

Responses to Peer Reviewer Comments

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

Peer Reviewers (in alphabetical order)

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

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

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

Reviewer Comments, by Reviewer

In this document, the six questions designed to guide peer reviewer evaluation of the Inter-Agency Federal Panel’s draft report summarizing and responding to public comments (dated July 20, 2012) appear in bold type.

Comments from the three reviewers (identified as A, B, and C, based on the order in which their reviews were received at CDC) are listed under each of the six questions in standard font. Peer reviewer A provided an assessment containing specific comments, but without categorizing them under specific questions--many of this reviewer’s concerns focused on the adequacy and completeness of consideration given to public comments about potential adverse effects of fluoride. In order to create this summary of reviewers’ comments, those specific suggestions have been positioned under the question that seemed most congruent with each comment’s substance. When reviewer A appeared not to address certain questions, it has been noted in this document by the phrase “No Comments.” In addition, line and page numbers cited by Reviewers A and C are no longer accurate, given necessary editing of the document based on comments from all three reviewers, the Inter-Agency Federal Panel, and agency reviews.

The draft document peer reviewers received was presented as a recommendation from the Department of Health and Human Services (DHHS). After peer review was completed, DHHS clarified that this would be a recommendation of the Public Health Service—thus, reviewers’ *verbatim* references to the “HHS document” or “the HHS Panel” have not been changed, even though the “PHS recommendation” and “the Inter-Agency Federal Panel” are used in responses to their comments.

Actions taken in response to peer reviewer comments are described in italics, following each discrete comment by a reviewer.

- 1. Are there omissions of critical information or key studies related to the main reasons for the proposed change? Main reasons are the following:**
 - a. **Community water fluoridation remains an important, cost-effective source of fluoride;**
 - b. **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;**

- c. **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;**
- d. **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.**

Reviewer A

The draft document, "HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries" represents a brief summary of HHS rationale for recommending a fluoride concentration of 0.7 mg/L as a value that offers an optimal balance of protection from dental caries while limiting the risk of dental fluorosis. Based on findings that water intake (and hence water-borne fluoride dose) does not vary based on ambient outdoor temperature, the new guidance departs from a prior recommendation for a range of fluoride concentration (0.7 to 1.2 mg/L).

From a perspective primarily informed by issues relating to environmental health and toxicology, the following review comments are offered:

The initial section of the document that sets forth the HHS recommendation (up to page 10 line 205) focuses exclusively on dental fluorosis as a side effect associated with fluoride intake. Discussion of other potential adverse effects is confined to the section of the draft document (page 11 onward) that responds to public comments.

It would be useful if the initial section of the document presented the independent assessment and conclusion of HHS as to whether other adverse health risks may be posed by community fluoridation of drinking water.

Response

In the Process section of the document, language was added to clarify that the Inter-Agency Federal Panel accepted the extensive National Research Council (NRC) review of fluoride in drinking water as the summary of hazard. The NRC review focused on potential adverse effects of fluoride at 2-4 mg/L drinking water--rather than at the lower concentrations used for water fluoridation--and found no evidence substantial enough to support effects other than severe dental fluorosis at these levels. Because concerns about potential adverse health effects were raised by public comments, they were addressed primarily in that section of the document.

The draft document should reference the findings of the Australian National Health and Medical Research Council report, “A systematic review of the efficacy and safety of fluoridation” which reached similar conclusions to HHS regarding the risks and benefits of community water fluoridation. The reference for that report is: Yeung CA. A systematic review of the efficacy and safety of fluoridation. *Evidence-Based Dentistry* 9:39-48, 2007.

Response

Reference to the Yeung report of the Australian findings has been added, in discussion of both the effectiveness of water fluoridation in preventing caries, and in its lack of association with risk of osteosarcoma. In addition, the full original report (available online), as well as guidelines developed by the Australian Research Centre for Population Oral Health, are cited.

With respect to dental fluorosis as an adverse health effect, the draft HHS document cited a study by Beltran-Aguilar et al (2010) that between 1986-87 and 1999-2004, the prevalence of moderate to severe fluorosis among adolescents aged 12 to 15 increased almost 3-fold, from 1.3% to 3.6%.

The draft document would be improved by offering an expanded discussion regarding what is known regarding how this increase may have been associated with interval changes in the percentage of the population consuming fluoridated drinking water, the level of fluoride in drinking water, and exposure to fluoride in toothpaste and other products.

Response

In the Rationale section (Dental Fluorosis) text has been added to more fully describe interval changes in the percent of the U.S. population receiving fluoridated water for the period (1971 – 2000) during which adolescents examined in the two national surveys of 1986-1987 and 1999-2004 were at risk for development of dental fluorosis in their permanent teeth. In addition, data relevant to exposure to fluoride toothpaste also have been provided. Finally, a new section, Monitoring Implementation of the New Recommendation, describes enhanced national surveillance measures.

In like manner, on page 6, rather than stating, “More information on all sources of fluoride and their relative contributions to total fluoride exposure in the United States is presented in a

report by EPA (US EPA 2010a),” it would be useful for the draft HHS document to summarize data on the relative contribution of fluoridated drinking water to total fluoride dose among US children and adolescents.

Response

In the Rationale section (Trends in Availability of Fluoride Sources) a summary of major findings from the EPA Relative Source Contribution Analysis has been added, in a paragraph following the sentence quoted.

Reviewer B

I did not identify any critical information or key studies that were missing for the proposed changes. The summaries and justifications seemed very solid.

Reviewer C

I am unaware of any omissions in the critical information or key studies for main reasons C and D cited above. However, for main reasons A and B, this document does not provide any data to support the statements; it does provide references for those statements, but the data are not readily available by searching those documents, especially for A which is a supplemental volume of a journal and may not be readily available for many people. I had on-line access to the reference and it was not easy to use to find appropriate data.

For the main reason A above, the document does not provide any specific data to support statements about community water fluoridation being a cost-effective source of fluoride or the statements in the paragraph on cost-effectiveness (lines 437-444). That paragraph cites a 2011 Federal Register (FR) notice and Truman BI, et al., 2002. The 2011 FR article cites Truman BI, et al., too, but the FR article didn't have any obvious discussion of cost-effectiveness. Citing the FR article in this paragraph doesn't provide anything and should be removed. (A minor point is that the citation is given as HHS, 2011AR, but HHS is actually found in the reference list alphabetically under the U.S. Department of Health and Human Services.) The Truman, et al., reference is to a supplement that is entitled The Guide to Community Preventive Services. Interventions to prevent dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries seems to be a specific article in the supplement although trying to figure this out on-line and without a printed document is not easy. I briefly looked for specific cost effectiveness information in the supplement, but it was difficult and I gave up. At a minimum the cost-effectiveness references do not provide a transparent means of identifying any data to back up the statements. Providing a couple of sentences that provide specific data on its cost

effectiveness would strengthen the document. The following sentence is from a fact sheet from the Association of State and Territorial Dental Directors and is an example of the type of statement that would be useful in conjunction with information on the cost of dental caries. (See <http://www.astdd.org/use-of-fluoride-community-water-fluoridation-introduction/>. The citation is to a CDC web address that no longer exists.)

“Given the modest cost of less than 1 dollar per person per year to fluoridate water systems serving most people, community water fluoridation is recommended as a very effective and cost-effective method of preventing caries (4).”

Response

Citation of the original 2011 Federal Register notice was deleted, and the reference to DHHS corrected. To address Reviewer C’s concerns, additional, specific cost-effectiveness data, information, discussion, and references were added--primarily in the section addressing public comments questioning the cost-effectiveness of water fluoridation. The Truman et al. paper presents findings of a systematic review of economic evaluations completed by the Task Force on Community Preventive Services, and that citation has been retained in several places within the document.

For main reason B above, the document does not provide any specific data on the expected reduction in total fluoride intake of young children. The HHS document has related statements on lines 333-335 and lines 528-530.

Response

In Background, text has been added to describe estimated reductions in fluoride intake among young children.

The previously recommended range of 0.7 -1.2 mg/L is for community water systems that add fluoride to their water. Those systems with fluoride levels above 0.7 mg/L could be affected; if they reduce their concentration to 0.7 mg/L, it would likely reduce the fluoride intake for their customers, including young children. Those systems with naturally occurring fluoride levels above 0.7 mg/L may opt to treat their water based on this change; however, those systems are regulated by EPA and would be affected if EPA reduced the MCL for fluoride but not necessarily

by this change. The document should be transparent about which systems and subsequently which people may be affected by this recommendation and whose exposure is expected to be reduced. Although that information is in the document, it may not be obvious to everyone reading it.

I briefly reviewed the reference US EPA, 2010b. I did not see, although I might have missed it, any information on the number of people (or systems) served by water supplies that fluoridate water at concentrations ranging from 0.8-1.2 mg/L, e.g. those that might be affected by the change in this recommendation.

Response

In Background, estimates of the number of persons and systems likely to be affected by the change have been added. New text refers to EPA's ongoing review and estimates the number of persons whose water systems contain naturally occurring fluoride levels >0.7 mg/L. In addition, data showing changes in fluoride concentrations that adjusted systems reported to the Water Fluoridation Reporting System since release of the proposed recommendation have been inserted in a new section, Monitoring Implementation of the New Recommendation.

The EPA document has estimated total fluoride intake for different age categories with different levels of fluoride in the water supply. These tables could provide some support for an expected decrease in fluoride intake, if a system reduced the fluoride level. A statement such as, "The total fluoride intake of people (or children) drinking water that contains about # mg/L of fluoride is about x% higher than that of people drinking water that contains about # mg/L of fluoride" could be added to the document. It gives some data and justification for the statements about reduced fluoride intake and adds transparency to the document.

Response

In Background, text has been added to describe estimated reductions in fluoride intake among young children.

2. Are conclusions about the main reasons correct?

Reviewer A

(No comments)

Reviewer B

The conclusions about the main reasons seem correct.

Reviewer C

- A. Yes, but some data should be given to support statements about cost-effectiveness of fluoridation.
- B. Yes, but add some specific information to identify which people (e.g. those people served by systems affected by the change in the recommendation) could be expected to have their fluoride intake decreased. Also, add some data that supports the conclusion and adds transparency.
- C. Yes. The reasoning behind this change is provided and is easily understandable.
- D. Yes. The reasoning behind this change is provided and is easily understandable.

Response

- A. *Additional, specific data on the cost-effectiveness of water fluoridation have been added, as well as additional references and discussion.*
- B. *Specific information on people likely to be affected by the change in recommendation and estimated reductions in fluoride intake have been added in Background.*

3. Have public comments been appropriately considered in the final document?

Reviewer A

The section that responded to public comments noted the concern of some commenters that fluoridation may have adverse consequences on bone. These concerns were responded to with a single paragraph (page 17) that concluded with the statement, "A level established by EPA to prevent severe dental fluorosis also will protect against bone fractures and skeletal fluorosis (U.S. EPA, 2010b)."

The scientific basis for this statement merits further elaboration and discussion. Is it based solely on epidemiological findings? Is it based to any extent on experimental animal data and/or a mechanistic understanding of the pathogenesis of dental fluorosis and skeletal fluorosis that would indicate that deleterious effects on bone will not appear in the absence of severe dental fluorosis?

Response

Additional detail has been added from both the NRC Report (2006) and the 2010 EPA Dose Response Analysis for Non-Cancer Effects. Language focuses on EPA's conclusions that a level of fluoride intake low enough to protect against severe dental fluorosis in children also will protect against skeletal fluorosis and bone fractures in adults.

With respect to epidemiological findings, the document would be improved by a summary discussion of the studies that have examined this important endpoint [adverse consequences on bone]. It might note that in the 2010 EPA document cited, EPA concluded, "Overall, the available data indicates that exposure to concentrations of fluoride in drinking water of 4 mg/L and above is suggestive of and appears to be positively associated with increased relative risk of bone fractures in susceptible populations when compared to populations exposed to 1 mg F/L" (EPA 2010b, page 86).

Response

The suggested quote from the EPA 2010 study has been included.

HHS is encouraged to include an expanded discussion of the adequacy of the database that has examined the potential impact of fluoride intake at low to moderate levels on bone. HHS should describe the level of scientific confidence pertaining to any apparent threshold for the

emergence of adverse skeletal effects (e.g., a LOAEL or a benchmark does), as well as the margin of exposure between that level and the 0.7 mg/L guidance value.

Response

In the Overview of Public Comments addressing bone fractures and skeletal fluorosis, the EPA work in determining its own benchmark dose to prevent bone effects, and comparing it to those calculated by NRC and WHO, has been described—including EPA’s assessment of the database as inadequate for modeling the complex variation of bone strength by fluoride exposure. In Process, the text has been edited to note that the NRC Report focused on naturally-occurring fluoride concentrations of 2-4 mg/L water, rather than lower ones used for community water fluoridation.

With respect to the concerns of some commenters regarding fluoridation and the risk of cancer, particularly osteosarcoma, the draft document acknowledges the findings of Bassin et al (2006) and appropriately notes the absence of significant associations between bone fluoride concentration and osteosarcoma in the more recent study by Kim et al (2011).

Two other recent epidemiological studies that did not detect significant associations between fluoride and osteosarcoma should be briefly discussed:

Levy M, Leclerc BS. Fluoride in drinking water and osteosarcoma incidence rates in the continental United States among children and adolescents. *Cancer Epid* 36:e83-e88, 2012; and

Comber H et al. Drinking water fluoridation and osteosarcoma incidence on the island of Ireland. *Cancer Causes Control* 22:919-924, 2011.

However, when noting the absence of statistically significant associations in epidemiological studies, HHS should comment on the statistical power of the negative studies to have detected an association of public health significance.

Response

Citation and discussion of the two references were added to the section of the document addressing public concerns about osteosarcoma; the absence of an association was qualified by noting that authors discussed the statistical and methodological limitations of such ecologic studies.

In its response to public comments pertaining to a possible association of fluoride exposure and childhood IQ reported in certain Chinese studies, the HHS draft document cites the finding of NRC (2006) that the lack of details on aspects of the Chinese study designs yields uncertainty regarding their scientific validity and public health significance.

The HHS draft document should indicate whether it concurs with a related comment by the NRC panel that, “While the [Chinese] studies lacked sufficient detail for the committee to fully assess their quality and their relevance to U.S. populations, the consistency of the collective results warrant additional research on the effects of fluoride on intelligence” (NRC 2006, page 221).

Response

The IQ Section of the document was reworked to include the NRC recommendation for additional research on the effects of fluoride on intelligence.

The HHS draft document noted that the recent European assessment (SCHER, 2010) found that biological plausibility for a link between fluoridated water and IQ has not been established.

Since the HHS draft document has cited the NRC report in its response to the public comments on fluoride and IQ, it should comment on whether the possible neurotoxic modes of action of fluoride and aluminum-fluoride complexes discussed by NRC (NRC 2006, pp218-220) are relevant to the issue of biological plausibility of fluoride action at low dose.

Response

Additional sentences have been added to describe the NRC Committee’s speculation regarding potential mechanisms for nervous system changes, and their call for additional research. The paragraph also notes the NRC’s focus on water fluoride concentrations of 2-4 mg/L, rather than the lower exposures recommended for community water fluoridation (now, 0.7 mg/L).

In response to public comments pertaining to potential endocrinologic effects of fluoride, the draft HHS document (page 19, line 404 et seq) states that NRC noted study limitations with respect to hormone measurement, nutritional factors, and other confounders.

HHS should also refer to NRC’s concerns regarding the uncertainty in fluoride dose in these studies, a parameter highly relevant to the task of establishing guidance values for CWF programs.

Response

A phrase has been added, noting the NRC's call for better measurement of fluoride exposure in epidemiologic studies of endocrine effects.

Reviewer B

The public comments are summarized well and it appears to be properly balanced. In a few places, probably it would be helpful to clarify the approximate numbers of comments in the category a little better.

Response

Approximate numbers of comments have been included, most commonly for specific categories of concern.

Reviewer C

Yes.

4. Has inappropriate information been included? If so, what should be removed? Please explain.

Reviewer A

(No comments)

Reviewer B

I do not think any inappropriate information was presented.

Reviewer C

- a. For the most part, the information in the document is appropriate.
- b. Line 53. The web page cited on this line is not consistent with this report and should be updated or replaced with newer material.

Response

Citation of the web page (referring to CDC's 2001 "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States") has been removed.

- c. I recommend removing the sentence on lines 473-474. It doesn't add anything and uses a questionable comparison.

Response

The sentence, "Community water fluoridation ensures that all communities can enjoy benefits that some receive naturally in their water supplies," was removed.

- d. Also see responses to question 5.

5. Do you have concerns about technical or factual accuracy of statements? If so, please explain.

Reviewer A

(No comments)

Reviewer B

I do not have any substantial concerns about accuracy. See only small wording clarifications on attached manuscript.

Response

Most wording changes that clarified or added important meaning were made (n=29); suggested changes limited to style (e.g., punctuation, placement of a modifier) were not always made. Suggested changes that would have made the statement incorrect (e.g., the difference between reliability and validity) also were not made.

Examples of wording changes made:

- *Changed “measured” to “assessed” in several places*
- *Added a parenthetical “intake” after “fluoride exposures”*
- *Added the word “dietary” before “fluoride”*
- *Added the phrase “called dental fluorosis” after “changes in tooth enamel”*
- *Clarified that the CDC scientists who categorized comments in the unique submissions were not members of the Inter-Agency Federal Panel*
- *Changed the word “maximize” to “provide”*
- *Reworded a phrase to clarify, “locations in the reported residence history”*
- *Changed “suggest” to “conclude”*
- *Reworded a phrase to “concentrations of contaminants in drinking water”*
- *Changed “those concerns” to “their contents” to clarify that all comments in the unique responses were categorized, whether positive or negative*

Reviewer C

a. Lines 63 - 67. The statement is not clear. It gives data from 2 surveys, one for 12-17 year olds and one for 12-19 year olds. The foot note is clear, but what isn't clear is whether the data provided in these lines is for 12-17 year olds for the 1975 survey and 12-19 year olds for the 2007 survey or if the 2007 data have been adjusted in some way to be for 12-17 year olds. As this sentence stands, it seems inaccurate. The sentence in lines 67-70 is worded better.

Response

The footnote has been deleted, and the sentence reworded to clarify that the comparison between the two groups did not employ age adjustment. It also describes more completely why dental caries would likely be higher among 12-19 year-olds than 12-17 year-olds, thus why making the comparison likely underestimates the decline in dental caries.

b. Line 73. Citing a 2001 reference for a statement made in 2012 for a revised review of fluoride doesn't seem appropriate.

Response

The statement, “Effective population-based interventions to prevent and control dental caries, such as community water fluoridation, are still needed” was deleted, along with that citation of the 2001 reference.

c. Lines 446–463. This response could be improved. The sentence, “Studies have shown that silicofluorides achieve virtually complete dissolution and ionic disassociation at concentrations added to drinking water...and thus, are indistinguishable from the fluoride ion produced by other additives, such as sodium fluoride.” Although the fluoride ion may not be different, the solution will have silicon present in some ionic form that would not be present if sodium fluoride were used. As is, the sentence appears to be inaccurate. Line 459-463 states that drinking water contaminants (no specific chemical is mentioned although one could infer that the metals mentioned in lines 457-458 – arsenic, lead and radionuclides- are being discussed) are at least two orders of magnitude below guideline values established by the World Health Organization. This is taken from a recent European report. EPA has set drinking water standards for contaminants (arsenic, lead and radionuclides) and this paragraph should include a comparison of the concentrations with EPA standards.

Response

The text now describes more completely the ANSI/NSF standards and how they relate to levels at which US EPA requires action; the reader is referred to the NSF website for additional information on the trace amounts of specific contaminants that actually have been found in chemicals used in water fluoridation. Language on dissociation has been taken from an EPA Fact Sheet (which is cited), and the words “indistinguishable from” have been replaced with “comparable to.”

d. Also see responses to question 6.

6. Is this document clear and easily understood by a general audience? If not, which sections need revision?

Reviewer A

(No comments)

Reviewer B

I think it depends on what is considered a general audience. I feel that the document is generally pretty clear and easily understood for dental and public health professionals. Some small specific areas to clarify are noted on the attached manuscript. I think that it will still be a little too technical for many lay people to understand.

Response

Within the limits of technical terms that must be used, some language was simplified further.

Reviewer C

a. For the most part, the document is clear and easily understood by a general audience. The following comments tend to be a combination of comments on clarity and technical issues. Some of them could also be responsive to question 5.

b. Line 171. Consider replacing the word change with decrease (assuming that is correct; if not, the sentence needs clarification).

Response

The word "decrease" was substituted for "change."

c. Line 244. Identifying the organization of the four scientists (e.g. Division of Oral Health, NCCDPHP, or USEPA or FDA, etc.) who reviewed the comments would increase the transparency of the document.

Response

The four scientists who categorized public comments were identified as being from CDC.

d. Line 290. Providing information to the public on how they can know or follow the progress and results from HHS's enhanced surveillance to detect changes in dental caries, dental fluorosis, and fluoride intake after the new recommendation is implemented would be useful and may help to increase transparency going forward. Line 507 provides relevant information. Perhaps adding a reference to line 507 or NHANES (2011-2012) here would be helpful.

Response

In Monitoring Implementation of the New Recommendation, specific information was added to identify how the public could access future NHANES surveillance data to monitor changes in dental caries, dental fluorosis, and/or fluoride intake.

e. Line 331. The sentence states that some parents may choose to use low fluoride bottled water to mix infant formula, if they are concerned about the increased chance for permanent teeth to have mild dental fluorosis. How will parents get this message? Dentists, HHS web page, other methods? One could argue that if parents aren't aware of the risk, they can't avoid it. On the other hand, the benefits of fluoride in preventing dental caries should also be included in any such message.

Response

Additional language was inserted to identify websites that currently include information on reconstituting infant formula to minimize the likelihood of mild dental fluorosis. In addition, CDC's plan for communicating the new fluoride concentration to the public includes information for parents, to raise awareness about the correct amount of fluoride for their young children.

f. Lines 437-44. The response about the cost-effectiveness of Community Water Fluoridation refers the reader to a Federal Register notice and states that "using the societal perspective, studies concluded that water fluoridation actually saves money." No specific data are provided and I don't think that most people would understand what is meant by the societal perspective (I am not sure either). Other responses in this section, e.g. Effectiveness of Community Water Fluoridation in Caries Prevention, include specific data. Providing at least some data and some additional information would improve this response.

In addition, the summary and conclusions state that the 0.7 mg/L recommendation is based on "Community fluoridation is the most cost-effective method of delivering fluoride for the prevention of tooth decay," along with three other factors. This document alone provides no specifics on this issue. See response to question 1.

Response

References to the societal perspective (a particular point-of-view often used in cost-effectiveness analysis) and to the original Federal Register notice have been deleted from this portion of the

document. Additional citations--as well as specific data--to support the cost-effectiveness of community water fluoridation have been added.

g. The paragraph beginning on line 476 seems to be 3 somewhat unrelated and disjointed sentences. Can a context be introduced that joins these statements? Regarding line 477, is FDA going to revise its concentration for fluoride in bottled water to agree with this guidance? In what context did the court systems review community water fluoridation?

Response

This paragraph has been reworked, with additional information and a context to link the statements, as well as specific note of the legal challenges that prompted court opinions. Although FDA retains responsibility for monitoring the quality of bottled water (including the concentration of fluoride under certain circumstances), the sentence describing FDA's role has been deleted from the document.

h. Line 519. The comments were reviewed by 4 scientists (line 244). Line 519 mentions that the comments were considered by the full HHS Federal Panel. The link between these two different groups isn't obvious. Adding a phrase or sentence that links them is needed (e.g. did the 4 scientists write a report for the full HHS panel?).

Response

Wording in the Public Comments section of the document was edited to indicate more clearly how the work of the four CDC scientists and the full Inter-Agency Federal Panel were linked.

i. Lines 535-539 do not provide specific information. Maybe referring to NHANES again would be useful. If any other specific surveillance is being carried out now, it could also be mentioned.

Response

Reference to future surveillance in Conclusions was reduced to a sentence and the lines cited deleted entirely. Enhanced national surveillance measures are described in a new section, Monitoring Implementation of the New Recommendation, that immediately precedes Conclusions.