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June 30, 2011

Office of Pesticide Programs
Docket No. EPA-HQ-OPP-2005-0174
Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

To Whom It May Concern:

On behalf of our 157,000 members, we are pleased to comment on the *Fluoride: Dose-Response Analysis For Non-cancer Effects* and *Fluoride: Exposure and Relative Source Contribution Analysis* documents developed by the Environmental Protection Agency's (EPA's) Office of Water (OW). We offer these comments in response to your Federal Register notices of January 19, 2011 (76 FR 3422) and April 6, 2011 (76 FR 19001).

In sum, we hope you will give weight to the Butler et al. study in any future decisions regarding MCLG and MCL levels. The Butler study demonstrates fluorosis prevalence at a time when fluoride was available from a number of sources, unlike the Dean study when fluoride intake was limited to drinking water and diet. Additionally, the OW benchmark and Reference Dose should be re-evaluated as the calculations used required numerous assumptions and uncertainties associated with the contributions from sources other than drinking water.

The ADA strongly supports the U.S. Department of Health and Human Services recommendation to set the level for optimally fluoridated water at 0.7 parts per million. The decision is consistent with our longstanding position that dental fluorosis can be minimized – and tooth decay can be reduced – by adjusting the fluoride content in drinking water to an *optimal* level.

Enclosed you will find more detailed comments regarding these issues. We commend the EPA for the work that has been begun and look forward to the EPA's continued effort to maintain the public's safety while working with the HHS to extend the benefits of fluoride in drinking water. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org.

Sincerely,

Raymond F. Gist, D.D.S.
President

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

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Comments on the

Environmental Protection Agency's

Fluoride Risk Assessment and Relative Risk Contribution Documents

Docket Number: EPA-HQ-OPP-2005-0174

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The American Dental Association (ADA) is pleased to comment on the *Fluoride: Dose-Response Analysis For Non-cancer Effects* and *Fluoride: Exposure and Relative Source Contribution Analysis* documents developed by the Environmental Protection Agency's (EPA's) Office of Water (OW). We offer these comments in response to docket number EPA-HQ-OPP-2005-0174, as published your Federal Register notices of January 19, 2011 (76 FR 3422) and April 6, 2011 (76 FR 19001).

The American Dental Association recommends the EPA should:

- **Clearly state that using severe dental fluorosis as the clinical end point will protect against skeletal fluorosis and any other toxic effects.**

As noted in the March 2006 National Research Council's report, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*[1], severe dental fluorosis occurs at a lower fluoride dose and over a shorter period of exposure time than does stage II skeletal fluorosis and/or bone fractures.

The ADA has long supported the secondary maximum contaminant level (SMCL) to protect against not only severe, but also moderate dental fluorosis.

The ADA notes with interest the increase in the prevalence of fluorosis as reported in the comparison of the CDC/NCHS National Health and Nutrition Examination Survey 1999-2004 and the National Institute of Dental Research, National Survey of Oral Health in U.S. Children, 1986-1987 outlined in the 2010 NCHS data brief, no 53.[2] While both surveys are national in scope, there are important differences to be noted. There are other factors beside fluoride exposure that may aid in explaining the increase in fluorosis prevalence. The CDC report states that "Differences in study design between NIDR 1986-1987 and NHANES 1999-2002 should be considered when drawing inferences about changes in prevalence and severity of enamel fluorosis."[3]

As noted in the NCHS data brief, "In the analyses of changes in prevalence between both national surveys, moderate and severe dental fluorosis were aggregated into one category because all estimates of severe fluorosis were statistically unreliable after stratification (standard error of the percentage was greater than 30% the value of the percentage)." The apparently unreliable estimate of low prevalence of severe dental fluorosis and its combination with moderate dental fluorosis makes it virtually impossible to determine with scientific confidence whether the increase seen is in moderate or severe fluorosis.

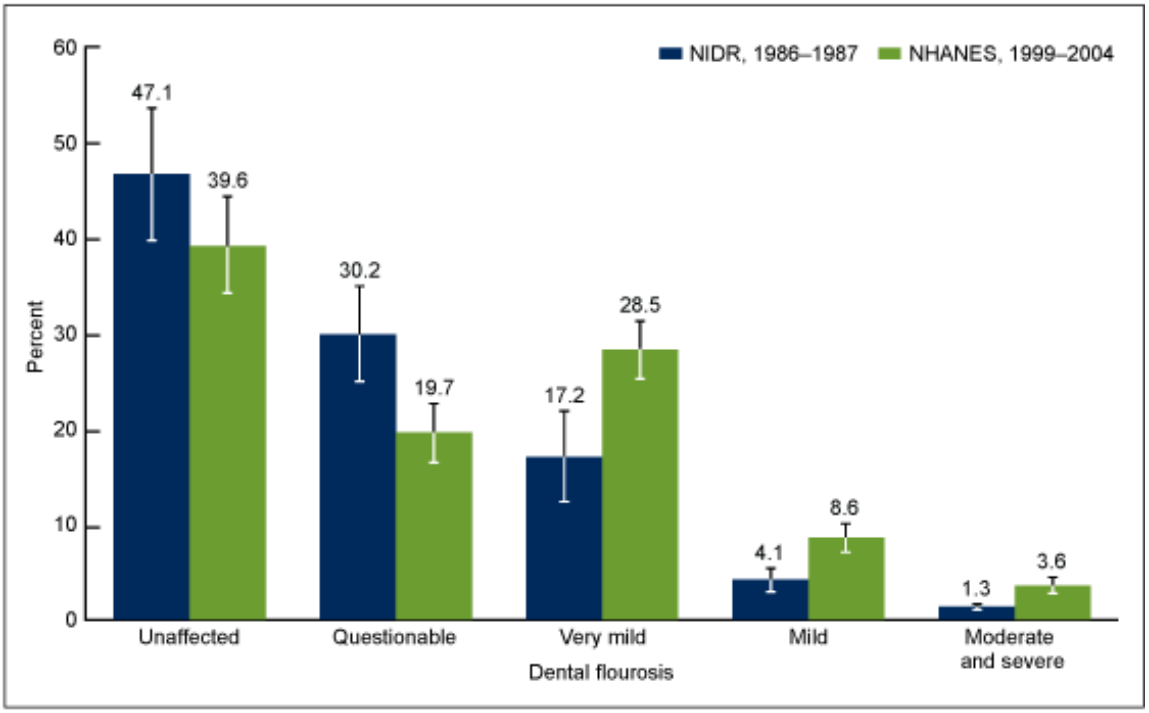
There are also major differences in the sample designs. The 1986–1987 NIDR sample included a selection of school districts, schools, and classrooms. Because the 1986–1987 NIDR survey

was school-based, children not attending school were not part of the sampling frame. The 1999-2004 NHANES survey was a household survey that included oversampling of non-Hispanic black and Mexican-American subgroups. Since fluorosis reportedly is more severe in non-Hispanic blacks[3], this can be an important difference.

While examiner reliability was considered generally acceptable in these surveys, it appears there were a significantly larger number of examiners in the 1986-87 survey (14) than in either the 1999-2002 (4)[3] or 2003-2004 NHANES survey (2).[4] While examiners in the first two surveys were calibrated against a standard examiner, an interrater evaluation process was used in 2003-2004.[4] These types of process changes, along with perhaps a secular change in societal awareness and, therefore, a possible "examiner shift," regarding the desirability of the "perfect smile" may account for what appears to be a notable shift in prevalence away from "unaffected" and "questionable" to "very mild," "mild" and "moderate and severe." In fact, the reduction in "questionable" is almost completely reflected in the increase in "very mild." Of additional interest is dramatic change in the prevalence of "normal" and "questionable fluorosis" between the 1999-2002 and 1999-2004 survey estimates.

See Figure 3 from the NCHS Data Brief, No. 53[2] that follows, noting the changes in dental fluorosis prevalence between the 1986-1987 and 1999-2004 national surveys.

Figure 3. Change in dental fluorosis prevalence among children aged 12–15 participating in two national surveys: United States, 1986–1987 and 1999–2004



NOTES: Dental fluorosis is defined as having very mild, mild, moderate, or severe forms and is based on Dean's Fluorosis Index. Percentages do not sum to 100 due to rounding. Error bars represent 95% confidence intervals.

SOURCES: CDC/NCHS, National Health and Nutrition Examination Survey, 1999–2004 and National Institute of Dental Research, National Survey of Oral Health in U.S. School Children, 1986–1987.

Lastly, it is impossible to link fluorosis prevalence to types of fluoride exposures because neither survey reports any information related to fluoride histories of those examined. There is no information regarding years of residence in a fluoridated or non-fluoridated community or in a

community with naturally occurring fluoride over the MCL or MCLG. Nor is there information on use of topical fluoride products including toothpastes, dietary fluoride supplements or fluoride varnish. When the ADA first granted the seal to a fluoride toothpaste in 1964, the total market share of fluoride toothpaste was approximately 20%. By 1980, the market share had grown to 90% and today fluoride toothpaste is ubiquitous. By 1980, proportionately more young children were using fluoride toothpaste than in earlier times. Health care professionals did not widely stress the importance of limiting the amount of fluoride toothpaste used or the importance of monitoring children's toothbrushing until the early mid 1990s. The results of those changes on the prevalence of fluorosis will not be fully seen in the adolescent cohort until after 2004.[3]

- **Use the Butler et al. study[5] from Texas for determining the point of departure (POD) for severe dental fluorosis and consider a fluoride level where severe dental fluorosis is observed consistently.**

The ADA recognizes the EPA's desire to locate and use a study from a time period when water was the major, if not only, significant source of fluoride. And we recognize the value of the Dean study[6] from a number of perspectives. However, the choice of Dean's study may be problematic due to uncertainties associated with the study (analytical testing method/lack of fluoride exposure histories/lack of cultural diversity of participants).

The ADA recommends that the EPA focus on a study already included in the list of the EPA document references. This research conducted in 1980-81 and supported by a grant from the EPA was conducted by Butler et al. in sixteen communities in Texas using 2,592 school-aged children from "Black, Spanish and White"[5] families who were lifetime residents of their respective communities. This study shows a level of 3.3 mg/L as the point of departure (POD) for severe dental fluorosis.

In the Butler et al. study, the participants were exposed to multiple sources of fluoride. In the early 1980's fluoride toothpaste was ubiquitous and there were no recommendations regarding limiting the amount of fluoride toothpaste to be used. Additionally in the early 1980s, infant formula manufactures had not yet voluntarily lowered the fluoride levels of infant formulas. In this study, few individuals used dietary fluoride supplements but many subjects had received professionally applied topical fluoride treatments. It would appear that the fluoride exposures and intakes for individuals may have been greater in these communities in Texas at the time of the study than it is today. The Butler et al. study provides a population threshold to establish the point of departure for severe fluorosis when other sources of fluoride are available. This eliminates the uncertainties associated with the estimates of fluoride ingested from sources other than drinking water.

Additionally, when compared to Dean's study, the Butler et al. study was conducted when there were improved methods to analyze the levels of fluoride and other contaminants in drinking water. The Butler et al. study has well-documented fluoride histories and a cultural diverse group of study participants.

- **Use the 95th percentile exposure column in Table 5-4 (rather than the mean) to determine the Reference Dose (RfD) and revise the Office of Water benchmark.**

According to the EPA Dose Response Analysis document, the BMD is very close to the LOAEL of 2.2 mg/L for 0.7% severe dental fluorosis identified in the Dean (1942) study (see Table 4-1.) and the BMDL is only slightly below the NOAEL of 1.9 mg/L identified for the community of

Galesburg, IL. This suggests that children in Clovis, NM whose drinking water intake estimates were in the 95th percentile exposure column in Table 5-4., that follows, did not develop severe dental fluorosis.

***Table 5-4. Estimates of Fluoride Doses at Specific Tap Water Intakes for Age Groupings During the Sensitive Window for Development of Severe Enamel Fluorosis (at 1.87 mg F/L)**

Age Range (Years)	Fluoride Exposure (mg/kg/day)			
	Mean	75th Percentile	90th Percentile	95th Percentile
Ershow and Cantor, 1989				
0.5 – 0.9[a]	0.07	0.10	0.14	0.16
1–3	0.09	0.10	0.15	0.19
4–6	0.07	0.09	0.12	0.14
7–10	0.05	0.06	0.08	0.10
11–14	0.04	0.05	0.06	0.08

[a]Dose estimates for infants may underestimate the actual doses because of the lack of reliable information on the type of formula used for bottle-fed infants.

*Excerpted from Fluoride: Dose-Response Analysis For Non-cancer Effects, 820-R-10-019; page 101.

- **Use the Benchmark Dose lower 95% bound (BMDL) approach based on the Butler et al. to developing the Maximum Contaminant Level Goal (MCLG) due to uncertainties with the RFD estimate.**

When conducting risk assessments involving exposures through drinking water, the BMDL of 1.87 mg/L should be used in place of the RfD as the appropriate point of departure for determination of the MCLG, as it does not include the uncertainties associated with assumptions used to calculate the RfD. The determination of fluoride intake computed from recall estimates of diet and toothpaste use weakens the RfD. We note that the EPA notes the confidence in the RfD derivation as “medium.”

- **Due to the uncertainties outlined in these documents, the EPA should conduct/support studies to obtain more accurate estimates of the prevalence of severe fluorosis at varying levels of fluoride in drinking water and fluoride intake (particularly from fluoride toothpaste). Currently, the population data are not consistent with the EPA model.**

Fluorosis studies indicated that fluorosis has increased in both fluoridated and non-fluoridated communities.[7,8] However, moderate and severe fluorosis remain at low levels and appear to be somewhat isolated except in cases where children are subject to drinking water above 2 mg/L. Figure 4-1 below, shows the plot of more than 94 prevalence estimates conducted over a period spanning half a century. Despite a wide range of methodologies, fluorosis indices, fluoride measurement methods and population characteristics, a clear trend is evident. In communities with water fluoride concentrations below 2 mg/L, the prevalence of severe fluorosis is close to zero. Lowering the fluoride level in adjusted water systems alone may not appreciably affect the prevalence of severe dental fluorosis.

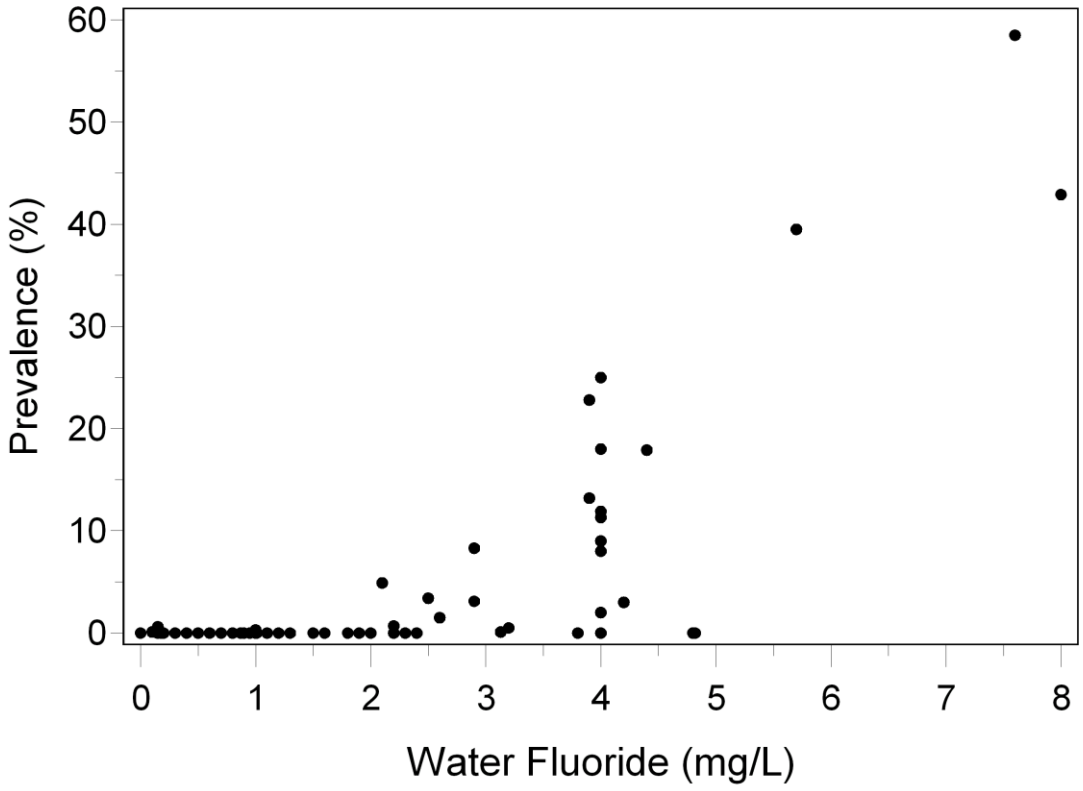


FIGURE 4-1 Prevalence of severe enamel fluorosis at the person level by water fluoride concentration, permanent teeth, age < 20 years, U.S. communities.[1]

The EPA should also work to assist water systems with fluoride levels above the MCLG to come into compliance. While most are small systems, many systems across the country still provide water to consumers with levels above the MCLG and MCL.

References

[1] National Research Council. Fluoride in Drinking Water: A Scientific Review of EPA's Standards. National Academies Press. Washington, DC. 2006

[2] Beltrán-Aguilar ED, Barker L, Dye BA. Prevalence and severity of dental fluorosis in the United States, 1999–2004. NCHS data brief, no 53. Hyattsville, MD: National Center for Health Statistics. 2010.

[3] Centers for Disease Control and Prevention. Surveillance for dental caries, dental sealants, tooth retention, edentulism, and enamel fluorosis - United States, 1988–1994 and 1999–2002. In: Surveillance Summaries, August 26, 2005. MMWR 2005:54(No. SS-3).

[4] Dye BA, Nowjack-Raymer R, Barker LK, Nunn JH, Steele JG, Tan S, Lewis BG and Beltran-Aguilar ED. Overview and Quality Assurance for the Oral Health Component of the National Health and Nutrition Examination Survey (NHANES), 2003-04. Journal Pub Health Dent 2008;68(4):218-236.

[5] Butler WJ, Segreto V, and Collins E. Prevalence of Dental Mottling in School-aged Lifetime Residents of 16 Texas Communities. Am J Public Health 1985; 75:1408-1412.

[6] Dean, H.T. The investigation of physiological effects by the epidemiology method. In: Fluoride and Dental Health. Publ. Amer. Assoc Advanc. Sci., no. 19. 1942: 23–31.

[7] Pendrys DG. Katz RV, Morse DE. Risk factors for enamel fluorosis in a nonfluoridated population. Am J Epidemiol 1996;143(8):808-15.

[8] Pendrys DG. Risk of enamel fluorosis in nonfluoridated and optimally fluoridated populations: considerations for the dental professional. J Am Dent Assoc 2000;131(6):746-55.