Illinois EPA asks the Board to accept this Statement of Reasons and proceed to hearings on the above-captioned rulemaking proposal.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

By: /s/Joanne M. Olson
Joanne M. Olson
Assistant Counsel
Division of Legal Counsel

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DRINKING WATER STANDARDS:	)	
35 ILL. ADM. CODE 611	)	

MOTION FOR ACCEPTANCE

NOW COMES the Illinois Environmental Protection Agency ("Illinois EPA"), by and through its attorneys, and pursuant to 35 Ill. Adm. Code 102.106, 102.200, and 102.202, moves that the Illinois Pollution Control Board accept for hearing the Illinois EPA's proposal for the adoption of amendments to 35 Ill. Adm. Code 611.125. This regulatory proposal includes (1) Notice of Filing; (2) Appearance; (3) Statement of Reasons and Exhibits; (4) Motion to Expedite; (5) Certification of Origination; and (6) Proposed Amendments.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

By: /s/Joanne M. Olson
Joanne M. Olson
Assistant Counsel
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MOTION FOR EXPEDITED REVIEW

NOW COMES the ILLINOIS ENVIRONMENTAL PROTECTION AGENCY ("Illinois EPA" or "Agency"), by one of its attorneys, and pursuant to 35 Ill. Adm. Code 101.512, respectfully submits this Motion for Expedited Review. In support of this motion, the Illinois EPA states as follows:

1. On May 1, 2015, the United States Department of Health and Human Services ("HHS") issued its recommendation that community water supplies that add fluoride to their water maintain the fluoride concentration of 0.7 mg/l.

2. The Illinois Pollution Control Board's ("Board") current regulations require community water supplies that add fluoride must maintain a fluoride ion concentration between 0.9 and 1.2 mg/l.

3. Illinois statutes require fluoridation only to levels recommended by the HHS. Section 7a of the Public Water Supply Regulation Act provides that the Illinois Department of Public Health ("IDPH") shall adopt rules to provide for the addition of fluoride to public water supplies, and such rules shall incorporate the recommendations on optimal fluoridation adopted by the HHS. 415 ILCS 40/7a (2104).

4. Since the HHS issued its recommendation, the Agency has received over a numerous calls inquiring when the Board's standard will be changed.

5. The Illinois EPA projects water systems that add fluoride could see a reduction of 20% to 30% in the cost of their chemical addition for fluoride. A moderately sized surface water treatment plant that currently adds fluoride could save $8,000 to $10,000 per year. A large private utility estimates that revising the standard will save them approximately $150,000 per year. The City Chicago estimates that it will save all most $1,000,000 a year with the lower standard. The savings for all CWS across the state can begin immediately upon the Board's adoption of the proposed lower standard.

6. The City of Chicago, Illinois American Water Company, Aqua support this motion to expedite.

7. Material prejudice will not result from this motion being granted. If this motion is denied, community water supplies are required to follow the Board's current fluoride standard of 0.9 mg/l to 0.7 mg/l, resulting in higher costs.

9. The Agency's proposed changes are not controversial. The new fluoridation requirement is based on both an Illinois statutory requirement and a federal recommendation.

10. In light of the foregoing, it is necessary to expedite review in this matter.

11. As required by 35 Ill. Adm. Code Section 101.512, this Motion is accompanied by an Affirmation attesting that the facts cited herein are true.

WHEREFORE, for the reasons set forth above, the Illinois EPA respectfully requests that the Board expedite review in this matter, and proceed to First Notice immediately.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

By: /s/Joanne M. Olson
Joanne M. Olson
Assistant Counsel
Division of Legal Counsel

Joanne M. Olson #6293500
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AFFIRMATION

I, David McMillian, under oath, hereby state and affirm that I am the manager of the Division of Public Water Supplies at the Illinois Environmental Protection Agency and that the facts cited in the foregoing Motion for Expedited Review are true and correct to the best of my information and belief.

s/David McMillian
David McMillian

SUBSCRIBED AND SWORN TO BEFORE ME
This 15 day of May, 2015

s/ Michael J McCabe
Notary Public

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

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CERTIFICATION OF ORIGINATION

NOW COMES the ILLINOIS ENVIRONMENTAL PROTECTION AGENCY ("Illinois EPA"), by one of its attorneys, and pursuant to 35 Ill. Adm. Code 102.202(i), the Illinois EPA certifies that the regulatory proposal in the above captioned matter amends the most recent version of Part 611 of the Illinois Pollution Control Board's regulations, as published on the Board's website.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

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TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE F: PUBLIC WATER SUPPLIES
CHAPTER I: POLLUTION CONTROL BOARD

PART 611
PRIMARY DRINKING WATER STANDARDS

SUBPART A: GENERAL

Section

SUBPART B: FILTRATION AND DISINFECTION

Section

SUBPART C: USE OF NON-CENTRALIZED TREATMENT DEVICES

SUBPART D: TREATMENT TECHNIQUES

SUBPART F: MAXIMUM CONTAMINANT LEVELS (MCLs) AND MAXIMUM RESIDUAL DISINFECTANT LEVELS (MRDLs)

SUBPART G: LEAD AND COPPER

SUBPART I: DISINFECTANT RESIDUALS, DISINFECTION BYPRODUCTS, AND DISINFECTION BYPRODUCT PRECURSORS

SUBPART K: GENERAL MONITORING AND ANALYTICAL REQUIREMENTS

SUBPART L: MICROBIOLOGICAL MONITORING AND ANALYTICAL REQUIREMENTS

SUBPART M: TURBIDITY MONITORING AND ANALYTICAL REQUIREMENTS

SUBPART N: INORGANIC MONITORING AND ANALYTICAL REQUIREMENTS

SUBPART O: ORGANIC MONITORING AND ANALYTICAL REQUIREMENTS

SUBPART P: THM MONITORING AND ANALYTICAL REQUIREMENTS (REPEALED)

SUBPART Q: RADIOLOGICAL MONITORING AND ANALYTICAL REQUIREMENTS

Section
611.720 Analytical Methods
611.731 Gross Alpha
611.732 Beta Particle and Photon Radioactivity
611.733 General Monitoring and Compliance Requirements

SUBPART R: ENHANCED FILTRATION AND DISINFECTION: SYSTEMS THAT SERVE 10,000 OR MORE PEOPLE

Section
611.740 General Requirements
611.741 Standards for Avoiding Filtration
611.742 Disinfection Profiling and Benchmarking
611.743 Filtration
611.744 Filtration Sampling Requirements
611.745 Reporting and Recordkeeping Requirements

SUBPART S: GROUNDWATER RULE

Section
611.800 General Requirements and Applicability
611.801 Sanitary Surveys for GWS Suppliers
611.802 Groundwater Source Microbial Monitoring and Analytical Methods
611.803 Treatment Technique Requirements for GWS Suppliers
611.804 Treatment Technique Violations for GWS Suppliers
611.805 Reporting and Recordkeeping for GWS Suppliers

SUBPART T: REPORTING AND RECORDKEEPING

Section
611.830 Applicability
611.831 Monthly Operating Report
611.832 Notice by Agency (Repealed)
611.833 Cross Connection Reporting
611.840 Reporting
611.851 Reporting MCL, MRDL, and other Violations (Repealed)
611.852 Reporting other Violations (Repealed)
611.853 Notice to New Billing Units (Repealed)
611.854 General Content of Public Notice (Repealed)
611.855 Mandatory Health Effects Language (Repealed)
611.856 Fluoride Notice (Repealed)
611.858 Fluoride Secondary Standard ~~(Repealed)~~
611.860 Record Maintenance
611.870 List of 36 Contaminants (Repealed)

SUBPART U: CONSUMER CONFIDENCE REPORTS

SUBPART V: PUBLIC NOTIFICATION OF DRINKING WATER VIOLATIONS

SUBPART W: INITIAL DISTRIBUTION SYSTEM EVALUATIONS

SUBPART X: ENHANCED FILTRATION AND DISINFECTION—SYSTEMS SERVING FEWER THAN 10,000 PEOPLE

SUBPART Y: STAGE 2 DISINFECTION BYPRODUCTS REQUIREMENTS

Section

SUBPART Z: ENHANCED TREATMENT FOR CRYPTOSPORIDIUM

Section

SUBPART AA: REVISED TOTAL COLIFORM RULE

Section

611.TABLE F	Number of Water Quality Parameter Sampling Sites
611.TABLE G	Summary of Section 611.357 Monitoring Requirements for Water Quality Parameters
611.TABLE H	CT Values (mg·min/ℓ) for Cryptosporidium Inactivation by Chlorine Dioxide
611.TABLE I	CT Values (mg·min/ℓ) for Cryptosporidium Inactivation by Ozone
611.TABLE J	UV Dose Table for Cryptosporidium, Giardia lamblia, and Virus Inactivation Credit
611.TABLE Z	Federal Effective Dates

AUTHORITY: Implementing Sections 7.2, 17, and 17.5 and authorized by Section 27 of the Environmental Protection Act [415 ILCS 5/7.2, 17, 17.5, and 27].

SOURCE: Adopted in R88-26 at 14 Ill. Reg. 16517, effective September 20, 1990; amended in R90-21 at 14 Ill. Reg. 20448, effective December 11, 1990; amended in R90-13 at 15 Ill. Reg. 1562, effective January 22, 1991; amended in R91-3 at 16 Ill. Reg. 19010, effective December 1, 1992; amended in R92-3 at 17 Ill. Reg. 7796, effective May 18, 1993; amended in R93-1 at 17 Ill. Reg. 12650, effective July 23, 1993; amended in R94-4 at 18 Ill. Reg. 12291, effective July 28, 1994; amended in R94-23 at 19 Ill. Reg. 8613, effective June 20, 1995; amended in R95-17 at 20 Ill. Reg. 14493, effective October 22, 1996; amended in R98-2 at 22 Ill. Reg. 5020, effective March 5, 1998; amended in R99-6 at 23 Ill. Reg. 2756, effective February 17, 1999; amended in R99-12 at 23 Ill. Reg. 10348, effective August 11, 1999; amended in R00-8 at 23 Ill. Reg. 14715, effective December 8, 1999; amended in R00-10 at 24 Ill. Reg. 14226, effective September 11, 2000; amended in R01-7 at 25 Ill. Reg. 1329, effective January 11, 2001; amended in R01-20 at 25 Ill. Reg. 13611, effective October 9, 2001; amended in R02-5 at 26 Ill. Reg. 3522, effective February 22, 2002; amended in R03-4 at 27 Ill. Reg. 1183, effective January 10, 2003; amended in R03-15 at 27 Ill. Reg. 16447, effective October 10, 2003; amended in R04-3 at 28 Ill. Reg. 5269, effective March 10, 2004; amended in R04-13 at 28 Ill. Reg. 12666, effective August 26, 2004; amended in R05-6 at 29 Ill. Reg. 2287, effective January 28, 2005; amended in R06-15 at 30 Ill. Reg. 17004, effective October 13, 2006; amended in R07-2/R07-11 at 31 Ill. Reg. 11757, effective July 27, 2007; amended in R08-7/R08-13 at 33 Ill. Reg. 633, effective December 30, 2008; amended in R10-1/R10-17/R11-6 at 34 Ill. Reg. 19848, effective December 7, 2010; amended in R12-4 at 36 Ill. Reg. 36 Ill. Reg. 7110, effective April 25, 2012; amended in R13-2 at 37 Ill. Reg. 1978, effective February 4, 2013; amended in R14-8 at 38 Ill. Reg. 3608, effective January 27, 2014; amended in R14-9 at 38 Ill. Reg. 9792, effective April 21, 2014.

SUBPART A: GENERAL

Section 611.125 Fluoridation Requirement

All CWSs that are required to add fluoride to the water must maintain a fluoride ion concentration, reported as F, of 0.7~~0.9 to 1.2~~ mg/ℓ in its distribution system~~, as required by Section 7a of the Public Water Supply Regulation Act [415 ILCS 40/7a]~~.

BOARD NOTE: This is an additional State requirement.

(Source: Amended at __ Ill. Reg. _____, effective _____)

SUBPART T: REPORTING AND RECORDKEEPING

Section 611.858 Fluoride Secondary Standard

The secondary standard for fluoride is 2.0 mg/L.

BOARD NOTE: Derived from 40 CFR 143.3 (2014).

(Source: Section repealed at 25 Ill. Reg. 1329, effective January 11, 2001, new section adopted at __ Ill. Reg. _____, effective _____)

CERTIFICATE OF SERVICE

Joanne M. Olson, Assistant Counsel for the Illinois EPA, herein certifies that she has served a copy of the foregoing NOTICE OF FILING; APPEARANCE; STATEMENT OF REASONS; MOTION FOR ACCEPTANCE; MOTION FOR EXPEDITED REVIEW; CERTIFICATE OF ORIGINATION; and PROPOSED AMENDMENTS TO 35 ILL. ADM. CODE PART 611 upon persons listed on the Service List by mailing, unless otherwise noted on the Service List, a true copy thereof in an envelope duly addressed bearing proper first class postage and deposited in the United States mail at Springfield, Illinois on May 20, 2015.

/s/Joanne M. Olson
Joanne M. Olson

SERVICE LIST

Paper Document Service

Matthew J. Dunn, Chief
Environmental Enforcement/Asbestos
Litigation Division
Illinois Attorney General's Office
500 South Second Street
Springfield, IL 62706

Office of Legal Services
Illinois Department of Natural Resources
One Natural Resources Way
Springfield, IL 62702-1271

Electronic Document Service

Public Health Service

DRINKING WATER STANDARDS

1962

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service

Public Health Service Drinking Water Standards

Revised 1962

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

Washington 25, D.C.

Public Health Service Publication No. 956
First Printed August 1962
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UNITED STATES
GOVERNMENT PRINTING OFFICE
WASHINGTON : 1962

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington 25, D.C. - Price 30 cents (Paper cover)

THE PUBLIC HEALTH SERVICE DRINKING WATER STANDARDS—1962

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
Washington 25, D.C., May 6, 1962.

The Standards published herein have been promulgated as Public Health Regulations in the Federal Register. As such they became effective April 5, 1962, as the Standards to which drinking water and water supply systems used by carriers and others subject to Federal quarantine regulations must conform.

The Division of Environmental Engineering and Food Protection is responsible for the application of these Standards to all carrier water supplies.

These Standards supersede the Public Health Service Drinking Water Standards—1946, as amended in 1956. The new Standards were developed with the assistance of an Advisory Committee appointed by the Public Health Service to revise the Standards of 1946. The Committee in its deliberations took cognizance of man's changing environment and its effect on water supplies. Accordingly, new sections, such as one on radioactivity, have been added and substantive changes have been made elsewhere.

The new Standards are in a form believed useful in evaluating the quality and safety of water supplies generally and they are hereby recommended for such use.

LUTHER L. TERRY,
Surgeon General, Public Health Service.

ENDORSEMENT BY THE AMERICAN WATER WORKS ASSOCIATION

Acting on behalf of the Officers and Directors, the AWWA Executive Committee adopted a resolution endorsing the 1962 revision of the USPHS Drinking Water Standards as "minimum" standards for all public water supplies.

The resolution, which will be included with the published standards, read:

WHEREAS, the 1962 Drinking Water Standards of the U.S. Public Health Service, as prepared by the Advisory Committee on Revision of U.S. Public Health Service 1946 Drinking Water Standards and promulgated for use in the administration of interstate quarantine regulations, are intended to apply only to water used on common carriers engaged in interstate commerce;

WHEREAS, the 1962 Drinking Water Standards are to serve as minimum requirements to protect the health and promote the well-being of individuals and of communities;

WHEREAS, it is the desire of the American Water Works Association to support all efforts to promote health through safe water supplies and to recognize reasonable standards of quality for water furnished by public water supply systems; and,

WHEREAS, it is the hope of the American Water Works Association that its acceptance of the 1962 Drinking Water Standards will establish these standards as minimum criteria of quality for all public water supplies in the United States; now, therefore, be it

Resolved by the Officers and Directors of the American Water Works Association, that the 1962 Drinking Water Standards of the U.S. Public Health Service be accepted as minimum standards for all public water supplies.

ADVISORY COMMITTEE REPORT

Domestic water supplies should protect the health and promote the well-being of individuals and the community. In this report on the revision of the 1946 edition of the Public Health Service Drinking Water Standards, the objective of the Committee is to recommend minimum requirements for reaching this goal.

The Public Health Service Drinking Water Standards were first adopted in 1914 to protect the health of the traveling public. The general and widespread use of these Standards since that time has led to a series of revisions which have been applicable to water supplies generally. The development of atomic energy and other technological advances requires that these Standards again be revised. To carry out this revision, the Chief Sanitary Engineer of the Public Health Service appointed the Advisory Committee. A Technical Subcommittee of Public Health Service Officers and a Toxicological Task Force were established to collect information and prepare suggestions for the consideration of the Advisory Committee.

In preparing this report on the revision of the Standards, the Committee established the following guidelines:

1. The proposed standards should be discussed widely and due cognizance should be given to International and other standards of water quality before a final report is submitted.
2. A new section on radioactivity should be added.
3. Greater attention should be given to the chemical substances being encountered increasingly in both variety and quantity in water sources.
4. In establishing limits for toxic substances, intake from food and air should be considered.
5. The rationale employed in determining the various limits should be included in an appendix.
6. The proposed format, with the exceptions noted above, should not differ greatly from the present Standards.
7. The Standards should be generally acceptable and should be applicable to all public water supplies in the United States, as well as those supplies used by carriers subject to the Public Health Service regulations.
8. The following two types of limits used in previous editions should be continued:

   (*a*) Limits which, if exceeded, shall be grounds for rejection of the supply. Substances in this category may have adverse effects on health when present in concentrations above the limit.

   (*b*) Limits which should not be exceeded whenever more suitable supplies are, or can be made, available at reasonable cost. Substances in this category, when present in concentrations above the limit, are either objectionable to an appreciable number of people or exceed the levels required by good water quality control practices.

9. These limits should apply to the water at the free-flowing outlet of the ultimate consumer.

This revision of the Drinking Water Standards includes, for the first time, limiting concentrations of radioactivity in water. The effects on large popula-

tion groups of chronic exposure to low levels of radioactivity are not yet well defined. The limits presented herein are an effort to derive conservative values from the best information now available and may be adjusted upward or downward as new and better data become available.

The Committee has taken cognizance of the growing problem of potentially harmful chemicals in sources of drinking water. Limits for several new chemicals have been added, including a gross limit for the concentration of some types of synthetic chemicals. It was not feasible, however, to include limits for all the many chemicals that have varying degrees of toxic potential. Consideration was given to the more common chlorinated hydrocarbon and organophosphate insecticides but the information available was not sufficient to establish specific limits for these chemicals. Moreover, the concentrations of these chemicals, where tested, have been below those which would constitute a known health hazard. The Committee believes that pollution of water supplies with such contaminants can become significant and urges that the problem be kept under closer surveillance. Further, the Committee recommends that regulatory actions be taken to minimize concentrations of such chemicals in drinking water.

In view of the accelerating pace of new developments affecting water quality, the Committee recommends that a mechanism be established for continual appraisal and appropriate revision of the Standards. It also recommends that the Public Health Service intensify its continuing studies toward the development of basic information on the relationship of the biological, chemical, physical, and radiological aspects of water quality to health.

The following pages contain the Drinking Water Standards recommended by the Committee, the membership of which is listed in appendix F.

CONTENTS

5.22 The presence of the following substances in excess of the concentrations listed shall constitute grounds for rejection of the supply:

Substance	Concentration in mg/l
Arsenic (As)	0.05
Barium (Ba)	1.0
Cadmium (Cd)	0.01
Chromium (Hexavalent) (Cr^{+6})	0.05
Cyanide (CN)	0.2
Fluoride (F)	(See 5.23)
Lead (Pb)	0.05
Selenium (Se)	0.01
Silver (Ag)	0.05

5.23 *Fluoride.*—When fluoride is naturally present in drinking water, the concentration should not average more than the appropriate upper limit in Table I. Presence of fluoride in average concentrations greater than two times the optimum values in Table I shall constitute grounds for rejection of the supply.

Where fluoridation (supplementation of fluoride in drinking water) is practiced, the average fluoride concentration shall be kept within the upper and lower control limits in Table I.

TABLE 1.

Annual average of maximum daily air temperatures [1]	Recommended control limits—Fluoride concentrations in mg/l		
	Lower	Optimum	Upper
50.0–53.7	0.9	1.2	1.7
53.8–58.3	0.8	1.1	1.5
58.4–63.8	0.8	1.0	1.3
63.9–70.6	0.7	0.9	1.2
70.7–79.2	0.7	0.8	1.0
79.3–90.5	0.6	0.7	0.8

[1] Based on temperature data obtained for a minimum of five years.

In addition to the sampling required by paragraph 5.1 above, fluoridated and defluoridated supplies shall be sampled with sufficient frequency to determine that the desired fluoride concentration is maintained.

6. RADIOACTIVITY

6.1 *Sampling.*

6.11 The frequency of sampling and analysis for radioactivity shall be determined by the Reporting Agency and the Certifying Authority after consideration of the likelihood of significant amounts being present. Where concentrations of Ra^{226} or Sr^{90} may vary considerably, quarterly samples composited over a period of three months are recommended. Samples for determina-

STATE OF ILLINOIS
Division of Sanitary Engineering
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

Technical Release 10-3 : August, 1967
Revised 1/15/69

FLUORIDATION OF PUBLIC WATER SUPPLIES

Law

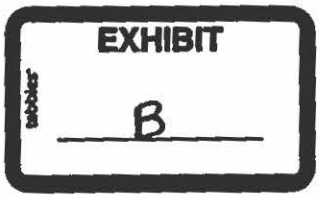
During the 1967 Session of the Illinois General Assembly, the Illinois Public Water Supply Control Law was amended. The amendment requires that rules and regulations be established to provide for the addition of fluoride to all public water supplies to protect the dental health of all citizens, especially children in Illinois

Rules and Regulations

Based on the above mentioned fluoridation amendment to the Public Water Supply Control Law, the existing Rules and Regulations for public water supply systems have been amended.

Where the average natural fluoride ion content of the water from any source for a public water supply is less than 0.9 mg/l, equipment shall be provided to adjust the fluoride ion concentration to a level of 0.9 to 1.2 mg/l.

The operation of fluoridation equipment shall be such as to maintain a fluoride ion concentration of 0.9 to 1.2 mg/l in all water discharged to the distribution system. At least one representative sample of fluoridated water shall be submitted per month to the Department Laboratory in containers furnished by the Department in accordance with the provisions of Section 8 of the Public Water Supply Control Law. Daily records of the fluoride ion concentration shall be maintained by owners, official custodians or their representatives. A copy of these records shall be submitted monthly to the Department in accordance with the provisions of Section 9 of the Public Water Supply Control Law.



AMENDMENTS TO PUBLIC WATER SUPPLY RULES AND REGULATIONS

Rule 2.93. Cause for Revocation of Approval - Any representations or statements made by the owner or operator of a public water supply or his agent in the application for the approval of proposed public water supply installations, changes, or additions found to be incorrect subsequent to the issuance of approval may be cause for revocation of the approval. An approval may be revoked for a violation of Rule 2.71.

Rule 2.94. Procedure for Revocation of Approval - Upon evidence of incorrect representations or statements contained in the application or of a violation of Rule 2.71, the Department shall notify the owner or operator of a public water supply, his agent and other interested parties in writing of the revocation of the approval issued and the reason therefor..

Rule 2.95. Waiver of Rights - If an approval is revoked under Rule 2.94, the owner or operator of the existing or proposed public water supply waives all rights granted by the approval.

Rule 2.98. Right of Inspection - During the progress of construction or installation of a waterworks system or improvements thereto, the Department shall, through its authorized representatives, have the right, at all reasonable times, to inspect such work, and after erection of installation to inspect the same or the operation thereof.

Rule 3.05. Repealed 1/15/69

Rule 3.06. Repealed 1/15/69

Rule 3.07. Design of Fluoridation Facilities - Detailed plans and specifications for fluoridation installations shall be prepared in accordance with accepted engineering practices, Technical Release 10-3 of the Division of Sanitary Engineering and in accordance with Articles II and III of these Rules and Regulations.

Rule 3.47. Chemical Feeding - When the procedure for the application of any chemical to drinking water is originally established or significantly changed, permission shall be obtained from the Department. The design of chemical feeding installations shall be in conformance with accepted engineering practices and the "Great Lakes-Upper Mississippi River Board of State Sanitary Engineers Report on Policies for the Review and Approval of Plans and Sepcifications for Public Water Supplies."

Rule 5.15. Chemicals - Any chemicals used for the treatment of drinking water shall be approved by the U.S. Public Health Service for Public Water Supply Use. The container for any such chemical shall bear the name, address and telephone number of the supplier, along with a functional name or identification of the chemical and its strength.

Rule 5.28. Fluoridation - The operation of fluoridation equipment shall be such as to maintain a fluoride ion concentration of 0.9 to 1 2 mg/l in all water discharged to the distribution system. At least one representative sample of fluoridated water shall be submitted per month to the Department laboratory in containers furnished by the Department in accordance with the provisions of Section 8 of the Public Water Supply Control Law. Daily records of the fluoride ion concentration shall be maintained by owners, official custodians or their representatives. A copy of these records shall be submitted monthly to the Department in accordance with the provisions of Section 9 of the Public Water Supply Control Law.

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

2200 Churchill Road
62706

Springfield, Illinois
Phone: 217/786-6945

October 24, 1973

R73-13

Mr. Jacob D. Dumelle
Chairman
Illinois Pollution Control Board
309 West Washington Street
Chicago, Illinois 60606

Subject: Proposed Public Water Supply Rules

Dear Chairman Dumelle:

The Illinois Environmental Protection Agency has been operating under rules developed by the Illinois Department of Public Health in 1966 for the design, construction and operation of public water supplies. Experience gained by the Agency in implementing these rules has shown that some areas require strengthening, and that improvements in water supply technology during the intervening years should be reflected in related changes in the rules.

Over the past year the Agency has been developing a completely revised set of rules, which have been discussed in detail with several knowledgeable persons and public groups. These contacts have included the U. S. Environmental Protection Agency and the Illinois Section of AWWA, as well as the Illinois Operators Certification Advisory Board. The cooperation and assistance of all groups and individuals is gratefully acknowledged. We want to encourage them to continue this dialogue with the Agency, and to offer their expertise in testimony before the Board during the hearings on these proposals.

The proposed rules were designed to provide the basis for assurance of safe drinking water for the people served by public water supplies in Illinois. The general philosophy and basic thrusts of the existing "Public Water Supply Rules and Regulations" adopted by the Illinois Department of Public Health have not been changed. The attached rationale outlines the Agency's thinking used in developing this proposal.

Even though the basic philosophy of the existing rules is not being changed, they were adopted by direct administrative action. We believe that open hearings are a preferable method for rule making, and look forward to the discussion at those hearings. In addition, the proposed rules have been put in a form consistent with other rules adopted by the Board.

One item requires special mention in this letter. We have included a recommendation for the modification of Board Rule 204 in Chapter 3: Water Pollution. This is necessary to make that Chapter completely consistent with the algicide permit system contained in this proposal.

We respectfully request that the Board schedule hearings on this proposal in accordance with the provisions of the Environmental Protection Act, with a view toward final adoption of new rules for public water supplies in Illinois.

Respectfully submitted,

John M. Marco
Acting Director

JMM:JPA:aa

Zammit, President/CEO. *Application Type:* QI Change.

Dated: January 7, 2011.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–574 Filed 1–12–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/address	Date reissued
004027F	U.S. Airfreight, Inc., 2624 N.W. 112th Avenue, Miami, FL 33172	October 28, 2010.
017330N	Geomarine Shipping Inc., 27 Cambridge Road, East Rockaway, NY 11518	November 10, 2010.
018429F	AB Shipping, Inc., 5428 El Monte Avenue, Temple City, CA 91780	November 15, 2010.
018525N	Valu Freight Consolidators, Inc., 1325 NW 21th Street, Miami, FL 33142	November 19, 2010.
020258NF	Sistemas Aereos LLC, 11027 NW 122nd Street, Medley, FL 33178	November 19, 2010.
020264N	Empire Shipping Co. Inc., 100 East Peddie Street, Newark, NJ 07114	November 6, 2010.
021534N	Martinez Cargo Express, Corp., 8026 Sunport Drive, Units 301–302, Orlando, FL 32809.	November 19, 2010.
021694N	Wheelsky Logistics, Inc., 14515 East Don Julian Road, City of Industry, CA 91746	November 19, 2010.
022244N	Golden Freight, Inc., dba Saigon Express, 510 Parrott Street, Suite 2, San Jose, CA 95112.	November 15, 2010.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2011–576 Filed 1–12–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Rescission of Order of Revocation

Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR Part 515.

License Number: 020667N.

Name: Atlas Logistics (U.S.A.), Inc.

Address: 2401 E. Atlantic Blvd., Suite 310, Pompano Beach, FL 33062.

Order Published: FR: 12/22/10 (Volume 75, No. 245, Pg. 80501).

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2011–575 Filed 1–12–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 28, 2011.

A. Federal Reserve Bank of Atlanta (Clifford Stanford, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. *SG–BBC, LLC, and The Stephens Group, LLC,* both of Little Rock, Arkansas; to acquire voting shares of Brand Group Holdings, Inc., and thereby indirectly acquire voting shares of The Brand Banking Company, both of Lawrenceville, Georgia.

Board of Governors of the Federal Reserve System, January 10, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–599 Filed 1–12–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Meeting

TIME AND DATE: 9 a.m. (Eastern Time), January 25, 2011.

PLACE: 4th Floor Conference Room, 1250 H Street, NW., Washington, DC 20005.

STATUS: Parts will be open to the public and parts closed to the public.

MATTERS TO BE CONSIDERED:

Parts Open to the Public

1. Approval of the minutes of the December 13, 2010 Board member meeting
2. Thrift Savings Plan activity report by the Executive Director
   a. Monthly Participant Activity Report
   b. Quarterly Investment Policy Review
   c. Legislative Report
3. Vendor Financials Report
4. Annual Expense Ratio Review
5. Erroneous Required Minimum Distribution Payment Report
6. TSP Investment Funds DVD Demonstration

Parts Closed to the Public

7. Confidential Financial Information
8. Personnel

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: January 10, 2011.

Thomas K. Emswiler,

Secretary, Federal Retirement Thrift Investment Board.

[FR Doc. 2011–719 Filed 1–11–11; 4:15 pm]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

EXHIBIT D

SUMMARY: The Department of Health and Human Services (HHS) seeks public comment on proposed new guidance which will update and replace the 1962 U.S. Public Health Service Drinking Water Standards related to recommendations for fluoride concentrations in drinking water. The U.S. Public Health Service recommendations for optimal fluoride concentrations were based on ambient air temperature of geographic areas and ranged from 0.7–1.2 mg/L.

HHS proposes that community water systems adjust the amount of fluoride to 0.7 mg/L to achieve an optimal fluoride level. For the purpose of this guidance, the optimal concentration of fluoride in drinking water is that concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. Community water fluoridation is the adjusting and monitoring of fluoride in drinking water to reach the optimal concentration (Truman BI, *et al*, 2002).

This updated guidance is intended to apply to community water systems that are currently fluoridating or will initiate fluoridation.[1] This guidance is based on several considerations that include:

- Scientific evidence related to effectiveness of water fluoridation on caries prevention and control across all age groups.
- Fluoride in drinking water as one of several available fluoride sources.
- Trends in the prevalence and severity of dental fluorosis.
- Current evidence on fluid intake in children across various ambient air temperatures.

DATES: To receive consideration, comments on the proposed recommendations for fluoride concentration in drinking water for the prevention of dental caries should be received no later than February 14, 2011.

ADDRESSES: Comments are preferred electronically and may be addressed to *CWFcomments@cdc.gov*. Written responses should be addressed to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, CWF Comments, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Highway, NE, MS F–10, Atlanta, GA 30341–3717.

FOR FURTHER INFORMATION CONTACT: Barbara F. Gooch, Associate Director for Science (Acting), 770–488–6054, *CWFcomments@cdc.gov*, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention, 4770 Buford Highway, NE., MS F–10, Atlanta, GA 30341–3717.

SUPPLEMENTARY INFORMATION: The U.S. Public Health Service has provided recommendations regarding optimal fluoride concentrations in drinking water from community water systems (CWS)[2] for the prevention of dental caries (US DHEW, 1962). HHS proposes to update and replace these recommendations because of new data that address changes in the prevalence of dental fluorosis, fluid intake among children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. As of December 31, 2008, the Centers for Disease Control and Prevention (CDC) estimated that 16,977 community water systems provided fluoridated water to 196 million people. 95% of the population receiving fluoridated water was served by community water systems that added fluoride to water, or purchased water with added fluoride from other systems. The remaining 5% were served by systems with naturally occurring fluoride at or above the recommended level. More statistics about water fluoridation in the United States are available at *http://www.cdc.gov/fluoridation/statistics/2008stats.htm*. Guidance for systems with naturally occurring fluoride levels above the recommended level are beyond the scope of this document. Systems that have fluoride levels greater than the national primary (4.0 mg/L) or secondary (2.0 mg/L) drinking water standards established by EPA can find more information at the following EPA Web site: *http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm*. CDC's Recommendations for Fluoride Use (CDC, 2001b), available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5014a1.htm*, provides guidance on community water fluoridation and use of other fluoride-containing products.

Recommendation

HHS proposes that community water systems adjust their fluoride content to 0.7 mg/L [parts per million (ppm)].

Rationale

Importance of community water fluoridation:

Community water fluoridation is a major factor responsible for the decline of the prevalence and severity of dental caries (tooth decay) during the second half of the 20th century. From the early 1970's to the present, the prevalence of dental caries in at least one permanent tooth (excluding third molars) among adolescents, aged 12–17 years,[3] has decreased from 90% to 60% and the average number of teeth affected by dental caries (*i.e.*, decayed, missing and filled) from 6.2 to 2.6 (Kelly JE, 1975, Dye B, *et al*, 2007). Adults have also benefited from community water fluoridation. Among adults, aged 35–44 years,[4] the average number of affected teeth decreased from 18 in the early 1960's to 10 among adults, aged 35–49 years, in 1999–2004 (Kelly JE, *et al*, 1967; Dye B, *et al*, 2007). Although there have been notable declines in tooth decay, it remains one of the most common chronic diseases of childhood (USDHHS, 2000; Newacheck PW *et al*, 2000). Effective population-based interventions to prevent and control dental caries, such as community water fluoridation, are still needed (CDC, 2001a).

Systematic reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity (McDonagh MS, *et al*, 2000a, McDonagh MS, *et al*, 2000b, Truman BI, *et al*, 2002, Griffin SO, *et al*, 2007). Effects included significant increases in the proportion of children who were caries-free and significant reductions in the number of teeth or tooth surfaces with caries in both children and adults (McDonagh MS, *et al*, 2000b, Griffin SO, *et al*, 2007). When analyses were limited to studies

[1] Community water fluoridation of public drinking water systems has been demonstrated to be effective in reducing caries and producing cost-savings from a societal perspective. (Truman B *et al*, 2002). If local goals and resources permit, the use of this intervention should be continued, initiated, or increased (CDC 2001a).

[2] For purposes of this guidance, a water system is considered a community water system if so designated by the State drinking water administrator in accordance with the regulatory requirements of the U.S. Environmental Protection Agency. In general, public water systems provide water for human consumption through pipes or other constructed conveyances to at least 15 service connections or serves an average of at least 25 people for at least 60 days a year. A community water system is a public water system that supplies water to the same population year-round, *http://water.epa.gov/infrastructure/drinkingwater/pws/factoids.cfm*.

[3] There were slight differences in the age groups used in both surveys. The 1971–1974 survey reported on adolescents aged 12–17 years (Kelly JE, 1975) while the 1999–2004 survey reported on adolescents and youths aged 12–19 years (Dye B, *et al.*, 2007). Because the prevalence of dental caries increases with age, the estimates for 12–17 year olds in the most recent survey (1999–2004) should be slightly lower than those published for 12–19 year olds (Dye B, *et al*, 2007).

[4] There were slight differences in the age groups used in both surveys. The 1962 survey reported on adults aged 35–44 years (Kelly JE *et al* 1967) while the 1999–2004 survey reported on adults aged 35–49 years (Dye B, *et al*, 2007).

conducted after the introduction of other sources of fluoride, especially fluoride toothpaste, beneficial effects across the lifespan from community water fluoridation were still apparent (McDonagh MS, *et al*, 2000b; Griffin SO, *et al*, 2007).

Fluoride works primarily to prevent dental caries through topical remineralization of tooth surfaces when small amounts of fluoride, specifically in saliva and accumulated plaque, are present frequently in the mouth (Featherstone JDB, 1999). Consuming fluoridated water and beverages and foods prepared or processed with fluoridated water routinely introduces a low concentration of fluoride into the mouth. Although other fluoride-containing products 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 (CDC, 1999, Burt BA, 1989). Studies continue to find that community water fluoridation is cost-saving (Truman B, *et al*, 2002).

Trends in Availability of Fluoride Sources

Community water fluoridation and fluoride toothpaste are the most common sources of non-dietary fluoride in the United States (CDC, 2001b). Community water fluoridation began in 1945, reaching almost 50% of the U.S. population by 1975 and 64% by 2008, *http://www.cdc.gov/fluoridation/statistics/2008stats.htm*; *http://www.cdc.gov/fluoridation/pdf/statistics/1975.pdf*. Toothpaste containing fluoride was first marketed in the United States in 1955 (USDHEW, 1980) and by the 1990's accounted for more than 90 percent of the toothpaste market (Burt BA and Eklund SA, 2005). Other products that provide fluoride now include mouthrinses, fluoride supplements, and professionally applied fluoride compounds. More detailed explanations of these products are published elsewhere (CDC, 2001b) (ADA, 2006) (USDHHS, 2010). More information on all sources of fluoride and their relative contribution to total fluoride exposure in the United States is presented in a report by EPA (US EPA 2010a).

Dental Fluorosis

Fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel (Aoba T and Fejerskov O, 2002). Changes range from barely visible lacy white markings in milder cases to pitting of the teeth in the rare, severe form. The period of possible risk for fluorosis in the permanent teeth, excluding the third molars,[5] extends from about birth through 8 years of age when the preeruptive maturation of tooth enamel is complete (CDC, 2001b; Massler M and Schour I, 1958). When communities first began adding fluoride to their public water systems in 1945, drinking water and foods and beverages prepared with fluoridated water were the primary sources of fluoride for most children (McClure FJ, 1943). Since the 1940's, other sources of ingested fluoride, such as fluoride toothpaste (if swallowed) and fluoride supplements, have become available. Fluoride intake from these products, in addition to water and other beverages and infant formula prepared with fluoridated water, have been associated with increased risk of dental fluorosis (Levy SL, *et al*, 2010, Wong MCM, *et al*, 2010, Osuji OO *et al*, 1988, Pendrys DG *et al*, 1994, Pendrys DG and Katz RV 1989, Pendrys DG, 1995). Both the 1962 USPHS recommendations and the current proposal for fluoride concentrations in community drinking water were set to achieve a reduction in dental caries while minimizing the risk of dental fluorosis.

Results of two national surveys indicate that the prevalence of dental fluorosis has increased since the 1980's, but mostly in the very mild or mild forms. The most recent data on prevalence of dental fluorosis come from the National Health and Nutrition Examination Survey (NHANES), 1999–2004. NHANES assessed the prevalence and severity of dental fluorosis among persons, aged 6 to 49 years. Twenty-three percent had dental fluorosis of which the vast majority was very mild or mild. Approximately 2% of persons had moderate dental fluorosis, and less than 1% had severe. Prevalence was higher among younger persons and ranged from 41% among adolescents aged 12–15 years to 9% among adults, aged 40–49 years. The higher prevalence of dental fluorosis in the younger persons probably reflects the increase in fluoride exposures across the U.S. population through community water fluoridation and increased use of fluoride toothpaste.

The prevalence and severity of dental fluorosis among 12–15 year olds in 1999–2004 were compared to estimates from the Oral Health of United States Children Survey, 1986–87, which was the first national survey to include measures of dental fluorosis. Although these two national surveys differed in sampling and representation (schoolchildren versus household), findings support the hypothesis that there has been an increase in dental fluorosis that was very mild or greater between the two surveys. In 1986–87 and 1999–2004 the prevalence of dental fluorosis was 23% and 41%, respectively, among adolescents aged 12 to 15. (Beltrán-Aguilar ED, *et al*, 2010a). Similarly, the prevalence of very mild fluorosis (17.2% and 28.5%), mild fluorosis (4.1% and 8.6%) and moderate and severe fluorosis combined (1.3% and 3.6%) have increased. The estimates for severe fluorosis for adolescents in both surveys were statistically unreliable because of too few cases in the samples.

More information on fluoride concentrations in drinking water and the impact of severe dental fluorosis in children is presented in a report by EPA (US EPA 2010 b).

Relationship between dental caries and fluorosis at varying water fluoridation concentrations:

The 1986–87 Oral Health of United States Children Survey is the only national survey that measured the child's water fluoride exposure and can link that exposure to measures of caries and fluorosis (U.S. DHHS, 1989). An additional analysis of data from this survey examined the relationship between dental caries and fluorosis at varying water fluoride concentrations for children aged 6 to 17 years (Heller KE, *et al*, 1997). Findings indicate that there was a gradual decline in dental caries as fluoride content in water increased from negligible to 0.7 mg/L. Reductions plateaued at concentrations from 0.7 to 1.2 mg/L. In contrast, the percentage of children with at least very mild dental fluorosis increased with increasing fluoride concentrations in water. The published report did not report standard errors.

In Hong Kong a small change of about 0.2 mg/L[6] in the mean fluoride concentration in drinking water in 1978 was associated with a detectable reduction in fluorosis prevalence by the

[5] Risk for the third molars (*i.e.*, wisdom teeth) extends to age 14 years (Massler M, 1958). Third molars are much less likely than other teeth to erupt fully into a functional position due to space constraints in the dental arch and may be impacted, partially erupted, or extracted. For these reasons third molars are not assessed for dental caries or dental fluorosis in national surveys in the U.S. In addition, based on their placement, these teeth are unlikely to be of aesthetic concern.

[6] Fluoride concentrations in drinking water before and after the 1978 reduction were 0.82 and 0.64 mg F/L, respectively.

mid 1980's[7] (Evans R.W, Stamm JW., 1991). Across all age groups more than 90% of fluorosis cases were very mild or mild. (Evans R.W, Stamm JW., 1991). The study did not include measures of fluoride intake. Concurrently, dental caries prevalence did not increase. (Lo ECM *et al*, 1990). Although not fully generalizable to the current U.S. context, these findings, along with those from the 1986–87 survey of U.S. schoolchildren, suggest that risk of fluorosis can be reduced and caries prevention maintained toward the lower end (*i.e.*, 0.7 mg/L) of the 1962 USPHS recommendations for fluoride concentrations for community water systems.

Relationship of fluid intake and ambient temperature among children and adolescents in the United States:

The 1962 USPHS recommendations stated that community drinking water should contain 0.7–1.2 mg/L [ppm] fluoride, depending on the ambient air temperature of the area. These temperature-related guidelines were based on studies conducted in two communities in California in the early 1950's. Findings indicated that a lower fluoride concentration was appropriate for communities in warmer climates because children drank more tap water on warm days (Galagan DJ, 1953; Galagan DJ and Vermillion JR, 1957; Galagan DJ *et al*, 1957). Social and environmental changes, including increased use of air conditioning and more sedentary lifestyles, have occurred since the 1950's, and thus, the assumption that children living in warmer regions drink more tap water than children in cooler regions may no longer be valid.

Studies conducted since 2001 suggest that fluid intake in children does not increase with increases in ambient air temperature (Sohn W, *et al*, 2001; Beltrán-Aguilar ED, *et al*, 2010b). One study conducted among children using nationally representative data from 1988 to 1994 did not find an association between fluid intake and ambient air temperature (Sohn W, *et al*, 2001). A similar study using nationally representative data from 1999 to 2004 also found no association between fluid intake and ambient temperature among children or adolescents (Beltrán-Aguilar ED, *et al*, 2010b). These recent findings demonstrating a lack of an association between fluid intake among children and adolescents and ambient temperature support use of a single target concentration for community water fluoridation in all temperature zones of the United States.

Conclusions

HHS recommends an optimal fluoride concentration of 0.7 mg/L for community water systems based on the following information:

- Community water fluoridation is the most cost-effective method of delivering fluoride for the prevention of tooth decay;
- 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;
- 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 USPHS recommendation.
- 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.

Surveillance Activities

CDC and the National Institute of Dental and Craniofacial Research (NIDCR), in coordination with other Federal agencies, will enhance surveillance of dental caries, dental fluorosis, and fluoride intake with a focus on younger populations at higher risk of fluorosis to obtain the best available and most current information to support effective efforts to improve oral health.

Process

The U.S. Department of Health and Human Services (HHS) convened a Federal inter-departmental, inter-agency panel of scientists (Appendix A) to review scientific evidence related to the 1962 USPHS Drinking Water Standards related to recommendations for fluoride concentrations in drinking water in the United States and to update these proposed recommendations. Panelists included representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, the U.S. Environmental Protection Agency, and the U.S. Department of Agriculture. The panelists evaluated existing recommendations for fluoride in drinking water, systematic reviews of the risks and benefits from fluoride in drinking water, the epidemiology of dental caries and fluorosis in the U.S., and current data on fluid intake in children, aged 0 to 10 years, across temperature gradients in the U.S. Conclusions were reached and are summarized along with their rationale in this proposed guidance document. This guidance will be advisory, not regulatory, in nature. Guidance will be submitted to the **Federal Register** and will undergo public and stakeholder comment for 30 days, after which HHS will review comments and consider changes.

Dated: January 7, 2011.

Kathleen Sebelius,

Secretary.

[7] Fluorosis prevalence ranged from 64% (SE = 4.1) to 47% (SE = 4.5) based on the upper right central incisor only.

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U.S. EPA (U.S. Environmental Protection Agency). 2010b. *Fluoride: Dose-response Analysis for Non-cancer Effects.* Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, Washington, DC. EPA 820–R–10–019. Available at: *http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm.* Comments regarding the document, *Fluoride: Dose-response Analysis for Non-cancer Effects,* should be sent to EPA at *FluorideScience@epa.gov.*

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Appendix A—HHS Federal Panel on Community Water Fluoridation

Peter Briss, MD, MPH—Panel Chair, Medical Director, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Laurie K. Barker, MSPH, Statistician, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Eugenio Beltrán-Aguilar, DMD, MPH, DrPH, Senior Epidemiologist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Mary Beth Bigley, DrPH, MSN, ANP, Acting Director, Office of Science and Communications, Office of the Surgeon General, U.S. Department of Health and Human Services.

Linda Birnbaum, PhD, DABT, ATS, Director, National Institute of Environmental Health Sciences and National Toxicology Program, National Institutes of Health, U.S. Department of Health and Human Services.

John Bucher, PhD, Associate Director, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services.

Amit Chattopadhyay, PhD, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services.

Joyce Donohue, PhD, Health Scientist, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency.

Elizabeth Doyle, PhD, Chief, Human Health Risk Assessment Branch, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency.

Isabel Garcia, DDS, MPH, Acting Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services.

Barbara Gooch, DMD, MPH, Acting Associate Director for Science, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Jesse Goodman, MD, MPH, Chief Scientist and Deputy Commissioner for Science and Public Health, Food and Drug Administration, U.S. Department of Health and Human Services.

J. Nadine Gracia, MD, MSCE, Chief Medical Officer, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

Susan O. Griffin, PhD, Health Economist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Laurence Grummer-Strawn, PhD, Chief, Maternal and Child Nutrition Branch, Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Jay Hirschman, MPH, CNS, Director, Special Nutrition Staff, Office of Research and Analysis, Food and Nutrition Service, U.S. Department of Agriculture.

Frederick Hyman, DDS, MPH, Division of Dermatology and Dental Products, Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services.

Timothy Iafolla, DMD, MPH, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services.

William Kohn, DDS, Director, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Richard Manski, DDS, MBA, PhD, Senior Scholar, Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

Benson Silverman, MD, Staff Director, Infant Formula and Medical Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services.

Thomas Sinks, PhD, Deputy Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

[FR Doc. 2011–637 Filed 1–12–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a public meeting. The meeting is open to the public.

DATES: The NBSB will hold a public meeting on January 25, 2011 from 1:15 p.m. to 3 p.m. ET. The agenda is subject to change as priorities dictate.

ADDRESSES: Department of Health and Human Services; Hubert H. Humphrey Building, Room 800; 200 Independence Avenue, SW., Washington, DC 20201. To attend by teleconference, call 1–866–395–4129, pass-code "ASPR." Please call 15 minutes prior to the beginning of the conference call to facilitate attendance. Pre-registration is required for public attendance. Individuals who wish to attend the meeting in person should send an email to *NBSB@HHS.GOV* with "NBSB Registration" in the subject line.

FOR FURTHER INFORMATION CONTACT: E-mail: *NBSB@HHS.GOV*.

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (*42 U.S.C. 247d–7f*) and section 222 of the Public Health Service Act (*42 U.S.C. 217a*), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response on other matters related to public health emergency preparedness and response.

Background: A portion of this public meeting will be dedicated to swearing in the six new voting members who will replace the members whose 3-year terms expired on December 31, 2010. The Board will be asked to consider the various components of a science response to disasters. Subsequent agenda topics will be added as priorities dictate.

Availability of Materials: The meeting agenda and materials will be posted on the NBSB Web site at *http://www.phe.gov/Preparedness/legal/boards/nbsb/Pages/default.aspx* prior to the meeting.

Procedures for Providing Public Input: Any member of the public providing oral comments at the meeting must sign-in at the registration desk and provide his/her name, address, and affiliation. All written comments must be received prior to January 18, 2011 and should be sent by e-mail to *NBSB@HHS.GOV* with "NBSB Public Comment" as the subject line. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should e-mail *NBSB@HHS.GOV*.

Dated: January 7, 2011.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2011–684 Filed 1–12–11; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Federal Agency Responses to Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Recommendations on Two Nonradioactive Versions of the Murine Local Lymph Node Assay (LLNA) for Assessing Allergic Contact Dermatitis (ACD) Hazard Potential of Chemicals and Products, and Expanded Uses of the LLNA for Pesticide Formulations and Other Products; Notice of Availability

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

ACTION: Notice of Availability.

SUMMARY: U.S. Federal agency responses to ICCVAM test method recommendations on two nonradioactive versions of the LLNA for assessing the ACD hazard potential of chemicals and products and for expanded uses of the LLNA for pesticide formulations and other products are now available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/immunotox/llna.htm*. ICCVAM recommended the nonradioactive LLNA: 5-bromo-2-deoxyuridine-enzyme-linked immunosorbent assay

collection contact Memuna Ifedirah at 410–786–6849).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations; *Use:* Psychiatric residential treatment facilities are required to report deaths, serious injuries and attempted suicides to the State Medicaid Agency and the Protection and Advocacy Organization. They are also required to provide residents the restraint and seclusion policy in writing, and to document in the residents' records all activities involving the use of restraint and seclusion. *Form Number:* CMS–R–306 (OMB Control Number 0938–0833); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 390; *Total Annual Responses:* 1,466,795; *Total Annual Hours:* 431,062. (For policy questions regarding this collection contact Cindy Ruff at 410–786–5916).

Dated: April 28, 2015.

William N. Parham III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–10207 Filed 4–30–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Venkata J. Reddy, University of Minnesota: Based upon the evidence and findings of an investigation report by the University of Minnesota (UMN), an investigation conducted by another Federal agency, and additional information obtained by the Office of Research Integrity (ORI) during its oversight review of the UMN investigation, ORI found that Mr. Venkata J. Reddy, former Graduate Student, Department of Chemistry, UMN, engaged in research misconduct in research that was included in grant application R01 GM095559–01A1, submitted to the National Institute of General Medical Sciences (NIGMS), [illegible]s of Health (NIH).

ORI found by a preponderance of the evidence that the Respondent intentionally and knowingly engaged in research misconduct by falsifying and/or fabricating data that was provided to his mentor to include in grant application R01 GM095559–01A1 submitted to NIGMS, NIH, to obtain U.S. Public Health Service (PHS) funds. Specifically, ORI found that the Respondent falsified data included in Figures 4, 9, 11, 15, and 25 in R01 GM095559–01A1 for enantiomeric excess ("ee") to falsely show a high degree of selectivity for one enantiomer over another by a cut-and-paste method and manipulation of the instrument to give the desired result. Respondent also falsified the underlying nuclear magnetic resonance spectroscopy (NMR) data for Compound 22 reported in Figure 15 in R01 GM095559–01A1 by a cut-and-paste method to manipulate the NMR spectra and give the desired result.

Dr. Reddy has been debarred by the Federal agency with joint jurisdiction for a period of five (5) years, ending on August 26, 2018. ORI has implemented the following administrative action to coincide with the government-wide debarment:

(1) Respondent is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

Donald Wright,

Acting Director, Office of Research Integrity.

[FR Doc. 2015–10203 Filed 4–30–15; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries

AGENCY: Office of the Secretary, HHS.

SUMMARY: Through this final recommendation, the U.S. Public Health Service (PHS) updates and replaces its 1962 Drinking Water Standards related to community water fluoridation—the controlled addition of a fluoride compound to a community water supply to achieve a concentration optimal for dental caries prevention. For these community water systems that add fluoride, PHS now recommends an optimal fluoride concentration of 0.7 milligrams/liter (mg/L). In this guidance, the optimal concentration of fluoride in drinking water is the concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. The earlier PHS recommendation for fluoride concentrations was based on outdoor air temperature of geographic areas and ranged from 0.7–1.2 mg/L. This updated guidance is intended to apply to community water systems that currently fluoridate or that will initiate fluoridation, and is based on considerations that include:

- Scientific evidence related to the effectiveness of water fluoridation in caries prevention and control across all age groups,
- Fluoride in drinking water as one of several available fluoride sources,
- Trends in the prevalence and severity of dental fluorosis, and
- Current evidence on fluid intake of children across various outdoor air temperatures.

FOR FURTHER INFORMATION CONTACT: Barbara F. Gooch, DMD, MPH, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health, 4770 Buford Highway NE., MS F–80, Atlanta, GA 30341–3717; tel. 770–488–6054; fax 770–488–6080; email <*BGooch@cdc.gov*>.

SUPPLEMENTARY INFORMATION: Because fluoridation of public drinking water systems had been demonstrated as effective in reducing dental caries, the U.S. Public Health Service (PHS) provided recommendations regarding optimal fluoride concentrations in drinking water for community water systems in 1962 (U.S. DHEW, 1962). The U.S. Department of Health and Human Services (HHS) is releasing this updated PHS recommendation because of new data that address changes in the prevalence of dental fluorosis, the relationship between water intake and outdoor temperature in children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. Although PHS recommends community water fluoridation as an effective public health intervention, the decision to fluoridate water systems is made by state and local governments.

As of December 31, 2012, the Centers for Disease Control and Prevention (CDC) estimated that approximately 200 million people in the United States were served by 12,341 community water systems that added fluoride to water or

purchased water with added fluoride from other systems. For many years, nearly all of these fluoridated systems used fluoride concentrations ranging from 0.8 to 1.2 mg/L; fewer than 1% of these systems used a fluoride concentration at 0.7 mg/L (Unpublished data, Water Fluoridation Reporting System, CDC, 2010). When water systems that add fluoride implement the new PHS recommendation (0.7 mg/L), the fluoride concentration in these systems will be reduced by 0.1 to 0.5 mg/L and fluoride intake from water will decline among most people served by these systems.

It is expected that implementation of the new recommendation will lead to a reduction of approximately 25% (range: 12%–42%) in fluoride intake from drinking water alone and a reduction of approximately 14% (range: 5%–29%) in total fluoride intake. These estimates are based on intake among young children at the 90th percentile of drinking water intake for whom drinking water accounts for 40%–70% of total fluoride intake (U.S. EPA, 2010a). Furthermore, these estimates are based on a weighted mean fluoride concentration of 0.94 mg/L in systems that added fluoride (or purchased water from systems that added fluoride) in 2009 (Unpublished data, Water Fluoridation Reporting System, CDC, 2009). Community water systems that contain naturally occurring fluoride at concentrations greater than 0.7 mg/L (estimated to serve about 11 million people) will not be directly affected by the new PHS recommendation.

Under the Safe Drinking Water Act, the U.S. Environmental Protection Agency (EPA) sets standards for drinking water quality (*42 U.S.C.* 300f *et seq.* (1974)). EPA is in the process of reviewing the maximum amount of fluoride allowed in drinking water. Upon completion of its review, EPA will determine if it is appropriate to revise the drinking water standard for fluoride. Currently, the enforceable standard is set at 4.0 mg/L to protect against severe skeletal fluorosis, a rare condition in the United States (NRC, 2006; U.S. EPA, 2010b). If the EPA determines that it is appropriate to revise the standard, any revisions could affect certain community water systems that have naturally occurring fluoride. More information about EPA's existing drinking water standards for fluoride can be found at: *http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm.*

Recommendation

For community water systems that add fluoride to their water, PHS recommends a fluoride concentration of 0.7 mg/L (parts per million [ppm]) to maintain caries prevention benefits and reduce the risk of dental fluorosis.

Rationale

Importance of Community Water Fluoridation

Community water fluoridation is a major factor responsible for the decline in prevalence (occurrence) and severity of dental caries (tooth decay) during the second half of the 20th century (CDC, 1999). For adolescents, the prevalence of dental caries in at least one permanent tooth (excluding third molars) decreased from 90% among those aged 12–17 years in the 1960's (Kelly JE, 1975) to 60% among those aged 12–19 years in 1999–2004 (Dye B, *et al.*, 2007); during that interval, the number of permanent teeth affected by dental caries (*i.e.*, decayed, missing and filled) declined from 6.2 to 2.6, respectively. Adults also have benefited from community water fluoridation; the average number of affected teeth decreased from 18 among 35- to 44-year-old adults in the 1960s to 10 among 35- to 49-year-old adults in 1999–2004 (Kelly JE, *et al.*, 1973; Dye B, *et al.*, 2007). Although data were not age-adjusted, age groups in the 1999–2004 survey used a higher upper age limit, and both caries prevalence and number of teeth affected increased with age; thus, these comparisons may underestimate caries decline over time.

Although there have been notable declines in tooth decay, it remains one of the most common chronic diseases of childhood (U.S. DHHS, 2000; Newacheck PW *et al.*, 2000). In 2009–2010, national survey data showed that untreated dental caries among children varied by race/ethnicity and federal poverty level. About one in four children living below 100% of the federal poverty level had untreated decay (Dye BA *et al.*, 2012). Untreated tooth decay can result in pain, school absences, and poorer school performance (Lewis C, *et al.*, 2010; Detty AMR, *et al.*, 2014; Jackson SL, *et al.*, 2011; Seirawan H, *et al.*, 2012).

Systematic reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity (McDonagh MS, *et al.*, 2000a; McDonagh MS, *et al.*, 2000b; Truman BI, *et al.*, 2002; ARCPOH 2006; Griffin SO, *et al.*, 2007; Yeung, 2008; CPSTF, 2013). Effects included significant increases in the proportion of children who were caries-free and significant reductions in the number of teeth or tooth surfaces with caries in both children and adults (McDonagh MS, *et al.*, 2000b; ARCPOH 2006; Griffin SO, *et al.*, 2007; Yeung, 2008; CPSTF, 2013). When analyses were limited to studies conducted after the introduction of other sources of fluoride, especially fluoride toothpaste, beneficial effects across the lifespan from community water fluoridation were still apparent (McDonagh MS, *et al.*, 2000b; Griffin SO, *et al.*, 2007; Slade, *et al.*, 2013).

Fluoride in saliva and dental plaque works to prevent dental caries primarily through topical remineralization of tooth surfaces (Koulourides T, 1990; Featherstone JDB, 1999). Consuming fluoridated water and beverages, and foods prepared or processed with fluoridated water, throughout the day maintains a low concentration of fluoride in saliva and plaque that enhances remineralization. Although other fluoride-containing products 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 (CDC, 1999; Burt BA, 1989). Studies continue to find that community water fluoridation is cost-saving (Truman B, *et al.*, 2002; O'Connell JM, *et al.*, 2005; Campain AC, *et al.*, 2010; Cobiac LJ and Vos T, 2012).

Trends in Availability of Fluoride Sources

Community water fluoridation and fluoride toothpaste are the most common sources of non-dietary fluoride in the United States (CDC, 2001b). Community water fluoridation began in 1945, reaching 49% of the U.S. population by 1975 and 67% by 2012 (*http://www.cdc.gov/fluoridation/statistics/2012stats.htm; http://www.cdc.gov/nohss/FSGrowth_text.htm*). Toothpaste containing fluoride was first marketed in the United States in 1955 (USDHEW, 1980). By 1983, more than 90% of children and adolescents 5–19 years of age, and almost 70% of young children 2–4 years of age, reportedly used fluoride toothpaste (Ismail AI, *et al*, 1987). By 1986, more than 90% of young children 2–4 years of age also were reported to use fluoride toothpaste (NCHS, 1988). And by the 1990s, fluoride toothpaste accounted for more than 90 percent of the toothpaste market (Burt BA and Eklund SA, 2005). Other products that provide fluoride now include mouth rinses, dietary fluoride supplements, and professionally applied fluoride compounds. More detailed explanations

of these products are published elsewhere. (CDC, 2001b; ADA, 2006; USDHHS, 2010)

More information on major sources of ingested fluoride and their relative contributions to total fluoride exposure in the United States is presented in an EPA report (U.S. EPA 2010a). To protect the majority of the population, EPA uses the 90th percentile of drinking water intake for all age groups in calculating the relative contribution for each fluoride source. The EPA definition of "drinking water" includes tap water ingested alone or with beverages and certain foods reconstituted in the home. Among children aged 6 months to 14 years, drinking water accounts for 40%–70% of total fluoride intake; for adults, drinking water provides 60% of total fluoride intake. Toothpaste that has been swallowed inadvertently is estimated to account for about 20 percent of total fluoride intake in very young children (1–3 years of age) (U.S. EPA 2010a). Other major contributors to total daily fluoride intake are commercial beverages and solid foods.

Dental Fluorosis

Fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel called dental fluorosis. Changes range from barely visible lacy white markings in milder cases to pitting of the teeth in the rare, severe form. The period of possible risk for fluorosis in the permanent teeth, excluding the third molars, extends from birth through 8 years of age when the pre-eruptive maturation of tooth enamel is complete (CDC, 2001b; Massler M and Schour I, 1958; Avery, 1987). The risk for and severity of dental fluorosis depends on the amount, timing, frequency, and duration of the exposure (CDC, 2001b). When communities first began adding fluoride to their public water systems in 1945, drinking water and local foods and beverages prepared with fluoridated water were the primary sources of fluoride for most children (McClure FJ, 1943; U.S. EPA, 2010b). At that time, only a few systems fluoridated their water, minimizing the amount of fluoride contributed by processed water to commercial foods and beverages. Since the 1940s, other sources of ingested fluoride such as fluoride toothpaste (if swallowed) and dietary fluoride supplements have become available. Fluoride intake from these products, in addition to water, other beverages, and infant formula prepared with fluoridated water, have been associated with increased risk of dental fluorosis (Levy SL, *et al.*, 2010; Wong MCM, *et al.*, 2010; Ismail AI and Hasson H, 2008; Osuji OO *et al.*, 1988; Pendrys DG *et al.*, 1994; Pendrys DG and Katz RV 1989; Pendrys DG, 1995). Both the 1962 PHS recommendations and the current updated recommendation for fluoride concentration in community drinking water were set to achieve reduction in dental caries while minimizing the risk of dental fluorosis.

Results of two national surveys indicate that the prevalence of dental fluorosis has increased since the 1980s, but mostly in very mild or mild forms. Data on prevalence of dental fluorosis come from the National Health and Nutrition Examination Survey (NHANES), 1999–2004 (Beltrán-Aguilar ED, *et al.*, 2010a). NHANES assessed the prevalence and severity of dental fluorosis among people aged 6 to 49 years. Twenty-three percent (95% confidence interval [CI]: 20.1, 26.1) had dental fluorosis, of which the vast majority was very mild or mild. Approximately 2% (95% CI: 1.5, 2.5) of people had moderate dental fluorosis, and less than 1% (95% CI: 0.1, 0.4) had severe fluorosis. Prevalence of dental fluorosis that was very mild or greater was higher among young people and ranged from 41% (95% CI: 36.3, 44.9) among adolescents aged 12–15 years to 9% (95% CI: 6.1, 11.4) among adults, aged 40–49 years.

The prevalence and severity of dental fluorosis among 12- to 15-year-olds in 1999–2004 also were compared with estimates from the Oral Health of United States Children survey, 1986–1987 (USDHHS, 1989), which was the first national survey to include measures of dental fluorosis. Although these two national surveys differed in sampling and representation (household vs. schoolchildren), findings support the hypothesis that there was an increase in dental fluorosis that was very mild or greater during the time between the two surveys. In 1986–1987 and 1999–2004, the prevalence of dental fluorosis was 23% and 41%, respectively, among adolescents aged 12 to 15 years. (Beltrán-Aguilar ED, *et al.*, 2010a). Similarly, the prevalence of very mild fluorosis (17.2% and 28.5%), mild fluorosis (4.1% and 8.6%), and moderate and severe fluorosis combined (1.3% and 3.6%) among 12- to 15-year-old adolescents during 1986–1987 and 1999–2004, respectively, all showed increases. Estimates limited to severe fluorosis among adolescents in both surveys, however, were statistically unreliable because there were too few cases among survey participants examined. The higher prevalence of dental fluorosis in young people in 1999–2004 may reflect increases in fluoride exposures (intake) across the U.S. population.

Children are at risk for fluorosis in the permanent teeth from birth through 8 years of age. Adolescents who were 12–15 years of age when they participated in the national surveys of 1986–1987 and 1999–2004 would have been at risk for dental fluorosis from 1971–1983 and from 1984–2000, respectively.

By 1969, the percentage (number) of the U.S. population receiving fluoridated water was 44% (88,475,684). By 1985, this percentage (number) increased about 10 percentage points, reaching 55% (130,172,334). By 2000, this percentage (number) was 57% (161,924,080). Although the percentage point increases in more recent years appear small (2 percentage points from 1985 to 2000), it is important to note that the total size of the U.S. population also continued to expand during the time period. As a result, the 10-percentage-point increase from 1969 to 1985 reflects an increase of more than 40 million people receiving fluoridated water whereas the 2-percentage-point increase from 1985 to 2000 represents an increase of more than 30 million people.

Available data do not support additional detailed examination of changes in the percentage of children and adolescents using fluoride toothpaste. As previously described in Trends in Availability of Fluoride Sources, by 1983, more than 90% of children and adolescents, 5–19 years, and almost 70% of young children, 2–4 years of age, were reportedly using fluoride toothpaste (Ismail AI, *et al.*, 1987); by 1986 more than 90% of young children were also using fluoride toothpaste (NCHS, 1988). As mentioned, recent EPA estimates indicate that toothpaste swallowed inadvertently accounts for about 20 percent of total fluoride intake in very young children (U.S. EPA 2010a).

More information on fluoride concentrations in drinking water and the risk of severe dental fluorosis in children is presented in a report by EPA (U.S. EPA 2010b). EPA's scientific assessments considered new data on dental fluorosis and updated exposure estimates to reflect current conditions. Based on original data from a study that predated widespread water fluoridation in the United States, EPA determined that the benchmark dose for a 0.5% prevalence of severe dental fluorosis was a drinking water fluoride concentration of 2.14 mg/L, with a lower 95% CI of 1.87 mg/L (U.S. EPA 2010b). Categorical regression modeling (U.S. EPA, 2011 presentation) also indicated that the concentration of

fluoride in water associated with a 1% prevalence of severe dental fluorosis decreased over time (1940–2000). These findings are consistent with an increase in exposures from other sources of fluoride and support the conclusion that a fluoride concentration in drinking water of 0.7 mg F/L would reduce the chance of dental fluorosis—especially severe dental fluorosis—in the current context of multiple fluoride sources.

The two EPA assessments of fluoride (U.S. EPA, 2010a; U.S. EPA, 2010b) responded to earlier findings of the National Research Council (NRC) of the National Academies of Science (NRC, 2006). The NRC had reviewed new data on fluoride at EPA's request and in 2006 recommended that EPA update health and exposure assessments to consider all sources of fluoride and to take into account dental effects—specifically, pitting of teeth (*i.e.*, severe dental fluorosis) in children. The NRC identified severe dental fluorosis as an adverse health effect, because pitting of the enamel compromises its protective function. The NRC's report focused on the potential for adverse effects from naturally occurring fluoride at 2–4 mg/L in drinking water; it did not examine benefits or risks that might occur at lower concentrations typically used for community water fluoridation (0.7 to 1.2 mg/L) (NRC, 2006). For this PHS recommendation, Panel scientists did review the balance of benefits and potential for unwanted effects of water fluoridation at those lower levels (U.S. EPA, 2010b).

Relationship Between Dental Caries and Fluorosis at Varying Water Fluoridation Concentrations

The 1986–1987 Oral Health of United States Children survey has been the only national survey that assessed the child's water fluoride exposure, thus allowing linkage of that exposure to measures of caries and fluorosis (USDHHS, 1989). An additional analysis of data from this survey examined the relationship between dental caries and fluorosis at varying water fluoride concentrations for children and adolescents (Heller KE, *et al.*, 1997). Findings indicate that there was a gradual decline in dental caries as fluoride content in water increased from negligible to 0.7 mg/L. Reductions plateaued at concentrations from 0.7–1.2 mg/L. In contrast, the percentage of children with at least very mild dental fluorosis increased from 13.5% (standard error [SE] = 1.9) to 41.4% (SE = 4.4) as fluoride concentrations in water increased from <0.3 mg/L to >1.2 mg/L.

In Hong Kong, a small decrease of about 0.2 mg/L in the mean fluoride concentration in drinking water in 1978 (from 0.82 mg/L to 0.64 mg/L) was associated with a detectable reduction in fluorosis prevalence by the mid-1980s, from 64% (SE = 4.1) to 47% (SE = 4.5), based on the upper right central incisor only. Across all age groups, more than 90 percent of fluorosis cases were very mild or mild (Evans RW and Stamm JW, 1991). The study did not include measures of fluoride intake. Concurrently, dental caries prevalence did not increase (Lo ECM, *et al.*, 1990). Although not fully generalizable to the current U.S. context, these findings, along with findings from the 1986–1987 survey of U.S. schoolchildren, suggest that the risk of fluorosis can be reduced and caries prevention maintained toward the lower end (*i.e.*, 0.7 mg/L) of the 1962 PHS recommendations for community water fluoridation.

Relationship of Water Intake and Outdoor Temperature Among Children and Adolescents in the United States

The 1962 PHS recommendations stated that community drinking water should contain 0.7–1.2 mg/L (ppm) fluoride, depending on the outdoor air temperature of the area. These temperature-related guidelines were based on studies conducted in two communities in California in the early 1950s. Findings indicated that a lower fluoride concentration was appropriate for communities in warmer climates because children drank more water on warm days (Galagan DJ, 1953; Galagan DJ and Vermillion JR, 1957; Galagan DJ, *et al.*, 1957). Social and environmental changes, including increased use of air conditioning and more sedentary lifestyles, have occurred since the 1950s—thus, the assumption that children living in warmer regions drink more tap water than children in cooler regions may no longer be valid (Heller, *et al.*, 1999).

Studies conducted since 2001 suggest that children's water intake does not increase with increases in outdoor air temperature (Sohn W, *et al.*, 2001; Beltrán-Aguilar ED, *et al.*, 2010b). One study conducted among children using nationally representative data from NHANES 1988–1994 did not find an association between either total or plain water intake and outdoor air temperature (Sohn W, *et al.*, 2001). Although a similar study using nationally representative data from NHANES 1999–2004 also found no association between total water intake and outdoor temperature among children or adolescents (Beltrán-Aguilar ED, *et al.*, 2010b), additional analyses of these data detected a small but statistically significant association between plain water intake and outdoor temperature (Beltrán-Aguilar ED, *et al.*, manuscript for Public Health Reports). Temperature explained less than 1% of the variation in plain water intake; thus, these findings support use of one target concentration for community water fluoridation in all temperature zones of the United States, a standard far simpler to implement than the 1962 temperature-based recommendations. In these analyses, "plain water" was defined as from the tap or bottled water and "total water" included water from or mixed with other beverages, such as juice, soda, sport drinks, and non-dairy milk, as well as water from or mixed with foods (Beltrán-Aguilar ED, *et al.*, manuscript for Public Health Reports).

Process

HHS convened a federal inter-departmental, inter-agency panel of scientists (Appendix A) to review scientific evidence relevant to the 1962 PHS Drinking Water Standards for fluoride concentrations in drinking water in the United States and to update these recommendations based on current science. Panelists included representatives from the CDC, the National Institutes of Health, the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, the EPA, and the U.S. Department of Agriculture. The Panel evaluated recent systematic reviews of the effectiveness of fluoride in drinking water to prevent dental caries, as well as published reports about the epidemiology of dental caries and fluorosis in the United States and the relationship of these conditions with varying water fluoridation concentrations. The Panel also reviewed existing recommendations for fluoride in drinking water and newer data on the relationship between water intake in children and outdoor air temperature in the United States—a relationship that had served as the basis for the 1962 recommendation.

Recent systematic reviews of evidence on the effectiveness of community water fluoridation were from the Community Preventive Services Task Force (CPSTF), first published in 2001 and updated in 2013, and the Australian National Health and Medical Research Council in 2007 (Truman BI, *et al.*, 2002; CPSTF, 2013). Both reviews updated a comprehensive systematic review of water fluoridation completed by the National Health Service Centre for Reviews and Dissemination, University of York, in 2000 (McDonagh MS *et al.*,

2000a, McDonagh MS *et al.*, 2000b). In these reviews, estimates of fluoridation effectiveness in preventing caries were limited to children and adolescents and based on comparative studies. Random assignment of individuals usually is not feasible for studies of water fluoridation, because the intervention occurs in the community water system. Another systematic review examined the effectiveness of water fluoridation in preventing dental caries in adults. Findings were based primarily on cross-sectional studies of lifelong residents of communities with fluoridated or non-fluoridated water (Griffin SO, et al, 2007). Studies in these systematic reviews were not limited to the United States.

Panel scientists accepted an extensive review of fluoride in drinking water by the NRC (NRC, 2006) as the summary of hazard. The NRC review focused on potential adverse effects of naturally occurring fluoride at 2–4 mg/L in drinking water; it found no evidence substantial enough to support effects other than severe dental fluorosis at these levels. A majority of NRC Committee members also concluded that lifetime exposure to fluoride at a drinking water concentration of 4.0 mg/L (the enforceable standard established by EPA) is likely to increase bone fracture rates in the population, compared with exposures at 1.0 mg/L (NRC, 2006). Fluoride concentrations used for water fluoridation have been substantially lower than the enforceable standard EPA established to protect against severe skeletal fluorosis (USDHEW, 1962; NRC, 2006).

Conclusions of the Panel were summarized, along with their rationale, in the **Federal Register** document (USDHHS, 2011). PHS guidance is advisory, not regulatory, in nature.

Overview of Public Comments: The public comment period for the Proposed Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries lasted for 93 days; it began with publication of the **Federal Register** notice on January 13, 2011, and was extended from its original deadline of February 14, 2011, to April 15, 2011 to allow adequate time for interested organizations and members of the public to respond. Duplicate comments (*e.g.*, electronic and paper submissions from the same source) were counted as one comment. Although the 51 responses received electronically or postmarked after the deadline (midnight ET, April 15, 2011) were not reviewed, all other comments were considered carefully.

Approximately 19,300 responses were received; of these responses, approximately 18,500 (96 percent) were nearly identical to a letter submitted by an organization opposing community water fluoridation, often originating from the Web site of that organization; hereafter, these responses are called "standard letters." Of the remaining 746 unique responses, 79 anecdotes described personal experiences, often citing potentially harmful effects, and 18 consisted of attachments only. Attachments to the unique submissions were examined to ensure that they addressed the recommendation, and to determine whether they supported it, opposed it as too low, or opposed it as too high. Although nearly all responses came from the general public, comments also were submitted by organizations, such as those representing dental, public health, or water supply professionals; those that advocate cessation of community water fluoridation; or commercial companies.

Of the unique responses, most opposed the recommendation as still too high and presented multiple concerns. Four CDC scientists (who did not serve on the inter-agency Federal Panel) reviewed all unique responses and used an electronic list of descriptors to categorize their contents. Comments were summarized and reported to the full Federal Panel, along with examples reflecting a range of differing opinions regarding the new recommendation. The following sections summarize frequent comments and provide the Federal Panel's response, divided into three categories: Comments that opposed the recommendation as still too high, comments that opposed the recommendation as too low to achieve prevention of dental caries, and comments that supported the recommendation. Data on the approximate numbers of comments received in support of and opposed to the new recommendation are provided for informational purposes. Responses to these comments are based primarily on conclusions of evidence-based reviews and/or expert panels that reviewed and evaluated the best available science.

Comments That Opposed the Recommendation as Too High

Nearly all submissions opposed community water fluoridation at any concentration; they stated that the new recommendation remains too high, and most asked that all fluoride be removed from drinking water. These submissions include the standard letters (~18,500) and unique responses (~700 said the new level was too high; of these ~500 specifically asked for all fluoride to be removed). Nearly all of these submissions listed possible adverse health effects as concerns specifically, severe dental fluorosis, bone fractures, skeletal fluorosis, carcinogenicity, lowered IQ and other neurological effects, and endocrine disruption.

In response to these concerns, PHS again reviewed the scientific information cited to support actions announced in January 2011 by the HHS (U.S. DHHS, 2011) and the EPA (U.S. EPA, 2010a; U.S. EPA, 2010b)—and again considered carefully whether or not the proposed recommendations and standards on fluoride in drinking water continue to provide the health benefits of community water fluoridation while minimizing the chance of unwanted health effects from too much fluoride. After a thorough review of the comments opposing the recommendation, the Federal Panel did not identify compelling new information to alter its assessment that the recommended fluoride concentration (0.7 mg/L) provides the best balance of benefit to potential harm.

Dental Fluorosis

The standard letters stated that the new recommendation would not eliminate dental fluorosis and cited its current prevalence among U.S. adolescents. In national surveys cited by the initial **Federal Register** notice, however, more than 90 percent of dental fluorosis in the United States is the very mild or mild form, most often appearing as barely visible lacy white markings or spots on the enamel (Beltrán-Aguilar, ED, *at al.*, 2010a). EPA considers the severe form of dental fluorosis, with staining and pitting of the tooth surface, as the "adverse health effect" to be prevented (U.S. EPA, 2010b). Severe dental fluorosis is rare in the United States, and its prevalence could not be estimated among adolescents in a national survey because there were too few cases among the survey participants examined to achieve statistical reliability (Beltrán-Aguilar, ED, et al, 2010a). The NRC review noted that prevalence of severe dental fluorosis was near zero at fluoride concentrations below 2 mg/L (NRC, 2006, p. 10). In addition, the most recent review of community water fluoridation by the Community Preventive Services Task Force concluded that "there is no evidence that community water fluoridation results in severe dental fluorosis" (CPSTF, 2013).

Standard letter submissions also expressed concern that infants fed formula reconstituted with fluoridated drinking water would receive too much fluoride. If an infant is consuming only

infant formula mixed with fluoridated water, there may be an increased chance for permanent teeth (when they erupt at ~ age 6) to have mild dental fluorosis (ADA, 2011). To lessen this chance, parents may choose to use low-fluoride bottled water some of the time to mix infant formula, *e.g.*, bottled waters labeled as de-ionized, purified, demineralized, or distilled, and without any fluoride added after purification treatment (FDA requires the label to indicate when fluoride is added). Such guidance currently is found on the Web sites of both CDC (*http://www.cdc.gov/fluoridation/safety/infant_formula.htm*) and the American Dental Association (*http://www.mouthhealthy.org/en/az-topics/f/fluorosis.aspx*). The PHS recommendation to lower the fluoride concentration for community water fluoridation should decrease fluoride exposure during the time of enamel formation, from birth through 8 years of age for most permanent teeth (CDC, 2001b; Avery, 1987; Massler M and Schour I, 1958), and further lessen the chance for children's teeth to have dental fluorosis, while keeping the decay prevention benefits of fluoridated water.

Bone Fractures and Skeletal Fluorosis

Some unique comments (~100) cited fractures or other pathology of bone, while the standard letters expressed concern about skeletal fluorosis (*i.e.*, a bone disease caused by excessive fluoride intake for a long period of time that in advanced stages can cause pain or damage to bones and joints) and suggested that symptoms of stage II skeletal fluorosis (*i.e.*, a clinical stage associated with chronic pain) are identical to those of arthritis (*i.e.*, sporadic pain and stiffness of the joints). The NRC review found no recent studies to evaluate the prevalence of skeletal fluorosis in U.S. populations exposed to fluoride at the current maximum level of 4.0 mg/L (NRC, 2006). On the basis of existing epidemiologic literature, the NRC concluded that stage III skeletal fluorosis (*i.e.*, a clinical stage associated with significant bone or joint damage) "appears to be a rare condition in the United States" and stated that the committee "could not determine whether stage II skeletal fluorosis is occurring in U.S. residents who drink water with fluoride at 4 mg/L" (NRC, 2006).

The NRC also recommended that EPA consider additional long-term effects on bone in adults—stage II skeletal fluorosis and bone fractures—as well as the health endpoint that had been evaluated previously (*i.e.* stage III skeletal fluorosis) (NRC, 2006). In response, the EPA Dose-Response Analysis for Non-Cancer Effects noted that, although existing data were inadequate to model the relationship of fluoride exposure and its impact on bone strength, skeletal effects among adults are unlikely to occur at the fluoride intake level estimated to protect against severe dental fluorosis among children (U.S. EPA, 2010b). The EPA report concluded that exposure to concentrations of fluoride in drinking water of 4 mg/L and above appears to be positively associated with the increased relative risk of bone fractures in susceptible populations when compared with populations consuming fluoride concentrations of 1 mg/L (U.S. EPA, 2010b). Recently, a large cohort study of older adults in Sweden reported no association between long-term exposure to drinking water with fluoride concentrations up to 2.7 mg/L and hip fracture (Näsman P. *et al.*, 2013).

The fluoride intake estimated by EPA to protect against severe dental fluorosis among children during the critical period of enamel formation was determined to be "likely also protective against fluoride-related adverse effects in adults, including skeletal fluorosis and an increased risk of bone fractures" (U.S. EPA, 2010b). EPA compared its own risk assessments for skeletal effects with those made both by the NRC in 2006 and by the World Health Organization in 2002. EPA concluded that its own dose recommendation is protective compared with each of these other benchmarks and, thus, is "applicable to the entire population since it is also protective for the endpoints of severe fluorosis of primary teeth, skeletal fluorosis, and increased risk of bone fractures in adults" (U.S. EPA, 2010b).

Carcinogenicity

Some unique comments (~100) mentioned concerns regarding fluoride as a carcinogen, and the standard letters called attention to one study (Bassin, *et al.*, 2006) that reported an association between osteosarcoma (*i.e.*, a type of bone cancer) among young males and estimated fluoride exposure from drinking water, based on residence history. The study examined an initial set of cases from a hospital-based case-control study of osteosarcoma and fluoride exposure. Findings from subsequent cases (Kim, *et al.*, 2011) were published in 2011. This later study assessed fluoride exposure using actual bone fluoride concentration—a more accurate and objective measure than previous estimates based on reported fluoride concentrations in drinking water at locations in the reported residence history. The later study showed no significant association between bone fluoride levels and osteosarcoma risk (Kim, *et al.*, 2011). This finding is consistent with systematic reviews (McDonagh, 2000b; Parnell, 2009; ARCPOH, 2006, Yeung, 2008) and three recent ecological studies (Comber, *et al.*, 2011; Levy and Leclerc, 2012; Blakey K, *et al.*, 2014) that found no association between incidence of this rare cancer and the fluoride content of community water. Although study authors acknowledged the statistical and methodological limitations of ecological analyses, they also noted that their findings were consistent with the hypothesis that low concentrations of fluoride in water do not increase the risk of osteosarcoma development.

A critical review of fluoride and fluoridating agents of drinking water, accepted by the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) in 2010, used a weight-of-evidence approach and concluded that epidemiological studies did not indicate a clear link between fluoride in drinking water and osteosarcoma or cancer in general. In addition, the committee found that the available data from animal studies, in combination with the epidemiology results, did not support classifying fluoride as a carcinogen (SCHER, 2010). Finally, the Proposition 65 Carcinogen Identification Committee, convened by the Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, determined in 2011 that fluoride and its salts have not clearly been shown to cause cancer (OEHHA CA, 2011).

IQ and Other Neurological Effects

The standard letters and approximately 100 unique responses expressed concern about fluoride's impact on the brain, specifically citing lower IQ in children. Several Chinese studies (Xiang, *et al.*, 2003; Lu, *et al.*, 2000; Zhao, *et al.*, 1996) considered in detail by the NRC review reported lower IQ among children exposed to fluoride in drinking water at mean concentrations of 2.5–4.1 mg/L—several times higher than concentrations recommended for community water fluoridation. The NRC found that "the significance of these Chinese studies is uncertain" because important procedural details were omitted, but also stated that findings warranted additional research on the effects of fluoride on intelligence (NRC, 2006).

Based on animal studies, the NRC committee speculated about potential

mechanisms for nervous system changes and called for more research "to clarify the effect of fluoride on brain chemistry and function" (NRC, 2006). These recommendations should be considered in the context of the NRC review, which limited its conclusions regarding adverse effects to water fluoride concentrations of 2–4 mg/L and did "not address the lower exposures commonly experienced by most U.S. citizens" (NRC, 2006). A recent meta-analysis of studies conducted in rural China, including those considered by the NRC report, identified an association between high fluoride exposure (*i.e.*, drinking water concentrations ranging up to 11.5 mg/L) and lower IQ scores; study authors noted the low quality of included studies and the inability to rule out other explanations (Choi, *et al.*, 2012). A subsequent review cited this meta-analysis to support its identification of "raised fluoride concentrations" in drinking water as a developmental neurotoxicant (Grandjean and Landrigan, 2014).

A review by SCHER also considered the neurotoxicity of fluoride in water and determined that there was not enough evidence from well-controlled studies to conclude if fluoride in drinking water at concentrations used for community fluoridation might impair the IQ of children (SCHER, 2010). The review also noted that "a biological plausibility for the link between fluoridated water and IQ has not been established" (SCHER, 2010). Findings of a recent prospective study of a birth cohort in New Zealand did not support an association between fluoride exposure, including residence in an area with fluoridated water during early childhood, and IQ measured repeatedly during childhood and at age 38 years (Broadbent, *et al.*, 2014).

Endocrine Disruption

All of the standard letters and some of the unique comments (~100) expressed concern that fluoride disrupts endocrine system function, especially for young children or for individuals with high water intake. The 2006 NRC review considered a potential association between fluoride exposure (2–4 mg/L) and changes in the thyroid, parathyroid, and pineal glands in experimental animals and humans (NRC, 2006). The report noted that available studies of the effects of fluoride exposure on endocrine function have limitations. For example, many studies did not measure actual hormone concentrations, and several studies did not report nutritional status or other factors likely to confound findings. The NRC called for better measurement of exposure to fluoride in epidemiological studies and for further research "to characterize the direct and indirect mechanisms of fluoride's action on the endocrine system and factors that determine the response, if any, in a given individual" (NRC, 2006). A review did not find evidence that consuming drinking water with fluoride at the level used in community water fluoridation presents health risks for people with chronic kidney disease (Ludlow, *et al.*, 2007).

Effectiveness of Community Water Fluoridation in Caries Prevention

In addition to citing potential adverse health effects, the standard letters stated that the benefits of community water fluoridation have never been documented in any randomized controlled trial. There are no randomized, double-blind, controlled trials of water fluoridation because its community-wide nature does not permit randomization of individuals to study and control groups or blinding of participants. However, community trials have been conducted, and these studies were included in systematic reviews of the effectiveness of community water fluoridation (McDonagh, *et al.*, 2000b; Truman BI, *et al.*, 2002; CPSTF, 2013). As noted, these reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity.

Standard letters also stated that African-American and low-income children would not be protected by the recommendation, as they have experienced more tooth decay than other racial/ethnic groups, despite exposure to fluoride through drinking water and other sources. Data from the NHANES (Dye B, *et al.*, 2007) do not support this statement and, instead, document a decline in the prevalence and severity of dental caries (tooth decay) across racial/ethnic groups. For example, in 1999–2004, compared with 1988–1994, the percentage of adolescents aged 12–19 years who had experienced dental caries in their permanent teeth, by race/ethnicity, was 54% in African-American (down from 63%), 58% in non-Hispanic white (down from 68%), and 64% in Mexican-American (down from 69%) adolescents (Dye B, *et al.*, 2007). For adolescents whose family income was less than 100% of the federal poverty level, a similar decline occurred: 66% had experienced dental caries in 1999–2004, down from 72% in 1988–1994. Although disparities in caries prevalence among these adolescent groups remain, the prevalence for each group was lower in 1999–2004 than in 1988–1994. Concurrent with these reductions in the prevalence of dental caries, the percentage (number) of the U.S. population receiving fluoridated water increased from 56% (144,217,476) in 1992 to 62% (180,632,481) in 2004 (*http://www.cdc.gov/nohss/fsgrowth.htm*). This change represented an increase of more than 36 million people.

Cost-Effectiveness of Community Water Fluoridation

Some unique comments (~200) called attention to the cost of water fluoridation or stated that it was unnecessary or inefficient given the availability of other fluoride modalities and the amount of water used for purposes other than drinking. Cost-effectiveness studies that included costs incurred in treating all community water with fluoride additives still found fluoridation to be cost-saving (Truman, *et al.*, 2002, Griffin, *et al.*, 2001). Although the annual per-person cost varies by size of the water system (from $0.50 in communities of 20,000 or more to $3.70 for communities of 5,000 or fewer, updated to 2010 dollars using the Consumer Price Index [CPI]), it remains only a fraction of the cost of one dental filling. The annual per person cost savings for those aged 6 to 65 years ranged from $35.90 to $28.70 for larger and smaller communities, respectively (Griffin, *et al.*, 2001, updated to 2010 dollars using CPI-dental services). Studies in the United States and Australia also have documented the cost-effectiveness of community water fluoridation (Truman BI, *et al.*, 2002; O'Connell JM *et al.*, 2005; Campain AC *et al.*, 2010; Cobiac LJ and Vos T, 2012).

Safety of Fluoride Additives

Unique comments (~300) expressed concern that fluoride is poison and an industrial waste product; standard letters noted the lack of specific data on the safety of silicofluoride compounds used by many water systems for community water fluoridation. All additives used to treat water, including those used for community water fluoridation, are subject to a system of standards, testing, and certification involving participation of the American Water Works Association, NSF International, and the American National Standards Institute (ANSI)—entities that are nonprofit, nongovernmental organizations. Most states require that water utilities use products that have been certified against *ANSI/NSF Standard 60: Drinking Water Treatment Chemicals—Health Effects*

(hereinafter, Standard 60) by an ANSI-accredited laboratory (U.S. EPA, 2000). All fluoride products evaluated against Standard 60 are tested to ensure that the levels of regulated impurities present in the product will not contribute to the treated drinking water more than 10% of the corresponding Maximum Contaminant Level (MCL) established by EPA for that contaminant (U.S. EPA, 2000). Results from 2000–2011, reported on the NSF International Web site (*http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf*) found that no contaminants exceeded the concentration allowed by Standard 60.

Although commenters expressed concerns about silicofluorides, studies have shown that these compounds achieve virtually complete dissolution and ionic disassociation at concentrations added to drinking water and thus, are comparable to the fluoride ion produced by other additives, such as sodium fluoride (Crosby, 1969; Finney, *et al.*, 2006, U.S. EPA, 2000). At the pH of drinking water, usually 6.5–8.5, and at a fluoride concentration of 1 mg/L, the degree of hydrolysis of hexafluorosilicic acid has been described as "essentially 100%" (U.S. EPA, 2000). Standard 60 provides criteria to develop an allowable concentration when no MCL has been established by the EPA. Using this protocol, NSF International calculations showed that a sodium fluorosilicate concentration needed to achieve 1.2 mg F/L would result in 0.8 mg/L of silicate, or about 5% of the allowable concentration calculated by NSF International. (*http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf*).

SCHER also considered health and environmental risks associated with the use of silicofluoride compounds in community water fluoridation and concurred that in water they are rapidly hydrolyzed to fluoride, and that concentrations of contaminants in drinking water are well below guideline values established by the World Health Organization (SCHER, 2010).

Ethics of Community Water Fluoridation

All standard letters and some unique comments (~200) stated that water fluoridation is unethical mass medication of the population. To determine if a public health action that may encroach on individual preferences is ethical, a careful analysis of its benefits and risks must occur. In the case of water fluoridation, the literature offers clear evidence of its benefits in reducing dental decay (McDonagh MS, *et al.*, 2000a; McDonagh MS, *et al.*, 2000b; Truman BI, *et al.*, 2002; ARCPOH, 2006; Griffin SO, *et al.*, 2007; Yeung, 2008; CPSTF, 2013), with documented risk limited to dental fluorosis (U.S. EPA, 2010a; U.S. EPA, 2010b; McDonagh MS, *et al.*, 2000a; ARCPOH, 2006; CPSTF, 2013).

Several aspects of decision-making related to water fluoridation reflect careful analysis and lend support to viewing the measure as a sound public health intervention. State and local governments decide whether or not to implement water fluoridation, after considering evidence regarding its benefits and risks. Often, voters themselves make the final decision to adopt or retain community water fluoridation. Although technical support is available from HHS, federal agencies do not initiate efforts to fluoridate individual water systems. In addition, court systems in the United States have thoroughly reviewed legal challenges to community water fluoridation, and have viewed it as a proper means of furthering public health and welfare (*http://fluidlaw.org*).

Comments That Opposed the Recommendation as Too Low

Several unique comments said that 0.7mg/L is too low to offer adequate protection against tooth decay. Evidence, however, does suggest that 0.7 mg/L will maintain caries preventive benefits. Analysis of data from the 1986–1987 Oral Health of United States Children survey found that reductions in dental caries plateaued between 0.7–1.2 mg/L of fluoride (Heller KE *et al.*, 1997). In addition, fluoride in drinking water is only one of several available fluoride sources, such as toothpaste, mouth rinses, and professionally applied fluoride compounds.

Comments That Supported the Recommendation

Some submissions specifically endorsed lowering the concentration of fluoride in drinking water for the prevention of dental caries. Other commenters asked for guidance on the operational range for implementing the recommended concentration of 0.7 mg/L and on consistent messaging regarding the recommended change. Currently, CDC is reviewing available data and collaborating with organizations of water supply professionals to update operational guidance. In addition, CDC continues to support local and state infrastructure needed to implement and monitor the recommendation. Examples of this support include maintenance of the Water Fluoridation Reporting System; provision of training opportunities for water supply professionals; assisting state and local health agencies with health promotion and public education related to water fluoridation; and funding (in coordination with other Federal agencies, including the National Institute of Dental and Craniofacial Research) for research and surveillance activities related to dental caries, dental fluorosis, and fluoride intake.

Monitoring Implementation of the New Recommendation

Unpublished data from the Water Fluoridation Reporting System show how rapidly the proposed change in recommended concentration has gained acceptance. In December 2010, about 63% of the population on water systems adjusting fluoride (or buying water from such systems) was at 1.0 mg/L or greater and fewer than 1% at 0.7 mg/L. By summer 2011, only 6 months after publication of the draft notice, 68% of that population was at 0.7 mg/L and about 28% was at 1.0 mg/L or greater.

Following broad implementation of the new recommendation, enhanced surveillance during the next decade will detect changes in the prevalence and severity of dental caries and of dental fluorosis that is very mild or greater, nationally and for selected socio-demographic groups. For example, the 2011–2012 NHANES included clinical examination of children and adolescents by dentists to assess decayed, missing and filled teeth; presence of dental sealants; and dental fluorosis. The 2013–2014 examination added fluoride content of home water (assessed using water taken from a faucet in the home), residence history (needed to estimate fluoride content of home tap water for each child since birth), and questions on use of other fluoride modalities (*e.g.*, toothpaste, prescription drops, and tablets). As findings from these and future examinations become available, they can be accessed through the CDC Web site (*http://www.cdc.gov/nchs/nhanes/nhanes_products.htm*).

Definitive evaluation of changes in dental fluorosis prevalence or severity, associated with reduction in fluoride concentration in drinking water, cannot occur until permanent teeth erupt in the mouths of children who drank that water during the period of tooth development. HHS agencies continue to give priority to the development of valid and reliable measures of fluorosis, as well as technologies that could assess individual fluoride exposure precisely. A recent study documented the validity of fingernail fluoride concentrations at age 2–7 years as a biomarker for dental fluorosis of the permanent teeth at age 10–15 years (Buzalaf MA, *et al.*, 2012).

Summary and Conclusions

PHS acknowledges the concerns of commenters and appreciates the efforts of all who submitted responses to the **Federal Register** notice describing its recommendation to lower the fluoride concentration in drinking water for the prevention of dental caries. The full Federal Panel considered these responses in the context of best available science but did not alter its recommendation that the optimal fluoride concentration in drinking water for prevention of dental caries in the United States should be reduced to 0.7 mg/L. from the previous range of 0.7–1.2 mg/L. based on the following information:

- 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.
- 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.
- Caries preventive benefits can be achieved and the risk of dental fluorosis reduced at a fluoride concentration of 0.7 mg/L.
- Recent data do not show a convincing relationship between water intake and outdoor air temperature. Thus, recommendations for water fluoride concentrations that differ based on outdoor temperature are unnecessary.

Surveillance of dental caries, dental fluorosis, and fluoride intake will monitor changes that might occur, following implementation of the recommendation.

Dated: April 24, 2015.

Sylvia M. Burwell,

Secretary.

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Appendix A—HHS Federal Panel on Community Water Fluoridation

Peter Briss, MD, MPH—Panel Chair, Medical Director, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

William Bailey, DDS, MPH (*former Panel member*), Acting Director (2011–2013), Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

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Eugenio Beltrán-Aguilar, DMD, MPH, DrPH (*former Panel member*), Senior Epidemiologist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Mary Beth Bigley, DrPH, MSN, ANP (*former Panel member*), Acting Director, Office of Science and Communications, Office of the Surgeon General, U.S. Department of Health and Human Services

Linda Birnbaum, Ph.D., DABT, ATS, Director, National Institute of Environmental Health Sciences and National Toxicology Program, National Institutes of Health, U.S. Department of Health and Human Services

John Bucher, Ph.D., Associate Director, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services

Amit Chattopadhyay, PhD. (*former Panel member*), Epidemiologist, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

Joyce Donohue, Ph.D., Health Scientist, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency

Elizabeth Doyle, Ph.D., Chief, Human Health Risk Assessment Branch, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency

Isabel Garcia, DDS, MPH, Deputy Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

Barbara Gooch, DMD, MPH, Associate Director for Science, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Jesse Goodman, MD, MPH, Chief Scientist and Deputy Commissioner for Science and Public Health, Food and Drug Administration, U.S. Department of Health and Human Services

J. Nadine Gracia, MD, MSCE (*former Panel member*), Chief Medical Officer (2009–2011), Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Susan O. Griffin, Ph.D., Health Economist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Laurence Grummer-Strawn, Ph.D., Chief, Maternal and Child Nutrition Branch, Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Jay Hirschman, MPH, CNS, Director, Special Nutrition Staff, Office of Research and Analysis, Food and Nutrition Service, U.S. Department of Agriculture

Frederick Hyman, DDS, MPH, Dental Officer, Division of Dermatology and Dental Products, Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services

Timothy Iafolla, DMD, MPH, Supervisory Science Policy Analyst, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

William Kohn, DDS *(former Panel member)*, Director (2010–11), Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Arlene M. Lester, DDS, MPH, CAPT, United States Public Health Service, Regional Minority Health Consultant, Office of the Secretary, US Department of Health and Human Services

Nicholas S. Makrides, DMD, MA, MPH, Assistant Surgeon General, Chief Dental Officer, United States Public Health Service, Chief Dentist, Federal Bureau of Prisons, U.S. Department of Justice

Richard Manski, DDS, MBA, Ph.D., Senior Scholar, Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services

Ana Maria Osorio, MD, MPH, Senior Advisor for the Public Health Service, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Benson Silverman, MD *(former panel member, deceased)*, Staff Director, Infant Formula and Medical Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services

Thomas Sinks, Ph.D., Deputy Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues (the Commission) will conduct its twenty-first meeting on May 27, 2015. At this meeting, the Commission will discuss the role of deliberation and deliberative methods to engage the public and inform debate in bioethics, and how to integrate pubic dialogue into the bioethics conversation; bioethics education as a forum for fostering deliberative skills, and preparing students to participate in public dialogue in bioethics; goals and methods of bioethics education; and integrating bioethics education across a range of professional disciplines and educational levels.

DATES: The meeting will take place Wednesday, May 27, 2015, from 9 a.m. to approximately 5 p.m.

ADDRESSES: University of Pennsylvania Henry Jordan Medical Education Center, 5th Floor Lobby, 3400 Civic Center Boulevard, Philadelphia, PA 19104.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Telephone: 202–233–3960. Email: *Hillary.Viers@bioethics.gov*. Additional information may be obtained at *www.bioethics.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92–463, 5 U.S.C. app. 2, notice is hereby given of the twenty-first meeting of the Commission. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at *www.bioethics.gov*.

Under authority of E. O. 13521, dated November 24, 2009, the President established the Commission. The Commission is an expert panel of not more than 13 members who are drawn from the fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences. The Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda items for the Commission's twenty-first meeting are to discuss the role of deliberation and deliberative methods to engage the public and inform debate in bioethics, and how to integrate pubic dialogue into the bioethics conversation; bioethics education as a forum for fostering deliberative skills, and preparing students to participate in public dialogue in bioethics; goals and methods of bioethics education; and integrating bioethics education across a range of professional disciplines and educational levels. The draft meeting agenda and other information about the Commission, including information about access to the webcast, will be available at *www.bioethics.gov*.

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Commission. The Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Commission may make a random selection.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to *info@bioethics.gov*, or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233–3960, or email at *Esther.Yoo@bioethics.gov* in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Dated: April 22, 2015.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2015–10205 Filed 4–30–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

Code of Federal Regulations

40

Parts 136 to 149

Revised as of July 1, 2001

Protection of Environment

State comply with the requirements of the Act, this rule and the affordability criteria developed by the State.

(b) If the Administrator determines that small system variances granted by a State are not in compliance with the requirements of the Act, this rule or the affordability criteria developed by the State, the Administrator shall notify the State in writing of the deficiencies and make public the determinations.

(c) The Administrator's review will be based in part on quarterly reports prepared by the States pursuant to §142.15(a)(1) relating to violations of increments of progress or other violated terms or conditions of small system variances.

PART 143—NATIONAL SECONDARY DRINKING WATER REGULATIONS

AUTHORITY: 42 U.S.C. 300f *et seq.*

SOURCE: 44 FR 42198, July 19, 1979, unless otherwise noted.

§ 143.1 Purpose.

This part establishes National Secondary Drinking Water Regulations pursuant to section 1412 of the Safe Drinking Water Act, as amended (42 U.S.C. 300g–1). These regulations control contaminants in drinking water that primarily affect the aesthetic qualities relating to the public acceptance of drinking water. At considerably higher concentrations of these contaminants; health implications may also exist as well as aesthetic degradation. The regulations are not Federally enforceable but are intended as guidelines for the States.

§ 143.2 Definitions.

(a) *Act* means the Safe Drinking Water Act as amended (42 U.S.C. 300f *et seq.).*

(b) *Contaminant* means any physical, chemical, biological, or radiological substance or matter in water.

(c) *Public water system* means a system for the provision to the public of piped water for human consumption, if such a system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year. Such term includes (1) any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system, and (2) any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system. A public water system is either a "community water system" or a "non-community water system."

(d) *State* means the agency of the State or Tribal government which has jurisdiction over public water systems. During any period when a State does not have responsibility pursuant to section 1443 of the Act, the term "State" means the Regional Administrator, U.S. Environmental Protection Agency.

(e) *Supplier of water* means any person who owns or operates a public water system.

(f) *Secondary maximum contaminant levels* means SMCLs which apply to public water systems and which, in the judgement of the Administrator, are requisite to protect the public welfare. The SMCL means the maximum permissible level of a contaminant in water which is delivered to the free flowing outlet of the ultimate user of public water system. Contamimants added to the water under circumstances controlled by the user, except those resulting from corrosion of piping and plumbing caused by water quality, are excluded from this definition.

[44 FR 42198, July 19, 1979, as amended at 53 FR 37412, Sept. 26, 1988]

§ 143.3 Secondary maximum contaminant levels.

The secondary maximum contaminant levels for public water systems are as follows:

Contaminant	Level
Aluminum	0.05 to 0.2 mg/l.
Chloride	250 mg/l.
Color	15 color units.
Copper	1.0 mg/l.
Corrosivity	Non-corrosive.
Fluoride	2.0 mg/l.
Foaming agents	0.5 mg/l.
Iron	0.3 mg/l.
Manganese	0.05 mg/l.
Odor	3 threshold odor number.
pH	6.5–8.5.
Silver	0.1 mg/l.
Sulfate	250 mg/l.
Total dissolved solids (TDS)	500 mg/l.
Zinc	5 mg/l.

These levels represent reasonable goals for drinking water quality. The States may establish higher or lower levels which may be appropriate dependent upon local conditions such as unavailability of alternate source waters or other compelling factors, provided that public health and welfare are not adversely affected.

[44 FR 42198, July 19, 1979, as amended at 51 FR 11412, Apr. 2, 1986; 56 FR 3597, Jan. 30, 1991]

§ 143.4 Monitoring.

(a) It is recommended that the parameters in these regulations should be monitored at intervals no less frequent than the monitoring performed for inorganic chemical contaminants listed in the National Interim Primary Drinking Water Regulations as applicable to community water systems. More frequent monitoring would be appropriate for specific parameters such as pH, color, odor or others under certain circumstances as directed by the State.

(b) Measurement of pH, copper and fluoride to determine compliance under §143.3 may be conducted with one of the methods in §141.23(k)(1). Analyses of aluminum, chloride, foaming agents, iron, manganese, odor, silver, sulfate, total dissolved solids (TDS) and zinc to determine compliance under §143.3 may be conducted with the methods in the following table. Criteria for analyzing aluminum, copper, iron, manganese, silver and zinc samples with digestion or directly without digestion, and other analytical test procedures are contained in *Technical Notes on Drinking Water Methods*, EPA–600/R–94–173, October 1994, which is available at NTIS PB95–104766.

Contaminant	EPA	ASTM[3]	SM[4]	Other
Aluminum	[2]200.7		3120 B	
	[2]200.8		3113 B	
	[2]200.9		3111 D	
Chloride	[1]300.0	D4327–91	4110 B	
			4500–Cl⁻ D	
		D512–89B	4500–Cl⁻ B	
Color			2120 B	
Foaming Agents			5540 C	
Iron	[2]200.7		3120 B	
	[2]200.9		3111 B	
			3113 B	
Manganese	[2]200.7		3120 B	
	[2]200.8		3111 B	
	[2]200.9		3113 B	
Odor			2150 B	
Silver	[2]200.7		3120 B	[5]I–3720–85
	[2]200.8		3111 B	
	[2]200.9		3113 B	
Sulfate	[1]300.0	D4327–91	4110 B	
	[1]375.2		4500–SO_4^{2-} F	
			4500–SO_4^{2-} C, D	
		D516–90	4500–SO_4^{2-} E	
TDS			2540 C	
Zinc	[2]200.7		3120 B	
	[2]200.8		3111 B	

The procedures shall be done in accordance with the documents listed below. The incorporation by reference of the following documents was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the documents may be obtained from the sources listed below. Information regarding obtaining these documents can be obtained from the Safe Drinking Water Hotline at 800–426–4791. Documents may be inspected at EPA's Drinking Water Docket, 401 M St., SW., Washington, DC 20460 (Telephone: 202–260–3027); or at the Office of Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC 20408.

[1] "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R–93–100, August 1993. Available at NTIS, PB94–120821.

[2] "Methods for the Determination of Metals in Environmental Samples—Supplement I", EPA/600/R–94–111, May 1994. Available at NTIS, PB 95–125472.

[3] *Annual Book of ASTM Standards*, 1994 and 1996, Vols. 11.01 and 11.02, American Society for Testing and Materials. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428.