City of Loveland

Water and Power Department

Service Center • 200 North Wilson Avenue • Loveland, CO 80537
(970) 962-3000 • Fax (970) 962-3400 • TDD (970) 962-2620
www.cityofloveland.org

Larry W. Sarner
711 W. 9th Street
Loveland, CO 80537

Dear Mr. Sarner, July 24, 2014

This letter is in response to the concerns you expressed and the letter and graph you distributed at the Loveland Utilities Commission (LUC) meeting on June 25, 2014 regarding fluoridation levels in Loveland's drinking water. (Attachment 1.) We appreciate your interest and concern in this matter.

Staff thought it would be helpful to pass along some written background documentation on the use of fluoride. Please see the attached timeline for information such as motions, recommendations, and research regarding fluoride. (Attachment 2.)

The addition of fluoride to drinking water is recommended by the Colorado Department of Public Health and Environment (CDPHE), but it is not required. There are no minimum levels that must be achieved, but there is a secondary standard with a maximum contaminate threshold of 2.0 ppm fluoride. Secondary standards are non-enforceable guidelines regulating contaminants that may cause cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water. The decision to fluoridate a water supply is made by the state or local municipality and is not mandated by the Environmental Protection Agency (EPA) or any other federal entity.

Under City Code Section 2.49.010 (see box below), the Water and Power Director is delegated authority to direct the operation of the Water Treatment Plant. This authority includes the fluoridating of drinking water as directed by City Council.

> Chapter 2.49
>
> DEPARTMENT OF WATER AND POWER
>
> Sections:
> 2.49.010 Designated.
>
> 2.49.010 Designated.
> There is created a department of water and power which shall be under the direction of a director of water and power. It shall be the director's duty to organize, direct and manage the water, wastewater, stormwater, electric production, and electric distribution systems and plants of the city and the city's warehouse operations. The director shall be responsible for all matters relating to construction, management, maintenance, customer billing and operation of said systems and plants and shall perform such other functions as may be prescribed by the city manager. (Ord. 3975 § 10, 1994; Ord. 2072 § 2, 1982)

The city has historically been on the lower end of the acceptable range for fluoride addition. The natural background level of fluoride for Loveland's source water is approximately 0.25 ppm, with significant daily fluctuations. Loveland has added fluoride to the water supply in the form of sodium fluorosilicate except during periods when not feasible. One such instance occurred during the period of construction on Filter Plant 2 from October 2010 through July 2013. We previously researched whether it would be feasible to replace the existing

fluoride feeding equipment that feeds sodium fluorosilicate and determined that it was cost prohibitive and posed direct chemical exposure safety risks to our staff.

The construction of the Water Treatment Plant Expansion project is anticipated to begin in the fall of 2014 and be completed by spring of 2016. As part of this project, there will be a new state-of-the-art Chemical Building which will handle the storage and feeding of various chemicals, including fluoride. Once the project is complete, the city will change the type of fluoride it doses from sodium fluorosilicate (a powder form) to fluorosilic acid (a liquid form), which in the new Chemical Building will feed directly into the water, which not only provides a more accurate method to dose in the water but also reduces the chemical exposure risk to staff.

Following the newly-proposed recommendation from Health and Human Services (HHS) and the EPA in 2011, Water Treatment Plant staff reduced fluoridation levels to below 0.7 ppm, instead of targeting 0.7 ppm. In the days following your initial phone calls to management, staff made immediate corrective actions. Since Sunday, June 15, 2014, Water Treatment Plant staff have been producing potable water targeting 0.7 ppm of fluoride.

In your comments to the LUC, you expressed a desire to have fluoridation not only at 0.7 ppm, but closer to 1.2 ppm. The Water and Power Director, in consultation with Water Treatment Plant staff, set the fluoride target of 0.7 ppm for the following reasons:

1. **Proposed Recommendation:** Loveland Water & Power continues to follow the recommended guidelines of the organizations that have researched and recommended fluoridation of water for more than 50 years. The 0.7 ppm level is consistent with the proposed recommendation from HHS and EPA and in-line with recent scientific findings and research that take into account bone and dental effects of fluoride, current levels of tooth decay and dental fluorosis, all sources of fluoride, and fluid consumption across the United States.

2. **Consistent with Surrounding Communities:** The 0.7 ppm level is consistent with the majority of other Front Range communities. The table below summarizes fluoride concentration targets for a number of Front Range communities.

Do Not Add Fluoride		Adds Fluoride	
Utility	**Background Fluoride Level**	**Utility**	**Finished Water Fluoride Level (Background + Added Fluoride)**
Aurora	1.0 ppm	Greeley	0.7 ppm
Thornton	0.5 - 1.0 ppm	Boulder	0.7 ppm
Castle Rock	0.74 - 0.79 ppm	Loveland	0.7 ppm
Colorado Springs	0.13 to 1.36 ppm	Longmont	0.7 ppm
		Denver Water	0.7 ppm
		Soldier Canyon	0.7 ppm
		Carter Lake Filter Plant	0.7 ppm
		Westminster	0.8 ppm
		Fort Collins	1.0 ppm
		Broomfield	1.0 ppm

Please note: The utilities not adding fluoride have background fluoride levels at or near the recommended range.

3. **Fluorosis Risks:** A dental condition known as fluorosis can occur when higher levels of fluoride exist in drinking water sources. Fluorosis can cause streaking or mottling of dental enamel. The critical period of exposure for fluorosis is between the ages of one and four years. The 0.7 ppm concentration balances the benefit of reduced tooth decay with the risks of higher fluoride concentrations causing fluorosis. Americans now have more access to sources of fluoride than when water fluoridation was first introduced during the 1940s (i.e., fluoridated toothpastes and mouth rinses, prescription fluoride supplements, and fluoride applied by dental professionals.)

4. **Community Input:** The majority of community feedback we have received has been from those opposed to adding fluoride. Over the past ten years, we have averaged five phone calls per year expressing opposition to fluoride. During the past 10 years, we have only received feedback from you and one other community member expressing support of fluoride. In our 2014 residential customer survey with 1,526 customer responses, we received eleven comments opposed to fluoride and no comments expressing support. For the full survey results, please visit http://www.cityofloveland.org/modules/showdocument.aspx?documentid=20920.

As with most treatment processes, fluoridation has positive and negative aspects. Staff seeks to have a balanced approach in setting fluoridation levels by keeping in mind the benefits of reduced dental caries along with the increased risks of fluorosis if the levels are too high.

Per our phone conversation, I have secured a location for the September 30, 2014 LUC meeting for your presentation on fluoride. This meeting will begin at 4 PM and be conducted in the Loveland Police and Courts Building located at 810 East 10th Street, Loveland, CO 80537. We have scheduled up to three hours for this topic and ask that you keep your presentation to less than one hour to allow time for presentations by others, public comment, and commissioner questions and comment. Given the complex nature of this issue and the time we are allocating to this topic, we request that you email your presentation materials and any handouts to our LUC secretary so that they may be included in the September LUC packet. This will allow staff and board members sufficient time to study and become familiar with the materials that will be presented on this topic. See below for the details of item submittal:

Submit to: Allison Prokop, LUC Secretary
Email Address: Allison.Prokop@cityofloveland.org (preferred method)
Mail/Drop off: 200 N. Wilson Ave., Loveland, CO 80537

Submit by: 4 PM on Tuesday, September 23, 2014

Please contact the Water and Power Department if you have any questions or comments. The LUC and the Water and Power Department encourage citizens to become involved in local issues, and we appreciate your interest and concern in this matter.

Sincerely,

Eugene Packer

Eugene Packer
Chairman of the Board
Loveland Utilities Commission

List of Attachments:

1. Your letter and graph distributed at the June 25, 2014 LUC meeting
2. Fluoride timeline along with links and copies of some of the related fluoride documents
   - 2a. April 15, 1952 Loveland City Council Motion
   - 2b. January 7, 2011 Press Release from EPA and HHS
   - 2c. January 12, 2011 CDPHE Community Water Fluoridation Update
   - 2d. January 13, 2011 Federal Register
   - 2e. July-November 2012 Peer Review Period on the HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries
   - 2f. April 5, 2013 Congressional Research Service Report for Congress, "Fluoride in Drinking Water: A Review of Fluoridation and Regulation Issues"

Attachment 1

Loveland Utilities Commission
c/o Dave Schneider, Chairman
200 N. Wilson Ave.
Loveland, Colorado 80537

25 June 2016

Dear Members of the Loveland Utilities Commission:

I am a long-time resident of Loveland. I am also an ardent supporter of community water fluoridation (CWF), the time-tested public-health measure that is universally recognized as beneficial, safe, egalitarian, and economical. I had been pleased to live and raise a family in a community where the water supply has been fluoridated for six decades. Hence, I am alarmed to learn recently that the water has not been effectively fluoridated in recent years. I come before you with the expectation that this Commission will promptly addresses this deficiency, and assure that the oral health benefits of optimal fluoridation will once again flow uninterrupted in our city.

In June, 2012, you told a local resident, who was *objecting* to Loveland's CWF program:

> The detected level of fluoride, based on monthly analysis performed [CDPHE] Laboratory services, for the city's treated drinking water for 2011, was 0.68 ppm....In January of 2011 the [HHS] announced a recommendation that water systems using fluoridation, adjust their fluoride level to no more than 0.70 ppm, which the City of Loveland has met in 2011.

This response was factually misleading at the time of writing, and has not been true since. Loveland's fluoridation system was offline for 213 days in 2011. For the other 152 days, the average monthly fluoridation level reported to the CDPHE by LWD was 0.62. Moreover, at the time of writing these words, the system was offline and fluoridation levels were at background (as it was for the *entire year* of 2012, and much of 2013 as well).

Furthermore, the HHS guidance was not adjustment to *no more* than 0.70, but *not less* than that. The recommendation has not yet been released in final form, three and a half years after the announcement mentioned. The public comment on them was extended, and utter silence has followed. There has been much criticism leveled at this proposal.

In all events, Loveland's water system has not been meeting the optimal fluoride levels placed in its report to CDPHE. I personally undertook an analysis of the last four years of fluoridation reports. The fluoridation system in Loveland has been

offline a total of 2.3 years in that time. And of the remaining 1.7 years, the average fluoridation level has been 0.58.

It is important to remember that the purpose of CWF is to deliver a needed public health benefit. It is not good enough just to add fluoride, make reports, and blindly follow announcements of recommendations. The job is to prevent caries in children and adults. This means conscientously deliver an adequate amount of the fluoride mineral to all residents of Loveland.

I ask that you place this matter on the agenda of your next Commission meeting, and let myself and a panel of health/scientific/engineering experts present the urgent case for fully and consistently implementing the public policy of sufficiently adjusting fluoride levels in public water to levels that reap maximum health benefits for all people in Loveland.

Sincerely,

Larry W. Sarner
711 W. 9th St.
Loveland, Colorado 80537

cc: Steve Adams, Staff Liaison
Troy Krenning, Council Liaison

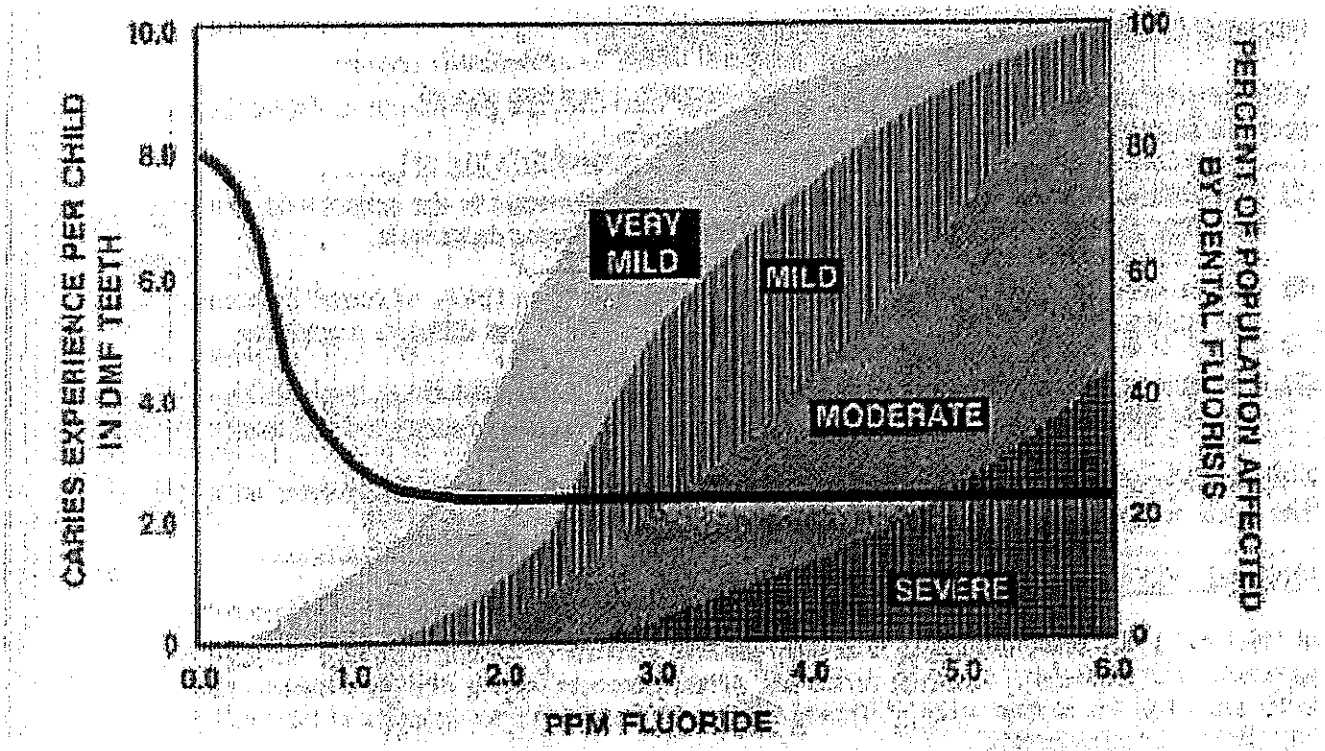

Figure 1. Dental caries and dental fluorosis in relation to fluoride in public water supplies (from U.S. Public Health Service, 1991)

Attachment 2

Fluoride Timeline: Below is a brief timeline of items related to fluoride including motions, recommendations and research by local and governmental agencies regarding fluoride.

- **April 15, 1952 Loveland City Council Motion:** "Councilman Hipps moved that the City Council recognizing the deficiency of fluorine in the Loveland water supply below the recommended optimum. It is moved that steps be taken to increase the amount of fluorine to proper amounts as recommended by the health and dental authorities. Motion seconded by Schroder and carried by all Councilmen present voting Aye to roll call." (See attachment 2a.)

- **1962 HHS Recommendation:** In 1962, the US Department of Health and Human Services (HHS) recommended fluoridation of community water from the range of 0.7 to 1.2 milligrams per liter. This range takes into consideration the different regions of the United States where in warmer, southern climates, it was believed that people drank more water and in cooler, northern climates, people drank less water and needed a higher fluoridation concentration to account for the lower ambient temperatures.
https://archive.org/stream/gov.law.usphs.956.1962/usphs.956.1962#page/n17/mode/2up

- **April 2003 Report of the Fort Collins Fluoride Technical Study Group:** This is a report that assesses risks and benefits of community water fluoridation in order to assist risk managers (The Larimer County Board of Health, the City of Fort Collins Water Board, and the Fort Collins City Council) to decide whether to continue, alter or discontinue the City of Fort Collin's water fluoridation program.
http://www.fcgov.com/utilities/img/site_specific/uploads/fluoride-report030903.pdf

- **January 7, 2011 Press Release:** The US Department of Health and Human Services (HHS) and the Environmental Protection Agency issued a joint press release with new proposed recommendations for community water fluoridation to change from a range of 0.7 to 1.2 milligrams per liter to a static 0.7 mg per liter because of the availability of additional fluoride sources and because no association was found between fluid intake among children and adolescents and outdoor ambient temperature.
http://yosemite.epa.gov/opa/admpress.nsf/6427a6b7538955c585257359003f0230/86964af577c37ab285257811005a8417!OpenDocument (See attachment 2b.)

- **January 12, 2011 CDPHE Community Water Fluoridation Update:** The Colorado Department of Public Health and Environment (CDPHE) issued a Community Water Fluoridation Update informing us that HHS is changing its recommendation on fluoridation from a range of 0.7 – 1.2 mg per liter to a static 0.7 mg per liter because of the availability of additional fluoride sources. (See attachment 2c.)

- **January 13, 2011 Federal Register:** 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.
http://www.gpo.gov/fdsys/pkg/FR-2011-01-13/pdf/2011-637.pdf (See attachment 2d.)

- **July-November 2012 Peer Review:** HHS Inter-Agency Panel's review of public comments and supporting references for the HHS's proposed recommendation for fluoride concentration in drinking water for the prevention of dental caries. http://aspe.hhs.gov/oash/floridation.shtml (See attachment 2e.)

- **April 5, 2013 Congressional Research Service Report for Congress, "Fluoride in Drinking Water: A Review of Fluoridation and Regulation Issues:** This report discusses the potential benefits and adverse effects associated with the fluoridation of drinking water supplies a well as the regulation of fluoride drinking water to protect against adverse health effects from exposer to higher levels of fluoride. The report reviews the status of federal efforts to update the health risk assessment for fluoride and the primary drinking water standard for fluoride. It presents information from research published in peer-reviewed scientific journals, reports, and statements of federal agencies and the World Health Organization, and studies by the National Research Council along with other sources.
http://fas.org/sgp/crs/misc/RL33280.pdf (See attachment 2f.)

Attachment 2a

Willard Battery Service	1.80
Harold Crawford	5.45
Mann's Stationery	22.31
Lighting Buildings	14.83
Interest	67.50
Due From	593.64
Plant Investment	327.89
Treasurer of U. S.	4464.00
University of Denver	18.00
Petty Cash	75.00
Mann's Stationery	68.90
State Treasurer	437.92
Water Department	35.00
Wall Electric Supply Co.	133.56
Schroders Motors Inc.	2.22
The Quick Print Shop	13.90
Boise Payette Lumber Co.	60.72
The States Tele. & Tele. Co.	24.20
Hendrie & Bolthoff Co.	107.97
Wall Electric Co.	215.20
Langert Tire Shop	21.75
A. F. Hansen Shop	15.75
U.S. Postmaster	60.61
Mine & Smelter Supply Co.	25.32
Jones Bros.	1.00
The Carson Machinery Co.	3.11
Chambers Plumbing & Heating	10.83
The Collins Brick & Tile Co.	70.00
Electric Department	157.08
Petty Cash Fund	7.50
Water Department	30.00
J. A. Martin	1.50
A.F. Hansed Shop	3.00
The States Tele. & Tele. Co.	7.70
Gateway Coal & Feed Co.	4.00
George A. Walker Farm Implement	43.20
American Pipe & Supply Co.	47.20
General Fund	842.25
C. R. Gates	125.00
Harold Allsup	25.00
Don Ramsey	25.00
T. A. Benson	75.00
General Fund	10.90
The States Tele. & Tele. Co.	5.20
Louden Irrigating Canal	59.55
Electric Department	3.65
National Cash Register Co.	7.36
Petty Cash	1.00
Lighting Streets	709.23
Gasoline	391.28
Meters Expense	8.25
Hydrants	400.00
Payroll	5650.60
U. S. Postmaster	80.30
Petty Cash	81.30
General Fund	8823.66
General Fund	833.00
Petty Cash	35.64
McGraw Hill Book Co.	6.24
Gray-Mar Electric Co.	95.60
Sutter's Conoco Station	4.08
Gateway Coal & Feed Co.	1.20
General Electric Supply Co.	101.47
Willard Battery Service Co.	13.40
Mine & Smelter Supply Co.	1564.08
J. A. Martin Shop	48.24
Ferguson Hardware Co.	38.87
Payroll	4025.90
American National Bank	467.00
The Texas Co.	10.34
Sutters Conoco Station	9.00
Crane O'Fallen Co.	17.07
Vorreiter Coal Co.	67.30
Wallace & Tiernan Sales Corp.	84.00
Holm's Stationery	27.05
General Fund	161.64
Ferguson Hardware Co.	51.60
Bob Hipps Co.	13.20
Willard Battery Service	5.75
Boise Payette Lumber Co.	77.24
Hendrie & Bolthoff Co.	619.44
Standard Oil Co.	5.40
C. R. Booton	16.00
Wm. H. Campbell	75.00
Fred Schroder	25.00
F. L. Pray	25.00
Tom Patterson	25.00
Payroll	699.00
Carson Brothers	137.28
Loveland Pipe Line Co.	160.50
W. H. Vorreiter Coal Co.	10.00
Big Lateral Ditch Co.	3.99
GRAND TOTAL	$ 49,658.51

Councilman Lybarger moved that the foregoing bills be allowed and paid. Motion seconded by Glassgow and carried.

There being no further business it was moved seconded and carried to adjourn.

Approved E. F. Garrett
Mayor

Attest Harold A. Vandapool
City Clerk

#1

Loveland, Colo.
April 15th, 1952.

The City Council met in regular session on the above date with Mayor E.F.Garrett presiding and Clerk Vandapool was present. The following Councilmen answered to roll call. Hipps, Ferguson, Patterson, Lybarger, Tyler, Gentry, Glassgow and Schroder.

The minutes of the regular meeting of the City Council held on the 1st day of April, 1952, were then read and on motion of Hipps seconded by Schroder and carried were approved as read.

Councilman Schroder then moved that a donation of $225.00 be made for the Stone Age Fair. Motion seconded by Lybarger and carried.

On motion of Schroder seconded by Tyler and carried, the application of a proposed addition to the City as submited by Dr. A.N.Grosboll was refered to the Planning Commission for further study.

Councilman Hipps moved that the City Council recognizing the deficiency of fluorime in the Loveland water supply below the recommended optimum. It is moved that steps be taken to increase the amount of fluorine to proper amounts as recommended by the health and dental authorities. Motion seconded by Schroder and carried by all Councilmen present voting Aye to roll call.

The following Resoltuion was then read to the Council.

R E S O L U T I O N

WHEREAS- The plant and non-expendable equipment of the Loveland Memorial Hospital was purchased and is owned by the City of Loveland, and

WHEREAS- former patients and other citizens of the community from time to time desire to make gifts of money and other assets to add to the permanent equipment of the Hospital, and

WHEREAS- it is the desire of the governing body of the City of Loveland to handle and administer such gifts in the most business like manner, now therefore

BE IT RESOLVED- that the Luthern Hospitals and Homes Society, operating agency of the Loveland Memorial Hospital, and its agents, shall hereafter deposit all such money gifts with the City Clerk of the City of Loveland, and that expenditures for new or added equipment from such funds shall hereafter be made only upon the recommendation of the Hospital Advisory Board.

#2

The foregoing resolution was adopted at a special meeting of the members of the Hospital Advisory Board by unanimous vote of all members present on April 8, 1952, and its adoption by the governing body of the City of Loveland is hereby urged by the board in order to conserve the funds of the City and facilicte the handling of money gifts and the purchase of additional equipment for the Loveland Memorial Hospital. Signed by E.M.Ivers, Chairman. H.E.Holden, F.S.Knox, Carl W. Kibbey, H. PArker Jackson an Eric J. Sundquist.

Councilman Lybarger moved that the foregoing Resolution be adopted by the City Council and a copy of same be sent to The Luthern Hospitals and Homes Society, Mr. Walker and Miss Larrence. Motion seconded by Gentry and carried by all Councilmen present voting Aye to roll call.

Councilman Ferguson then moved that an Ordinance vacating a portion of the Street in the Northwest part of Tomlinson subdivision of the North End Addition to the City of Loveland, Colorado, be passed on final reading and published. Motion seconded by Schroder and carried.

Councilman Glassgow moved that an Ordinance amending section 3, of Ordinance No. 281 of the Ordinances of the City of Loveland, known as the Zoning Ordinance be passed on final reading and Published. Motion seconded by Patterson and carried.

Councilman Lybarger then moved that an Ordinance for the regulation of traffic upon the public streets of the City of Loveland, adopting by reference "The Model Traffic Ordinance for Colorado Municipalities" as amended herein and repeling Ordinance No. 320 and all other Ordinances and sections of Ordinances in conflict therewith, be passed on final reading and published. Motion seconded by Tyler and carried by all Councilmen present voting Aye to roll call.

On motion of Glassgow seconded by Tyler and carried the schedule of fines as set up in the Municipal Court of the City of Loveland and appering under General Order No. 1 was approved and adopted and the Clerk was instructed to publish same in the Reporter Herald.

Councilman Ferguson moved that the Mayor and City Clerk be authorized to execute agreement with Willis D. and Harold L. Blackford in the matter of Bus Operators of the Loveland City Bus Co/

The following Resolution was then introduced to the Council

R E S O L U T I O N

WHEREAS, the following described property, to-wit: Lots one (1) to Twenty (20) inclusive, in Block One (1), Wilson Addition to the City of Loveland, Colorado, said addition lying between East Fourth and Fifth Streets and West of Factory Avenue are without sanitary sewers and the nature of the soil and the condition in said blocks is such that a sanitary sewer is necessary for the public health and safety of the City of Loveland and the inhabitants thereof and especially of the inhabitants of said blocks, and

WHEREAS, upon order of the City Council, the City Engineer has prepared full detailed specifications and maps describing the materials to be used in said sanitary sewer, the number of installments and time in which the costs of the improvements shall be payable, the rate of interest on unpaid and deferred installments and the property to be assessed for the same and a schedule showing the approximate amounts to be assessed upon the several lots and parcels of property within the district, which detailed specifications schedules and maps are now in file with the City Clerk, now

THEREFORE, be it resolved that a sanitary sewer in the above described territory is a necessity for the public health of the City of Loveland and the inhabitants thereof, and the inhabitants of the territory above described, and the detailed specifications, plans, estimates, schedules and maps prepared by the Engineer, aforesaid, and filed with the Clerk are hereby adopted and approved and the City Clerk is hereby authorized to give the required notice pursuant to Subdivision 6 of Section 66, Chapter 138, 1935 Colorado Statutes Annotated.

Councilman Patterson moved the adoption of the foregoing Resolution. Motion seconded by Hipps and carried by all Councilmen present voting Aye to roll call.

Attorney Conrad Ball then brought to the attention of the City Council the application of the Public Service Co to purchase the Highway Gas CO. After polling the Council Mayor Garrett announced that their were no objections to said application from said City Council.

Councilman Schroder then moved that the action of the Water Committee in purchasing $5380.58 in water pipe from the Pacific State Cast Iron Co. be approved by the Council. Motion seconded by Hipps and carried.

There being no further business it was moved seconded and carried to adjourn.

Approved _____ Mayor

Attest _____ City Clerk

Loveland Colo.
May 6th, 1952.

The City Council met in regular sessionoon the above date with Mayor E.F.Garret presiding and Clerk Vandapool was present. The following Councilmen answered to roll call. Hipps, Ferguson, Patterson, Lybarger, Tyler, Gentyr, Glassgow and Schroder.

The minutes of the regular meeting of the City Council held on the 15th day of April, 1952, were then read and on motion of Patterson seconded by Lybarger and carried were approved as read.

Councilman Hipps moved that the City sponsor the use of the Legeon room for a meeting of the Larimer County Health Asso. as of the evening of May 13th, 1952. Motion seconded by Glassgow and carried.

Councilman Patterson then moved that the petition to use East 4th Street from R.R.Ave to Jefferson Ave. to put on a Summer Festival Show as petitioned by the retail Auto Dealers, Implement Companys and Merchants of the City as of May the 27th, 1952, be granted. Motion seconded by Gentry and carried.

On motion duly made seconded and carried the report of City Attorney Conrad Ball on the North Loveland General Improvement District was accepted and ordered filed.

Councilman Hipps then moved that an Ordinance organizing a general improvement district in the City of Loveland, Colorado, adjudicating all questions of jurisdiction: declaring said district organized; and giving said district the name of "North Loveland General Improvement District". Beppassed on first reading and published, Motion seconded by Lybarger and carried by all Councilmen present voting Aye to roll call.

Attachment 2b

By Date

EPA and HHS Announce New Scientific Assessments and Actions on Fluoride / Agencies working together to maintain benefits of preventing tooth decay while preventing excessive exposure

Search this collection of releases | or search all news releases

Get news releases by email

View selected historical press releases from 1970 to 1998 in the EPA History website.

Recent additions

2014
2013
2012
2011
2010

Release Date: 01/07/2011

Contact Information: HHS Office of the Assistant, Secretary for Health (OASH)--, Public Affairs, ashmedia@hhs.gov, 202-205-0143, EPA, Jalil Isa (Media Inquiries Only), isa.jalil@epa.gov, 202-564-3226, 202-564-4355

WASHINGTON – The U.S. Department of Health and Human Services (HHS) and the U.S. Environmental Protection Agency (EPA) today are announcing important steps to ensure that standards and guidelines on fluoride in drinking water continue to provide the maximum protection to the American people to support good dental health, especially in children. HHS is proposing that the recommended level of fluoride in drinking water can be set at the lowest end of the current optimal range to prevent tooth decay, and EPA is initiating review of the maximum amount of fluoride allowed in drinking water.

These actions will maximize the health benefits of water fluoridation, an important tool in the prevention of tooth decay while reducing the possibility of children receiving too much fluoride. The Centers for Disease Control and Prevention named the fluoridation of drinking water one of the 10 great public health achievements of the 20th century.

"One of water fluoridation's biggest advantages is that it benefits all residents of a community—at home, work, school, or play," said HHS Assistant Secretary for Health Howard K. Koh, MD, MPH. "Today's announcement is part of our ongoing support of appropriate fluoridation for community water systems, and its effectiveness in preventing tooth decay throughout one's lifetime."

"Today both HHS and EPA are making announcements on fluoride based on the most up to date scientific data," said EPA Assistant Administrator for the Office of Water Peter Silva. "EPA's new analysis will help us make sure that people benefit from tooth decay prevention while at the same time avoiding the unwanted health effects from too much fluoride."

HHS and EPA reached an understanding of the latest science on fluoride and its effect on tooth decay prevention, and the development of dental fluorosis that may occur with excess fluoride consumption during the tooth forming years, age 8 and younger. Dental fluorosis in the United States appears mostly in the very mild or mild form – as barely visible lacy white markings or spots on the enamel. The severe form of dental fluorosis, with staining and pitting of the tooth surface, is rare in the United States.

There are several reasons for the changes seen over time, including that Americans have access to more sources of fluoride than they did when water fluoridation was first introduced in the United States in the 1940s. Water is now one of several sources of fluoride. Other common sources include dental products such as toothpaste and mouth rinses, prescription fluoride supplements, and fluoride applied by dental professionals. Water fluoridation and fluoride toothpaste are largely responsible for the significant decline in tooth decay in the U.S. over the past several decades.

HHS' proposed recommendation of 0.7 milligrams of fluoride per liter of water replaces the current recommended range of 0.7 to 1.2 milligrams. This updated recommendation is based on recent EPA and HHS scientific assessments to balance the benefits of preventing tooth decay while limiting any unwanted health effects. These scientific assessments will also guide EPA in making a determination of whether to lower the maximum amount of fluoride allowed in drinking water, which is set to prevent adverse health effects.

The new EPA assessments of fluoride were undertaken in response to findings of the National Academies of Science (NAS). At EPA's request, NAS reviewed new data on fluoride in 2006 and issued a report recommending that EPA update its health and exposure assessments to take into account bone and dental effects and to consider all sources of fluoride. In addition to EPA's new assessments and the NAS report, HHS also considered current levels of tooth decay and dental fluorosis and fluid consumption across the United States.

Comments regarding the EPA documents, Fluoride: Dose-Response Analysis For Non-cancer Effects and Fluoride: Exposure and Relative Source Contribution Analysis should be sent to EPA at FluorideScience@epa.gov. The documents can be found at http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm

The notice of the proposed recommendation will be published in the Federal Register soon and HHS will accept comments from the public and stakeholders on the proposed recommendation for 30 days at CWFcomments@cdc.gov. HHS is expecting to publish final guidance for community water fluoridation by spring 2011. You may view a prepublication version of the proposed recommendation at: http://www.hhs.gov/news/press/2011pres/01/pre_pub_frn_fluoride.html.

More information about the national drinking water regulations for fluoride:
http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm

Q&A's on latest EPA actions on fluoride:
http://water.epa.gov/lawsregs/rulesregs/regulatingcontaminants/sixyearreview/upload/2011_Fluoride_QuestionsAnswers.pdf

More information on EPA's fluoride assessment and to comment:
http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm

More information about community water fluoridation, information on tooth decay prevention and dental fluorosis:
http://www.cdc.gov/fluoridation

Receive our News Releases Automatically by Email

Last updated on Thursday, July 03, 2014

Attachment 2c

STATE OF COLORADO

Bill Ritter, Jr., Governor
Martha E. Rudolph, Executive Director

Dedicated to protecting and improving the health and environment of the people of Colorado

4300 Cherry Creek Dr. S.
Denver, Colorado 80246-1530
Phone (303) 692-2000
TDD Line (303) 691-7700
Located in Glendale, Colorado

http://www.cdphe.state.co.us

Laboratory Services Division
8100 Lowry Blvd.
Denver, Colorado 80230-6928
(303) 692-3090

Colorado Department of Public Health and Environment

Community Water Fluoridation Update

Jan. 12, 2011

The U.S. Department of Health and Human Services(HHS) and the Environmental Protection Agency (EPA) issued a joint press release Jan. 7, 2011, to announce new recommendations for community water fluoridation. HHS is changing its recommendation from a range of 0.7 – 1.2 milligrams per liter to a static 0.7 mg. per liter because of the availability of additional fluoride sources. ***The Colorado Department of Public Health and Environment supports community water fluoridation as an effective public health practice and will issue recommendations to Colorado water treatment facilities once HHS recommendation are made final.***

What is changing, when and why?

- Because of the proliferation of other fluoride products, HHS recognizes it is now possible to receive enough fluoride with slightly lower levels of fluoride in water.
- HHS will take public comments for 30 days and issue a final recommendation Spring 2011
- Community water fluoridation is voluntary in Colorado.
- CDPHE recommends community water fluoridation and provides technical support for water treatment operators.

Community water fluoridation remains the safest, most effective method for preventing and reducing tooth decay.

- Fluoride in drinking water has been shown to reduce tooth decay by 20 – 40%.
- More than five decades of study have shown water fluoridation to be safe and effective.
- A 2003 Colorado study showed community water fluoridation contributed to an annual savings of $149 million in avoided dental treatment, about $61 per person.
- About 65% of Colorado communities fluoridate their water, typically achieving a range of .9 – 1.1 mg. per liter.
- The CDC calls fluoridation one of 10 great public health interventions of the 20th Century.

-more-

Tell me more about fluoride

- Fluoride is naturally occurring element found in water.
- Not all communities have enough naturally occurring fluoride to effectively prevent and reduce tooth decay, so they add it.
- Routine consumption of fluoridated water and proper use of fluoride products is not harmful.
- Excess fluoride intake can cause dental fluorosis, a cosmetic effect evidenced by tiny white or brown spots.

Children and fluoride

- Children under 2 years old should not use toothpaste when brushing their teeth unless it is recommended by a health professional. They should brush with a soft bristle toothbrush and water.
- Parents should use a pea-sized amount of toothpaste on a child's toothbrush until they are 6 years old and supervise their brushing to teach them to spit, not swallow toothpaste.

Please call the CDPHE Oral Health Unit at 303-692-2470 with questions or concerns.

Attachment 2d

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.

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.

References

American Dental Association. Council on Scientific Affairs. Professionally applied topical fluoride—evidence-based clinical recommendations. J Am Dent Assoc 2006;137:1151–1159.

Aoba T, Fejerskov O. Dental fluorosis: Chemistry and biology. Critical Reviews in Oral Biology & Medicine 2002;13(2):155–70.

Beltran-Aguilar ED, Barker L, Dye BA. Prevalence and Severity of Enamel Fluorosis in the United States, 1986–2004. NCHS data brief no 53. Hyattsville, MD: National Center for Health Statistics. 2010a. Available at: *http://www.cdc.gov/nchs/data/databriefs/db53.htm.*

Beltrán-Aguilar ED, Barker L, Sohn W. Daily temperature and children's water intake in the United States. Accepted for publication, CDC's Division of Oral Health, 2010b. *http://www.cdc.gov/fluoridation/fact_sheets/totalwaterintake.htm.*

Burt BA (Ed). Proceedings for the workshop: Cost-effectiveness of caries prevention in dental public health, Ann Arbor, Michigan, May 17–19, 1989. J Public Health Dent 1989;49(special issue):331–7.

Burt BA, Eklund SA. Dentistry, Dental Practice, and the Community. 6th ed. St. Louis, MO: Elsevier Saunders; 2005.

Centers for Disease Control and Prevention. Promoting oral health: interventions for preventing dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries: a report on recommendations of the Task Force on Community Preventive Services. MMWR 2001a;50(No. RR–21):1–14.

Centers for Disease Control and Prevention. Recommendations for using fluoride to prevent and control dental caries in the United States. MMWR Recommendations and Reports 2001b;50(RR–14).

Centers for Disease Control and Prevention. Achievements in Public Health, 1900–1999: Fluoridation of drinking water to prevent dental caries. MMWR 1999;48(41):933–940.

Dye B, Tan S, Smith V, Lewis BG, Barker LK, Thornton-Evans G, Eke, P, Beltrán-Aguilar ED, Horowitz AM, Li C–H.

(2007). Trends in oral health status, United States, 1988–1994, *Vital and Health Statistics Series 11 No. 248.*
Evans RW, Stamm JW. Dental fluorosis following downward adjustment of fluoride in drinking water. J Public Health Dent 1991;51(2):91–98.
Featherstone JDB. Prevention and reversal of dental caries: role of low level fluoride. Community Dent Oral Epidemiol 1999;27:31–40.
Galagan DJ, Vermillion JR. Determining optimum fluoride concentrations. Public Health Rep 1957;72:491–3.
Galagan DJ. Climate and controlled fluoridation. J Am Dent Assoc 1953;47:159–70.
Galagan DJ, Vermillion JR, Nevitt GA, Stadt ZM, Dart RE. Climate and fluid intake. Public Health Rep 1957;72:484–90.
Griffin SO, Regnier E, Griffin PM, Huntley V. Effectiveness of fluoride in preventing caries in adults. J Dent Res 2007;86:410–415.
Heller KE, Eklund SA, Burt BA. Dental caries and dental fluorosis at varying water fluoride concentrations. J Public Health Dent 1997;57:136–43.
Heller KE, Sohn W, Burt BA, Eklund SA. Water consumption in the United States in 1994–96 and implications for water fluoridation policy. J Public Health Dent 1999;59:3–11.
Kelly JE. Decayed, missing and filled teeth among youths 12–17 years. Vital and Health Statistics Series 11, No. 144, 1975. DHEW Publication No. (HRA) 75–1626.
Kelly JE, Harvey CR. Basic dental examination findings of persons 1–74 years. In: Basic data on dental examination findings of persons 1–74 years, United States, 1971–1974. Vital and Health Statistics Series 11, No. 214, 1979. DHEW Publication No. (PHS) 79–1662.
Kelly JE, Van Kirk LE, Garst CC. Decayed, missing, and filled teeth in adults. Vital and Health Statistics Series 11, No. 23. 1973. DHEW Publication No. (HRA) 74–1278. Reprinted from Public Health Service publication series No. 1000, 1967.
Koulourides T. Summary of session II: fluoride and the caries process. J Dent Res 1990;69(Spec Iss):558.
Levy SM, Broffitt B, Marshall TA, Eichenberger-Gilmore JM, Warren JJ. Associations between fluorosis of permanent incisors and fluoride intake from infant formula, other dietary sources and dentifrice during early childhood. J Am Dent Assoc 2010;141:1190–1201.
Lo ECM, Evans RW, Lind OP, Dental caries status and treatment needs of the permanent dentition of 6–12 year-olds in Hong Kong. Community Dent Oral Epid 1990;18:9–11.
Massler M and Schour I. 1958. Atlas of the mouth in health and disease.2nd ed., 6th printing 1982. Chicago: American Dental Association.
McClure FJ. Ingestion of fluoride and dental caries. Am J dis Child 1943;66:362–9.
McDonagh MS, Whiting PF, Wilson PM, Sutton AJ, Chestnutt I, Cooper J, Misso K, Bradley M, Treasure E, Kleijnen J. Systematic review of water fluoridation Br Med J 2000a;321:855–859.
McDonagh MS, Whiting PF, Bradley M. *et al.* A systematic review of public water fluoridation. NHS Centre for Reviews and Dissemination. University of York, September 2000b. Available at: *http://www.york.ac.uk/inst/crd/CRD_Reports/crdreport18.pdf.*
Newacheck PW, Hughes DC, Hung YY, Wong S, Stoddard JJ. The unmet health needs of America's children. Pediatrics 2000;105(4 Pt 2):989–97.
Osuji OO, Leake JL, Chipman ML, Nikiforuk G, Locker D, Levine N. Risk factors for dental fluorosis in a fluoridated community. J Dent Res 1988;67:1488–92.
Pendrys DG, Katz RV, Morse DR. Risk factors for enamel fluorosis in a fluoridated population. Am J Epidemiol 1994;140:461–71.
Pendrys DG, Katz RV. Risk for enamel fluorosis associated with fluoride supplementation, infant formula, and fluoride dentifrice use. Am J Epidemiol 1989;130:1199–208.
Pendrys DG. Risk for fluorosis in a fluoridated population: implications for the dentist and hygienist. J Am Dent Assoc 1995;126:1617–24.
Sohn W, Heller KE, Burt BA. Fluid Consumption Related to Climate among Children in the United States. J Public Health Dent 2001;61:99–106.
Truman BI, Gooch BF, Evans CA Jr. (Eds.). The Guide to Community Preventive Services: Interventions to prevent dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries. Am J Prev Med 2002;23(1 Supp):1–84.
U.S. Department of Health and Human Services. Oral Health of United States Children. The National Survey of Dental Caries in U.S. School Children: 1986–1987. NIH Publication No. 89–2247, 1989.
U.S. Department of Health and Human Services. Oral Health in America; A Report of the Surgeon General. Rockville, MD: USDHHS, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000.
U.S. Department of Health and Human Services. Food and Drug Administration. 21 CFR Part 355. Anticaries drug products for over-the-counter human use. Code of Federal Regulations 2010: 306–311.
U.S. Department of Health, Education, and Welfare. Public Health Service drinking water standards, revised 1962. Washington, DC: Public Health Service Publication No. 956, 1962.
U.S. Department of Health, Education, and Welfare. Food and Drug Administration. Anticaries drug products for over-the-counter human use establishment of a monograph; Notice of proposed rulemaking. Fed Regist. 1980;45(62):20666–20691. To be codified at 21 CFR Part 355.
U.S. EPA (U.S. Environmental Protection Agency). 2010a. *Fluoride: Exposure and Relative Source Contribution Analysis.* Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, Washington, DC. EPA 820–R–10–015. Available at: *http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm.* Comments regarding the document, *Fluoride: Exposure and Relative Source Contribution Analysis,* should be sent to EPA at *FluorideScience@epa.gov.*
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.*
Wong MCM, Glenny AM, Tsang BWK, Lo ECM, Worthington HV, Marinho VCC. Topical fluoride as a cause of dental fluorosis in children. *Cochrane Database of Systematic Reviews* 2010, Issue 1. Art. No.: CD007693. DOI:10.1002/14651858.CD007693.pub2.

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

Attachment 2e

ASPE.hhs.gov U.S. Department of Health & Human Services

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

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

Subject of Planned Report: Recommended fluoride content (mg/L) in community water systems to prevent dental caries (tooth decay)

Purpose of Planned Report: To update and replace previous U.S. Public Health Service recommendations for adjusted fluoride concentration in drinking water to prevent dental caries, because of new data that address 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.

Type of Dissemination: Influential Scientific Information

Timing of Review: July – November, 2012

Type of Review: Individual

Opportunities for the Public to Comment: The HHS recommendation (proposed) was made available for public comment on January 13, 2011. The 30 day public comment period was extended through April 15, 2011.

Peer Reviewers Provided with Public Comments before the Review: Yes

Anticipated Number of Reviewers: 3

- Michael Kosnett

  Academic and Professional Credentials: MD, MPH Organizational Affiliation: Adjunct Associate Professor, Department of Environmental and Occupational Health, Colorado School of Public Health, Denver Areas of Expertise, Discipline, or Relevant Experience: Occupational and Environmental Toxicology; Clinical Toxicology of Heavy Metals Recommended by: HHS Federal Panel on Community Water Fluoridation

- Nancy K. Kim

  Academic and Professional Credentials: PhD Organizational Affiliation: Adjunct Associate Professor, School of Public Health, University at Albany, State University of New York Areas of Expertise, Discipline, or Relevant Experience: Environmental Health Recommended by: HHS Federal Panel on Community Water Fluoridation

- Steven M. Levy

  Academic and Professional Credentials: DDS, MPH Organizational Affiliation: Professor, College of Dentistry, University of Iowa, Iowa City Areas of Expertise, Discipline, or Relevant Experience: Oral Epidemiology; Epidemiology of Fluoride Intake, Caries, and Dental Fluorosis Recommended by: HHS Federal Panel on Community Water Fluoridation

Primary Disciplines or Expertise: Epidemiology, oral epidemiology, environmental health, metabolism and effects of fluoride on teeth

Reviewers Selected by: HHS Federal Panel on Community Water Fluoridation

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: A notice by the Department of Health and Human Services, *Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries*, was published in the Federal Register (FR) on January 11, 2011. This notice provides new guidance supported by available scientific information. The original document published in January 2011 has been revised with addition of the HHS Inter-Agency Panel's review of public comments and supporting references. We are requesting your critical review to determine if the revised document (HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries) is consistent with available scientific information. For purposes of this guidance, the optimal concentration of fluoride in drinking water provides the best balance of protection from dental caries while limiting the risk of dental fluorosis.

As you review both documents (original FR notice and summary of public comments), please assess whether any key studies have been left out or, in your opinion, misinterpreted--and whether the conclusions are appropriate, given the evidence. Please consider the information on cumulative sources of fluoride exposure and risk of severe dental fluorosis among children, provided by the U.S. Environmental Protection Agency and referenced in the document. These EPA assessments were externally peer-reviewed prior to publication in December 2010. In addition, please remember that final decisions on policy related to the fluoride concentration in drinking water to prevent dental caries remain within the purview of government. This review focuses on the scientific information that serves as a foundation for such policy.

Specific questions for your consideration include:

1. Are there omissions of critical information or key studies related to the main reasons for the proposed change? Main reasons are the following:
   - Community water fluoridation remains an important, cost-effective source of fluoride;
   - Given the current availability of fluoride from multiple sources, the proposed concentration of 0.7 mg/L is expected to reduce the risk of dental fluorosis among children. That value is the lowest concentration in the currently recommended range of 0.7-1.2 mg/L and is expected to reduce total fluoride intake of young children;
   - Given the current availability of fluoride from multiple sources, the proposed concentration of 0.7 mg/L is expected to achieve caries preventive benefits comparable to the currently recommended range of 0.7-1.2 mg/L;
   - Because no association was found between fluid intake among children and adolescents and outdoor ambient temperature, a rationale for the current recommended range of 0.7-1.2 mg/L no longer exists.
2. Are conclusions about the main reasons correct?
3. Have public comments been appropriately considered in the final document?
4. Has inappropriate information been included? If so, what should be removed? Please explain.

5. Do you have concerns about technical or factual accuracy of statements? If so, please explain.
6. Is this document clear and easily understood by a general audience? If not, which sections need revision?

Last Revised: 06/11/13

Attachment 2f

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

Mary Tiemann
Specialist in Environmental Policy

April 5, 2013

Congressional Research Service
7-5700
www.crs.gov
RL33280

CRS Report for Congress
Prepared for Members and Committees of Congress

Summary

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

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

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

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

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

Contents

Tables

Contacts

Introduction

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

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

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

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

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

Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

---

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

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

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

[12] Ibid.

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

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

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

Questions About the Safety and Benefits of Fluoridation

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

Dental Fluorosis

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

---

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

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

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

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

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

Because of the increased use of fluoridated dental products and the tendency for young children to swallow these products, concern over dental fluorosis and other potential effects of fluoride ingestion has increased. Questions have arisen as to whether current fluoridation practices and levels offer the most appropriate ways to provide the expected beneficial effects of fluoride while avoiding adverse effects that can result from ingesting too much fluoride. As noted by NRC in 1997, "In addition to fluoride in drinking water, people also can ingest fluoride in toothpaste, mouth rinse, and dietary fluoride supplements or in beverages and foods prepared with fluoridated water. As a result, many Americans might ingest more 'incidental' fluoride than was anticipated by the PHS and by EPA in recommending standards for drinking water."[19]

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

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

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

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

(...continued)

higher.

[19] Ibid.

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

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

[22] Ibid., p. 209.

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

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

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

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

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

Health Effects

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

---

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

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

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

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

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

Bone Fracture Incidence

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

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

Cancer Studies

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

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

---

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

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

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

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

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

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

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

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

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

---

[33] Ibid., p. 110.

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

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

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

[37] Ibid., p. 121.

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

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

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

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

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

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

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

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

Efficacy

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

---

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

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

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

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

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

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

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

Other Considerations

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

(...continued)

308-314.

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

[48] Ibid., p. 128.

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

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

[51] Ibid., p. 855.

[52] Ibid., p. 859.

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

Regulation of Fluoride in Drinking Water

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

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

Standard Setting

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

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

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

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

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

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

Current Fluoride Standards

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

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

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

---

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

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

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

Table 1. EPA Standards for Fluoride in Drinking Water

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

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

EPA Fluoride Standards Review: 2002

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

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

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

[59] Ibid., p. 11.

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

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

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

In March 2006, the NRC committee issued *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*. The study concluded that EPA's MCLG of 4 mg/L should be lowered, and that information gaps regarding fluoride "prevented the committee from making some judgments about the safety or the risks of fluoride at concentrations of 2 to 4 mg/L."[62] (Because NRC's charge was to evaluate the scientific basis and adequacy of EPA's drinking water standards for fluoride, *the committee did not address questions concerning the risks or benefits of artificial fluoridation.*) The NRC committee's major findings are reviewed below.

Dental Fluorosis

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

---

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

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

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

[63] Ibid, pp. 104-105. The NRC fluoride committee concluded that "... damage to teeth caused by severe dental fluorosis is a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effects." (Summary, p. 3.)

Skeletal Fluorosis

As noted, EPA set the fluoride MCLG and MCL to protect against the adverse health effect of crippling skeletal fluorosis (*stage III* skeletal fluorosis). In this latest review, the NRC committee concluded that *stage II* skeletal fluorosis, the symptoms of which include sporadic pain, joint stiffness, and abnormal thickening (osteosclerosis) of the pelvis and spine, also constitutes an adverse health effect. Based on comparison of bone ash concentrations of fluoride and related evidence of skeletal fluorosis, the committee further found the data to suggest that

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

Bone Fractures

The committee also reviewed the few studies available for evaluating bone fracture risks from exposure to fluoride at 2 to 4 mg/L or more. NRC reported that clinical studies indicated an increased risk of nonvertebral bone fracture and a slightly decreased risk of vertebral fractures in populations exposed to fluoride at 4 mg/L. The consensus of the committee was that, under certain conditions, fluoride can weaken bone and increase the risk of fractures. Moreover,

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

Carcinogenicity

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

---

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

[65] Ibid.,

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

overall, the literature does not clearly indicate that fluoride either is or is not carcinogenic in humans.[67] NRC noted that the Harvard School of Public Health was expected to publish a large, hospital-based case-control study of osteosarcoma and fluoride exposure in 2006, and that the results of that study might help to identify research needs. The NRC review did include an assessment of pre-publication data from an "exploratory analysis" of a subset of the Harvard data that found an association between exposure to fluoride in drinking water and the incidence of osteosarcoma in young males. The authors of this research noted several limitations with the analysis (e.g., relying on estimated fluoride exposure from drinking water) and concluded that further research was needed to confirm or refute the results.[68] The subsequent study evaluated whether bone fluoride levels were higher in individuals with osteosarcoma. In this study, reported in 2011, researchers detected no significant association between bone fluoride levels and osteosarcoma risk.[69] The authors noted that "the major advantage of this study is the use of bone fluoride concentrations as the measure of fluoride exposure, rather than estimated fluoride exposure in drinking water."[70]

Other Potential Effects

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

Research Needs

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

---

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

[68] Bassin, E.B., Wypij, D. Davis, R.B., Mittleman, M.A. *Age-specific Fluoride Exposure in Drinking Water and Osteosarcoma (United States)*, Cancer Causes and Control, 2006, v. 17, pp. 421-428. In a letter to the editor in this same issue, the principal investigator of the larger 15-year Harvard research project, Dr. C. W. Douglass, cautioned readers not to overinterpret the results of the Bassin study, and to wait for the results of the full study.

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

[70] Ibid., p. 1175.

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

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

NRC Recommendations

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

> To develop an MCLG that is protective of severe enamel fluorosis, clinical stage II skeletal fluorosis, and bone fractures, EPA should update the risk assessment of fluoride to include new data on health risks and better estimates of total exposure (relative source contribution) in individuals and to use current approaches to quantifying risk, considering susceptible subpopulations, and characterizing uncertainties and variability.[73]

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

EPA's Review of Fluoride Standards

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

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

[73] Ibid., p. 299.

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

[75] U.S. Environmental Protection Agency, "National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues," 75 *Federal Register* 1550, March 29, 2010.

[76] Ibid., p. 15544.

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

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

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

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

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

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

---

[78] Ibid., p. I.

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

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

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

[82] Ibid., p. 109.

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

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

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

Conclusion

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Author Contact Information

Mary Tiemann
Specialist in Environmental Policy
mtiemann@crs.loc.gov, 7-5937