ECONOMIC ASSESSMENT OF REDUCING FLUORIDE IN DRINKING WATER

November 1985

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November 1985

Submitted to:
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401 M Street SW (WH-550)
Washington, D.C. 20460

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1 AGENCY USE ONLY (Leave blank)	2 REPORT DATE Nov. 1985	3 REPORT TYPE AND DATES COVERED

4. TITLE AND SUBTITLE

Economic Assessment of Reducing Fluoride in Drinking Water

5 FUNDING NUMBERS

6 AUTHOR(S)

7 PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Abt Associates Inc.
55 Wheeler St.
Cambridge, Massachusetts

8 PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Environmental Protection Agency
Office of Water
401 M St., SW
Washington, DC 20460

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

EPA 570/9-86-001

11. SUPPLEMENTARY NOTES

12a DISTRIBUTION/AVAILABILITY STATEMENT

12b DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

This report assesses the economic impacts of reducing fluoride in drinking water. The principal elements of the report are: definition of the fluoride contamination problem, review of regulatory alternatives, assessment of the benefits of fluoride removal, assessment of the costs of removing fluoride, analysis of regulatory flexibility and paperwork requirements, and exploration of uncertainty in the estimates of costs and benefits.

14 SUBJECT TERMS

fluoride, fluoridation, drinking water, cost

15 NUMBER OF PAGES

84

16 PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18 SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
unclassified	unclassified	unclassified	unlimited

TABLE OF CONTENTS

Chapter 1 EXECUTIVE SUMMARY 1

1.1 Summary of Findings 1

1.2 Problem Definition 2

1.3 Regulatory Alternatives 3

1.4 Assessment of Benefits 4

1.5 Assessment of Costs 5

1.6 Regulatory Flexibility and Paperwork Analyses 7

1.7 Uncertainty of Benefit and Cost Estimates 8

1.8 Summary 9

Chapter 2 PROBLEM DEFINITION 12

2.1 Summary of Health Benefits of Fluoride Removal 12

2.2 Occurrence of Fluoride in Drinking Water 13

2.3 Control Technologies for Fluoride Removal 15

2.4 Management Strategies for Fluoride 15

2.4.1 Market Mechanisms 15

2.4.2 Safe Drinking Water Act 19

2.4.3 State Actions to Control Fluoride 19

2.5 Summary of Issues 19

Chapter 3 REGULATORY ALTERNATIVES 22

3.1 Option 1 22

3.2 Option 2 23

3.3 Option 3 23

Chapter 4 ASSESSMENT OF BENEFITS 25

4.1 Bone Effects 25

4.1.1 Osteosclerosis 25

4.1.2 Osteoporosis 29

4.2 Dental Effects 29

4.2.1 Adverse Dental Effects 29

4.2.2 Fluoride and Caries 30

Chapter 5 ASSESSMENT OF COSTS 34

5.1 Technologies for Reducing Fluoride 34

5.2 Probabilities of Selecting Removal Measures 35

5.3 Computation of Costs 36

5.3.1 Assumptions 36

5.3.2 Cost of Alternatives 38

5.3.3 Conclusions 45

5.4 Monitoring Requirements 47

Chapter 6 REGULATORY FLEXIBILITY ANALYSIS AND PAPERWORK ANALYSIS .49

6.1 Regulatory Flexibility Analysis 49

6.2 Paperwork Analysis 52

APPENDIX A Computation of Number of Cases of Severe and Moderate Dental Fluorosis Avoided 54

APPENDIX B Costs of Repair of Dental Fluorosis 63

APPENDIX C Uncertainty of Costs and Benefits 67

APPENDIX D Additional Costs for Caries Treatment If a Fluoride MCL is Set 71

LIST OF TABLES

TABLE 1-1 Summary of Issues and Findings 10

TABLE 1-1 (Cont.).....11

TABLE 2-1 Number of Water Systems Exceeding Fluoride Concentrations 14

TABLE 4-1 Dean's Fluorosis Index 32

TABLE 4-2 Relationship Between Community Fluoride Concentrations and Dental Caries -- Children 7 to 12 Years of Age 33

TABLE 5-1 Social Costs to the Nation of Fluoride Removal 40

TABLE 5-2 Social Costs Per System For Fluoride Removal 41

TABLE 5-3 Utility Cost Impacts--Median Water Rate 43

TABLE 5-4 Increase in Annual Household Water Bill Attributable to Fluoride Removal 44

TABLE 5-5 Utility Cost Impacts 46

TABLE 6-1 Number of Water Systems by Population Served 51

TABLE A-1 Percentage Distribution of Mottled Enamel Scores Among Texas Children 56

TABLE A-2 Percentage Distribution of Mottled Enamel Scores Among Illinois School Children 57

TABLE A-3 Dose-Response Relationships For Fluoride in Drinking Water and Dental Fluorosis 59

TABLE A-4 Estimated Population Exposed to Fluorides in Drinking Water and Dental Fluorosis 60

TABLE A-5 Number of Cases of Severe and Moderate Dental Fluorosis Avoided Annually at Alternate MCLS for Fluoride in Drinking Water 62

TABLE B-1 Average Costs for Repairing Cosmetic and Functional Damage to Teeth Due to Fluorosis 65

TABLE B-2 Avoided Costs for Remedial Repair of Moderate and Severe Dental Fluorosis if an MCL is Promulgated 66

Chapter 1

EXECUTIVE SUMMARY

This report assesses the economic impacts of reducing fluoride in drinking water. The principal elements of the report are: definition of the fluoride contamination problem, review of regulatory alternatives, assessment of the benefits of fluoride removal, assessment of the costs of removing fluoride, analysis of regulatory flexibility and paperwork requirements, and exploration of uncertainty in the estimates of costs and benefits. This Executive Summary highlights the issues and findings for each of these elements.

1.1 Summary of Findings

- Fluoride contamination of drinking water (above 1 mg/l) affects about 5000 water systems serving 30 million people; however, only 1300 water systems serving 900,000 people have concentrations above 2 mg/l, and 300 water systems serving 188,000 people concentrations above 4 mg/l.

- Fluoride contamination can lead to dental fluorosis in children and, where concentration levels exceed about 4 mg/l, to skeletal fluorosis, which, under some conditions, may be crippling.

- EPA can regulate fluoride to protect against dental fluorosis with a recommended maximum contaminant level of 1 or 2 mg/l, or to protect against skeletal fluorosis with a recommended MCL of 4 mg/l, or drop the primary drinking water regulation for fluoride altogether.

- The benefits of removing fluoride are reduced skeletal fluorosis (not quantifiable given the existing data) and reduced moderate and severe dental fluorosis -- 17,100 to 31,400 cases per year if an MCL of 1 mg/l is adopted, 1700 to 2700 cases per year if an MCL of 2 mg/l is adopted, and 300 to 500 cases per year if an MCL of 4 mg/l is adopted.

- The costs of fluoride removal, in present value terms, are $4.95 billion for an MCL of 1 mg/l, $206 million for an MCL of 2 mg/l, and $43 million for an MCL of 4 mg/l.

- There is a large range of uncertainty around the estimates of benefits; the uncertainty of costs has not yet been determined.

1.2 Problem Definition

A perspective on the fluoride problem can be gained by considering the kinds of effects on public health and welfare caused by fluoride contamination of drinking water, the pattern of occurrence of fluoride in drinking water, the technological means of reducing fluoride, and the institutional means available for managing fluoride contamination.

Fluoride contamination of drinking water can lead to objectionable dental effects and adverse skeletal effects. The dental effects of fluoride have been studied for at least fifty years and the general conclusions are widely agreed upon. Fluoride is beneficial in reducing caries in children but at concentrations above the dental optimum (about 1 mg/l or one part per million) moderate or severe dental fluorosis can occur in a fraction of the population of children. Moderate and severe forms of dental fluorosis are characterized by brown stains on many teeth and possibly pitting of the teeth. Osteosclerosis can occur in people exposed to at least 4 mg/l to 8 mg/l of fluoride in drinking water. This condition is characterized by thickening of the bones and in extreme situations, by crippling effects. Further detail on dental and skeletal effects is provided in section 1.3.

Fluoride occurs at concentrations of 1 mg/l or more in about 5000 public water systems. Most of these systems are small groundwater systems. At higher concentrations, the occurrence of fluoride drops off dramatically. For example, there are about 1300 systems with concentrations above 2 mg/l and about 300 systems with concentrations above 4 mg/l.

There exist several control technologies for removing fluoride. Those which are most likely to be selected by utilities wishing to reduce levels of fluoride are centralized activated alumina, centralized reverse osmosis, and point of use treatments for households having small children. Other possible measures for removing fluoride are: optimization of an existing lime softening plant, regionalization, tapping an alternate source, point of use treatments for all households, and possibly substitution of bottled water for drinking and cooking purposes.

There are several institutional means which might be used to register the demand for fluoride removal and increase the supply of fluoride-reduced water. One is the marketplace. However, market transactions are not likely to lead to an efficient allocation of resources in this case: people are often uninformed about the presence of high concentrations of fluoride and about the health and related risks associated with fluoride; people often cannot put dollar values on health risks avoided; and water is

supplied by regulated local monopolies, not by competing suppliers in a marketplace.

One institutional alternative to the marketplace is regulation under the Safe Drinking Water Act. Under this act, EPA must develop regulations for contaminants which may have any adverse effect on human health. These regulations may be in the form of maximum contaminant levels (MCLs) or required treatment techniques. Under the National Interim Primary Drinking Water Regulations established under the Safe Drinking Water Act, MCLs were set for fluoride as a function of annual average maximum daily air temperature. Revised regulations are to be developed by first setting a recommended MCL. Recommended maximum contaminant levels are to be set at a level at which no known or anticipated adverse human health effects occur, allowing for an adequate margin of safety. Then MCLs are to be set as close to the recommended MCLs as is feasible taking into account the best technology, treatment techniques, and other means, considering costs. Primary drinking water regulations pertain to contaminants which may have an adverse effect on human health. Secondary reguations deal with odor, appearance, or other characteristics of water which adversely affect the public welfare.

A third institutional alternative is state management of fluoride. States have, in general, not acted to remove fluoride from drinking water. There has been little enforcement of the existing standard under the National Interim Primary Drinking Water Standards. Moreover, several states have petitioned EPA to delete fluoride from the Primary Drinking Water Regulations because of the high cost of fluoride removal and because the states believe that fluoride does not present a health risk.

Thus the fluoride "problem" encompasses objectionable dental fluorosis and skeletal fluorosis which may, under some circumstances, be crippling. Fluoride occurs in the water supplies of about 5000 water systems at concentrations at or above 1 mg/l but in much fewer systems at higher concentrations. There exist several technological means to removing fluoride from drinking water. Market institutions and state management approaches are not likely to lead to reduced fluoride exposure. Under the Safe Drinking Water Act, EPA can issue regulations to reduce fluoride exposure and hence reduce the incidence of dental fluorosis and skeletal fluorosis.

1.3 Regulatory Alternatives

Under the Safe Drinking Water Act, EPA published proposed regulatory alternatives in the Federal Register of May 14, 1985. Three options were presented.

Option 1 proposes a primary drinking water regulation based upon protection from

moderate and severe dental fluorosis. This option regards dental fluorosis as a health effect, not simply a cosmetic effect. Psychological impairment due to the disfigurement resulting from dental fluorosis may also be regarded as a health effect. Under Option 1, EPA could issue a recommended MCL of either 1 or 2 mg/l, selecting different balances between caries prevention and fluorosis prevention.

Option 2 proposes a primary drinking water regulation based upon protection from crippling skeletal fluorosis. A primary recommended MCL of 4 mg/l would be established to protect against osteosclerosis. In addition, a secondary MCL of 2 mg/l would be established to provide guidance to the public, states, utilities, and physicians and dentists about the cosmetic effects of dental fluorosis. Dental fluorosis is regarded as an objectionable aesthetic effect, but not a health effect under this option. Notification of the public would be required if fluoride concentrations exceeded 2 mg/l.

Option 3 would delete fluoride from the primary drinking water regulations based upon a finding that levels of fluoride in U.S. drinking water are not associated with any adverse health effects. A secondary MCL of 2 mg/l would be established, however. This option presumes that there is an insignificant risk of crippling skeletal fluorosis given the concentrations of fluoride in drinking water supplies and that dental effects are cosmetic in nature.

1.4 Assessment of Benefits

Fluoride removal can affect the condition of both bones and teeth. Skeletal effects are discussed first.

Fluoride induces new bone formation in which calcium is replaced by fluoride. The result is densification and enlargement of bone--osteosclerosis. Early stages of osteosclerosis are characterized by slight enlargement of trabeculae in the lumbar spine. More advanced stages result in densification and enlargement of the pelvis and vertebral column. Densification then spreads to the ribs and extremities. Several studies have been conducted in the United States and elsewhere on the relationship between fluoride and ostesclerosis. There are insufficient data to develop a dose - response function, so the number of cases of osteosclerosis avoided at different MCLs cannot be calculated. The literature suggests that mild osteosclerosis is unlikely to occur at fluoride concentrations in drinking water below about 4 mg/l. Concentrations of fluoride would probably have to be higher to induce crippling fluorosis. Only a portion of the population exposed to fluoride would be likely to develop osteosclerosis. The Surgeon General has indicated that changes in bone density per se are not adverse health effects

but that crippling fluorosis and arthralgia are adverse health effects.

Fluoride may be beneficial in offsetting osteoporosis. Fluoride has been used as a treatment for osteoporosis and, in areas with high fluoride concentrations, the prevalence of osteoporosis may be less pronounced than elsewhere.

The use of fluoride to prevent dental caries is well established. However, concentrations of fluoride in drinking water above the dental optimum can lead to moderate or severe fluorosis of the teeth. Moderate fluorosis is characterized by brown stains on many teeth and severe fluorosis is characterized by pitting of the teeth and heavy brown stains on many teeth. Dose-response curves can be roughly estimated based on existing data. These indicate that, as the concentration of fluoride in drinking water increases, the proportion of children with moderate or severe dental fluorosis increases. At concentrations above about 2.5 mg/l, perhaps as many as ten to fifteen percent of the exposed children will develop severe or moderate dental fluorosis. At concentrations above 4 mg/l, the proportion of exposed children developing severe or moderate fluorosis may exceed 30% to 40%.

The number of cases of moderate and severe dental fluorosis avoided per year at various MCLs is estimated at:[1]

17,100 to 31,400 at an MCL of 1 mg/l
1,700 to 2,700 at an MCL of 2 mg/l
700 to 1,100 at an MCL of 3 mg/l
300 to 500 at an MCL of 4 mg/l

1.5 Assessment of Costs

In order to assess the costs of removing fluoride from drinking water it is necessary to consider the technologies available for removing fluoride, the probabilities that utilities would select each of these measures to reduce fluoride, and the capital and operating costs of fluoride reduction measures. The technologies available for reducing fluoride are indicated in section 1.2., centralized activated alumina, centralized reverse osmosis, and point-of-use treatments being most likely to be selected. The probability

[1]The ranges reflect two dose-response functions based upon two different studies, one in Texas and one in Illinois.

that a water system exceeding a fluoride standard would select a removal measure depends on system size, costs of the technology, effectiveness of the technology in removing fluoride, the population at risk (all households or households with children), and the likelihood of other inorganic contaminants being present along with fluoride. Systems serving fewer than 1000 people are most likely to select point of use treatments employing activated alumina. Only households with small children would receive these devices. Systems serving over 1000 people would be most likely to select central activated alumina.

In developing cost figures it was assumed that utilities facing a primary MCL would act to reduce the concentration of fluoride to the standard but that utilities would not invest in removal measures if they faced a secondary MCL. This is consistent with past utility behavior and enforcement of primary MCLs. To provide a range of cost estimates primary MCLs of 1 mg/l, 2 mg/l, 3mg/l, and 4 mg/l were analyzed. The cost data available for this analysis assume that the influent concentration of fluoride is 3.2 mg/l and that the standard is 2mg/l. Thus, for those removal measures whose costs are dependent on influent and effluent concentrations, the cost analysis must be regarded as preliminary.

Applying these assumptions to EPA's cost and technologies data, the capital costs (in 1982 dollars) for attaining various MCLs is:

$ 968 million for an MCL = 1 mg/l
$54.6 million for an MCL = 2 mg/l
$11.9 million for an MCL = 4 mg/l

The annual operating costs would be:

$ 268 million for an MCL = 1 mg/l
$10.2 million for an MCL = 2 mg/l
$ 2.1 million for an MCL = 4 mg/l

In terms of present value (calculated for a 20 year time horizon using a real interest rate of 3% as a social discount rate), the fluoride removal costs are:

$4.95 billion for an MCL = 1 mg/l
$ 206 million for an MCL = 2 mg/l
$ 43 million for an MCL = 4 mg/l

The drop in costs from an MCL of 1 mg/l to an MCL of 2 mg/l is due to the large number of systems with fluoride concentrations between 1 mg/l and 2 mg/l.

The increase in the household water bill, as estimated by EPA's Financing Needs Model, is likely to be around $40 to $70 per year for households in small communities which adopt point of use treatment employing activated alumina. This assumes that costs are spread over all customers of the water system. Other technologies used by small systems would raise the household water bill more. For larger systems, most would adopt centralized activated alumina. Household water bills would increase by $18 to $72 per year. Other treatments would cost more. Because of economies of scale, water bill increases would be lower in larger communities.

Under the National Interim Primary Drinking Water Regulations, water systems must now monitor for fluoride. Little additional cost for monitoring is anticipated under the regulatory options considered in this report. Nationwide monitoring costs are about $170,000 per year.

1.6 Regulatory Flexibility and Paperwork Analyses

The Regulatory Flexibility analysis is concerned with the significance of the effect of proposed regulations on a substantial number of small businesses. Most water systems qualify as a small business under Small Business Administration rules. The upper cut-off for a small business is a water system serving about 50,000 people and nearly all water systems fall into this category. As a guideline, EPA uses a figure of 20% of affected entities as being a substantial number. Fewer than 20% of water systems would be affected by any fluoride MCL and if the MCL were set at 2 mg/l or greater, fewer than 2.5% of water systems would be affected. The degree of impact on affected water systems can be ascertained by using EPA's Financing Needs Model. This model indicates that, for systems serving 500 or fewer people, 7% to 13% may suffer financial difficulty[1] attributable to a fluoride regulation (assuming these systems choose point of use treatment with activated alumina). For larger systems, 5% to 14% may suffer financial

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[1]Difficulty is defined as having to increase rates by at least $1.00 per thousand gallons, or having new capital costs exceed the value of existing assets, or having a water rate in excess of $3.00 per thousand gallons.

hardship attributable to a fluoride regulation (assuming these systems select centralized activated alumina).

The Paperwork Reduction Act is concerned with minimizing the Federal paperwork burden for small businesses and state and local governments. The principal paperwork burden resulting from a fluoride regulation is likely to be monitoring requirements. Additional monitoring requirements due to changes in existing fluoride regulations are likely to be very small. Approximately 30,000 samples of water are required per year. The specifications of this analysis are described in section 5.4 of this report. Groundwater systems must monitor for fluoride every three years and water systems using any surface water must monitor for fluoride every year. If the MCL is exceeded three additional analyses must be completed within one month. If the average concentration from these four tests exceeds the MCL, a state-designated monitoring frequency is to be followed until the concentration is less than the MCL on two successive samples. Typical laboratory costs per test are less than $10 per sample.

1.7 Uncertainty of Benefit and Cost Estimates

There exists uncertainty in the estimates of benefits and costs of fluoride removal. This uncertainty stems from unexplained variation and error in dose-response functions, error in the estimation of fluoride occurrence, error in the estimation of the population served by water systems having fluoride, error in treatment cost estimates, and errors in estimating the proportion of utilities which would select a given fluoride removal measure. Some of these uncertainties can be expressed in terms of statistical confidence intervals. The range of cases of dental fluorosis avoided per year based on the 95% confidence interval of the slope of the dose - response curve is as follows:

	Range of Cases of Dental Flurosis Avoided per Year (95% Confidence Interval)		
	Moderate Fluorosis		
	University of Texas Data	NIDR Data (Illinois)	Severe Fluorosis (NIDR data)
MCL			
1 mg/l	730 to 28884	0 to 19079	0 to 41085
2 mg/l	605 to 2004	0 to 1322	0 to 2839
3 mg/l	257 to 849	0 to 560	0 to 1196
4 mg/l	107 to 353	0 to 232	0 to 491

Because of the small number of communities involved and the omission of explanatory variables which would improve goodness of fit, the 95% confidence intervals for the dose-response functions are quite large. For other factors, especially factors affecting the cost estimates, sensitivity analyses are appropriate to determine the range of uncertainty. As of the date of this report, these sensitivity analyses had not been conducted.

1.8 Summary

Table 1-1 summarizes the main issues and findings of the economic assessment.

Table 1-1

SUMMARY OF ISSUES AND FINDINGS

Problem

- Fluoride contamination of drinking water leads to dental fluorosis and skeletal fluorosis

- About 5000 water systems have fluoride at concentrations greater than 1 mg/l, but only 1300 have fluoride at concentrations above 2 mg/l

- Control technologies exist to remove fluoride from drinking water, including activated alumina, reverse osmosis, and point of use treatments

- The marketplace and state management approaches are not likely to be as effective as EPA regulations in reducing fluoride exposure

Regulatory Alternatives

- Option 1: a primary recommended MCL of 1 mg/l or 2 mg/l to protect against dental fluorosis

- Option 2: a primary recommended MCL of 4 mg/l to protect against crippling fluorosis and a secondary MCL of 2 mg/l to protect against aesthetically objectionable dental fluorosis

- Option 3: no primary drinking water regulation for fluoride but a secondary MCL of 2 mg/l

Table 1-1 (continued)

Benefits of Fluoride Removal

- Reduced skeletal fluorosis (not quantifiable)

- Reduced moderate and severe dental fluorosis--roughly quantifiable: *17,100 to 31,400 cases of moderate and severe dental fluorosis avoided per year if MCL = 1 mg/l
  *1700 to 2700 cases of moderate and severe dental fluorosis avoided per year if MCL = 2 mg/l
  *300 to 500 cases of moderate and severe dental fluorosis avoided per year if MCL = 4 mg/l

Costs of Fluoride Removal

- Present value of social costs to the nation
  * $4.95 billion if MCL = 1 mg/l
  * $206 million if MCL = 2 mg/l
  * $43 million if MCL = 4 mg/l

- Additional monitoring costs negligible

Effects on Small Utilities

- Fewer than 20% affected if MCL = 1 mg/l, fewer than 2.5% affected if MCL = 2 mg/l or greater.

- Up to about 14% may suffer financial difficulty in complying with the regulation.

- Little additional paperwork required for monitoring.

Uncertainty

- Large range of uncertainty of benefits; uncertainty of costs not yet determined.

Chapter 2

PROBLEM DEFINITION

This chapter reviews the major issues concerning fluoride contamination of drinking water. The health effects of concentrations of fluoride in excess of the dental optimum are briefly discussed based upon the more detailed assessment of health benefits of fluoride removal found in Chapter 4 and Appendix A. The occurrence of fluoride in drinking water is then summarized. Following this, the technologies available for removing fluoride from drinking water are reviewed. Then, three mechanisms for managing fluoride contamination of drinking water are discussed: 1) the market 2) the Safe Drinking Water Act, and 3) state actions to control fluoride. The issues are summarized at the conclusion of the chapter.

2.1 Summary of Health Benefits of Fluoride Removal

Much of the literature on fluoride in drinking water is concerned with dental effects. Both the advantages and disadvantages of fluoride at various concentrations have been analyzed. The value of fluoride in preventing caries is well established and a dental optimum concentration of fluoride in drinking water has been set on the basis of this. At higher concentrations, however, dental fluorosis may occur. The percentage of children exhibiting moderate or severe cases of dental fluorosis generally increases as the concentration of fluoride increases. Moderate fluorosis is characterized by brown stain on the teeth and severe fluorosis is characterized by heavy brown stains and pitting of the enamel surfaces of many teeth.

The Surgeon General does not consider dental fluorosis to be an adverse health effect, however.[1] The ad hoc committee headed by the Chief Dental Officer of the U.S. Public Health Service stated that "No sound evidence exists which shows that drinking water with the various concentrations of fluoride found naturally in public water supplies

EPA, 50 Federal Register 20166; May 14, 1985

in the U.S. has any adverse effect on dental health as measured by loss of function and tooth mortality."[1]
Chapter 4 and Appendix A contain more detail on the benefits of reducing fluoride.

Fluoride in drinking water may also lead to certain skeletal effects. In particular, bone density may increase with prolonged exposure to fluoride. In its most severe form, skeletal fluorosis is characterized by the deposition of irregular bone deposits which can result in crippling in a fraction of the population. Changes in bone can be found in individuals exposed to more than 8 mg/l of fluoride in drinking water and possibly in individuals exposed to 4 to 8 mg/l. Unfortunately, there are insufficient data on skeletal effects of fluoride to construct a dose-response function and therefore to estimate the cases of skeletal fluorosis avoided by setting alternative drinking water standards. Further discussions of the health effects of fluoride in drinking water are found in Chapter 4.

2.2 Occurrence of Fluoride in Drinking Water

The occurrence of fluoride in drinking water is summarized in Table 2-1. Data are from the Community Water Supply Surveys and the Rural Water Survey for systems having low concentrations of fluoride and from the Federal Reporting Data System (FRDS) for systems having high concentrations of fluorides.[2] It is evident that very few systems have fluoride concentrations above 2 mg/l and even fewer have concentrations above 4 mg/l. There are, however, a large number of systems with concentrations of fluoride between 1 and 2 mg/l. Systems exhibiting high concentrations of fluoride in their drinking water tend to be small and obtain their water from undergroundsources.

The number of systems exceeding concentrations of 2 mg/l is about 1350. There are about 500 systems exceeding 3 mg/l, and about 300 systems exceeding 4 mg/l.

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[1] ibid

[2] Report prepared under contract to EPA by JRB Associates "Occurrence of Fluoride in Drinking Water, Air and Food," February 9, 1984.

Table 2-1

Number of Water Systems Exceeding Fluoride Concentrations

Concentration Exceeding	System Size Category (population served) 25-500	501-3300	3301-50,000	50,000+	TOTAL
1 mg/l	3460	935	470	75	4940
2 mg/l	1061	235	49	1	1346
3 mg/l	366	108	20	0	494
4 mg/l	223	47	12	0	282

Source: EPA, "Occurrence of Fluoride in Drinking Water, Air and Food," Report by JRB Associates, February 9, 1984

2.3 Control Technologies for Fluoride Removal

Several technologies could be used to remove excess fluoride from drinking water.[1] These include: centralized treatment with activated alumina, centralized treatment with reverse osmosis, optimization of lime softening at an existing softening plant, regionalization, tapping an alternate source, substitution of bottled water for tap water, and point of use treatments. Point of use treatments are assumed to be purchased, installed, and maintained by the water utility or community. Technologies available for point of use treatments are activated alumina and reverse osmosis.

The treatment technologies most likely to be selected are centralized activated alumina, centralized reverse osmosis, and point of use treatments for households having small children. These technologies and the likelihood of their being selected to remove fluoride are discussed in Chapter 5.

2.4 Management Strategies for Fluoride

This section reviews the basic management alternatives for removing fluoride. They are: using the market to register the demand for and supply of fluoride-reduced water, using the Safe Drinking Water Act, and using state regulatory mechanisms to control fluoride.

2.4.1 Market Mechanisms

The marketplace is one possible alternative to fluoride regulation. If there were no contaminant standards for fluoride, could the marketplace efficiently allocate resources? There are several reasons to think it cannot: a) people are often uninformed about the presence of high concentrations of fluoride and the health risks associated with high concentrations of fluoride, b) people typically cannot put a dollar value on health risks avoided, and c) water is supplied by local monopolies, not by competing utilities. Thus, there are difficulties in registering the demand for water quality, as a function of dollars, and in representing competitive costs of supply in the marketplace. The

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[1]EPA, Office of Drinking Water, "Technologies and Costs for the Removal of Fluoride from Potable Water Supplies", Report by V.J. Ciccone and Associates, May 25, 1984. The report was updated on September 10, 1985, but the costs did not change.

following discussion addresses these points in more detail.

Some economists argue that the common good is represented by economic efficiency, a state in which society has maximized its net benefits. Under the conditions of perfect competition with no externalities[1], efficiency can be reached through the process of individual actions in the marketplace. Thus, the characteristics of a perfectly operating market are used as a standard against which collective or governmental actions may be judged, and a justification for such collective actions would be "imperfections" in the market. This discussion examines imperfections in the demand and supply sides of the market for drinking water quality, and the need for government intervention in that market.

On the demand side, several strong conditions must be met before a perfectly operating market can exist. These conditions deal with the preferences of consumers of water (everyone served by public water systems).

The first condition for a preference function for water quality which will lead to a demand schedule is that money and water quality are desirable in and of themselves. This is an easily accepted condition.

The second condition is that money and water quality must be comparable, that is, each individual must be able to state preferences among any (reasonable) pair of bundles[2] of money and water quality characteristics. A major problem is the absence of market information. Since people may not have a clear understanding of the relationships between high concentrations of fluoride in their drinking water and their health, it is difficult to choose between money and water quality. There are two sources of lack of information. One is lack of knowledge of the occurrence of fluoride--many people may be unaware of the presence of fluoride in their drinking water. Second, most people are not well informed about health risks of high concentrations of fluoride and probably cannot express trade-offs between bundles of money and water quality. A study of eight California communities with drinking water contaminants, including fluoride, indicated

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[1]Externalities are social costs and benefits that are external to the firm's or individual's calculations of private costs and benefits. Pollution is a common example. A firm would probably not account for the costs to society of the water pollution it generates when deciding how to maximize profits. Economists argue that failure of the market to account for these social costs and benefits leads to inefficiency.

[2]That is, a market basket of goods and services. For simplicity we talk in terms of just two goods here -- water quality and all other goods represented as money.

that only a small percentage of the population clearly understood the problem, even after receiving notification of contamination.[1] That is, most respondents were not aware of the contaminant, health problems caused by the contaminant, and personal actions required to avoid the health problems. In addition, because there are generally no routine market transactions involving money and water quality, feedbacks about purchasing too much or too little water quality cannot be relied upon to clarify preferences among bundles of water quality and money and to allow for corrective actions as would be the case for goods and services purchased regularly. In short, the comparability condition is not met and so the demand for fluoride reduction is not well defined.

Several other conditions must also be met in order to make preference functions and demand schedules well behaved. Individuals must be able to: (1) state indifference among several bundles of money and water quality; (2) state preferences in a transitive manner so that if bundle A is preferred to bundle B and bundle B is preferred to bundle C, bundle A is preferred to bundle C; and (3) form a continuous line of equally preferred bundles between bundles which are preferred equally. Because most people's preference functions are unlikely to be so precisely defined, these conditions are highly unlikely to be met and any preference functions inferred from surveys or observed behavior could very well violate one or more of these conditions. For instance, people may not have transitive preference functions or may not be able to identify bundles of equal preference. Failure to meet these conditions will lead to demand schedules from which conclusions about economic efficiency may be erroneous or impossible to draw. For example, demand curves may be discontinuous or not exist logically and it may not be possible to identify a social optimum of net benefits.

On the supply side of the market for drinking water quality, it has been evident for decades that utilities do not meet the test for a competitive market. Each community, trailer park, city surburban tract, or other customer base is served by only one water supplier. Monopolistic conditions exist. Water utilities are natural monopolies[2] in that they exhibit large economies of scale and competitive services would not be cost

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[1] William Bruvold and John Gaston, "Public Notification: Pain or Panacea," Journal of the American Water Works Association, vol. 72 (March 1980), pp. 124-127.

[2] A "natural monopoly" exists when one firm can supply the market (in this case a water supply service area) at less cost than two or more firms because of economies of scale. It is cheaper to build one water supply system per community than two or three.

effective. (Moreover, some privately owned water companies are themselves owned by larger water supply companies). It is generally argued that monopolies may not be responsive to the demand for product quality and quantity because the pressure of competing suppliers is absent.

The existence of natural monopolies in water supply has three important implications for judging the efficiency of water markets. First, water utilities are regulated by the States with regard to how much they can charge for water. Thus the market price for water is not a free-market price and efficient allocation of water may not exist.

Second, because of the natural monopoly-economies of scale characteristics of the water industry it is not economical to offer several grades of drinking water quality in one service area. That is, suppliers of drinking water typically cannot treat the water of only the people who desire low concentrations of fluorides (unless home treatment units are used but this is often far more expensive than central treatment). Consequently a perfectly competitive market within a utility service area which provides grades of water quality is difficult to maintain. In many cases the water of all customers must be of the same quality.

Third because of the existence of only one water utility per community, water suppliers may not correctly perceive the willingness of their customers to pay for water quality improvements. Consumers cannot switch suppliers. Thus, feedbacks on price as a function of quality cannot be readily obtained. As a result, many utility managers simply assume that their customers would not be willing to pay for quality improvements[1], even though this might not be true.

The existence of other regulations and programs pertaining to water supply may also be regarded as market "imperfections". These include rate regulations, state and federal water quality regulations, the availability of grants for water systems, and the like.

In conclusion, neither the demand nor supply side of the market for drinking water meets the conditions for a perfectly competitive market. Therefore, economic efficiency cannot necessarily be achieved by EPA's refraining from issuing regulations on fluoride. In fact, market imperfections are so strong that government intervention is

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[1]Charles Stegman and Georgia Schneider, "The Cost and Effectiveness of Public Notification of MCL Violations," Journal of the American Water Works Association, vol. 74 (February 1982), pp. 59-65.

required to achieve efficiency. The economic demand for fluoride removal is not quantifiable, the public is not knowledgeable about fluoride health risks, fluoride occurrence is poorly understood by the public, suppliers of drinking water are natural monopolies, and drinking water cannot often be economically provided at different quality levels in the same service area. Thus the market does not provide a mechanism for registering the costs and benefits of fluoride reduction and for maximizing the net benefits of fluoride removal.

2.4.2 Safe Drinking Water Act

As an alternative to the marketplace, Congress passed the Safe Drinking Water Act. This Act requires the Environmental Protection Agency to develop regulations on drinking water quality for public water systems. In particular, EPA must develop regulations for contaminants which may have any adverse effect on human health. Regulations may be in the form of maximum contaminant levels (MCLs) or required treatment techniques.

EPA established National Interim Primary Drinking Water Standards as required by the Safe Drinking Water Act. Among the contaminants regulated by these interim standards is fluoride. The regulation specifies the following maximum contaminant levels for fluoride:

Annual Average Maximum Daily Air Temperature for the Location in Which the Community Water System is Situated (degrees Celsius)	Maximum Contaminant Level (milligrams per liter)
12.0 and below	2.4
12.1 to 14.6	2.2
14.7 to 17.6	2.0
17.7 to 21.4	1.8
21.5 to 26.2	1.6
26.3 to 32.5	1.4

These maximum contaminant levels were intended to reflect the greater volume of water consumed by people living in warmer areas.

The selection of these maximum contaminant levels for fluoride was based on the following considerations:

- The beneficial effect of fluoride in preventing dental caries; and
- The adverse health effects of high concentrations of fluoride, including fluorosis of the teeth.
- Generally available technology for fluoride removal.

The maximum contaminant levels for fluoride were set a twice the level at which maximum dental benefits are realized.

Revised regulations are to be developed using a two step procedure. First recommended MCLs are to be set at a level at which no known or anticipated adverse human health effects occur, allowing for an adequate margin of safety.[1] These recommended MCLs are not enforceable standards, however. The second step requires EPA to develop an MCL as an enforceable standard. MCLs must be set as close to recommended MCLs as is feasible taking into account the best technology, treatment techniques, and other means while considering costs.

The Safe Drinking Water Act distinguishes between primary and secondary standards. Primary regulations pertain to contaminants which may have an adverse effect on human health. Secondary regulations deal with odor, appearance, or other characteristics of water which may cause a substantial number of persons served by the water system to discontinue use or which may otherwise adversely affect the public welfare.

2.4.3 State Actions to Control Fluoride

State actions to control fluoride have been of two types: 1) general disinterest in reducing fluoride, with some exceptions, and 2) opposition to the current fluoride standard. Telephone conversations with EPA Regional Offices in Regions IV (Atlanta) and VI (Dallas) indicated that only a few systems in Region IV have acted to remove fluoride in response to the existing MCL and that no systems in Region VI have acted to remove fluoride in response to the MCL. Opposition to the current fluoride standard is reflected in the petition by South Carolina and other States to delete fluoride from the

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[1]See EPA, 50 Federal Register 20164ff (May 14, 1985) for the proposed recommended MCL.

Primary Drinking Water Regulations.[1] The petition contends that the cost of reducing fluoride is prohibitive and that fluoride does not present a health hazard but causes only an aesthetic effect on teeth. Thus state actions have generally not led to reduction of excess levels of fluoride in drinking water.

2.5 Summary of Issues

Contamination of drinking water by fluoride results in increased incidence of mottling and pitting of teeth (dental fluorosis) and osteosclerosis. EPA considers the dental effects not to be health effects. Crippling skeletal fluorosis is considered to be an adverse health effect, however. Unfortunately, there are insufficient data on skeletal effects of fluoride to estimate the number of cases of osteosclerosis avoided under alternative fluoride management strategies.

Fluoride occurs primarily in smaller water systems. Nearly 5000 public water systems have concentrations of fluoride exceeding 1 mg/l (ppm), 1300 systems exceed 2 mg/l, and about 300 systems exceed 4 mg/l.

There are several technologies available to control fluoride. The measures most likely to be adopted are centralized activated alumina, centralized reverse osmosis, and point of use treatments for households having small children.

The basic means to controlling fluoride are the marketplace, the Safe Drinking Water Act, and State programs. The marketplace is unable to deal with the issues primarily because of lack of public information about health risks, because of the difficulties people have putting a dollar value on avoiding risks from fluoride, and because of the absence of a competitive market in water since water utilities operate as regulated natural monopolies. The Safe Drinking water Act provides a means to controlling fluoride contamination through the existing National Interim Primary Drinking Water Standards and the establishment by EPA of recommended maximum contaminant levels and maximum contaminant levels. State actions have not led to significant reduction of excess fluoride in drinking water and indeed several states have petitioned EPA to delete fluoride from the primary drinking water standards.

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[1] 46 Federal Register 58345; December 1, 1981.

Chapter 3

REGULATORY ALTERNATIVES

Market mechanisms were shown in Chapter 2 to be ineffective for dealing with excess fluoride in drinking water. Thus a regulatory approach may be appropriate. This chapter reviews the regulatory options available to EPA. Three options are discussed based upon the presentation in the Federal Register of May 14, 1985.[1]

3.1 Option 1

Under this option EPA would promulgate a Primary Drinking Water Regulation to protect from moderate and severe dental fluorosis. The premises supporting this option are a) that moderate and severe dental fluorosis are adverse health effects themselves or b) that the psychological impairment resulting from the cosmetic effects of moderate and severe dental fluorosis constitute an adverse health effect. The Review Panel on the Psychological/Behavioral Effects of Dental Fluorosis concluded that "individuals who have suffered impaired dental appearance as the result of moderate to severe fluorosis are probably at increased risk for psychological and behavioral problems or difficulties".[2] Two suboptions can be considered.

Suboption A would set a recommended MCL at 1 mg/l. This balances the beneficial effects of fluoride in the prevention of tooth decay with the adverse effects of fluoride on teeth. Up to about 4% of the population in communities now exceeding 1 mg/l could be expected to develop moderate or severe dental fluorosis under this suboption. About 5000 communities now exceed a concentration of 1 mg/l.

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[1] 50 Federal Register 20171 to 20172; May 14, 1985. Note that EPA is considering dropping the graduated standard for different climates that now exists as part of the National Interim Primary Drinking Water Standards. See section 2.4.2.

[2] R. Kleck, Chairperson, Review Panel on Psychological/Behavioral Effects of Dental Fluorosis, Report to Office of Drinking Water, EPA, November 17, 1984, page 1.

Suboption B would set a recommended MCL at 2 mg/l. This option would allow for greater benefits of fluoride in protecting against caries. Up to about 14% of the population in communities now exceeding 2 mg/l could be expected to develop moderate or severe dental fluorosis under this suboption. About 1300 communities would be affected by this recommended MCL.

3.2 Option 2

Option 2 proposes a primary drinking water standard considering protection from crippling skeletal effects of fluoride and a secondary drinking water standard based on cosmetic effects of dental fluorosis. In particular a recommended MCL of 4 mg/l would be set to protect against crippling skeletal fluorosis with an adequate margin for safety. Chapter 4 discusses skeletal effects in more detail. Although no dose response curve for skeletal fluorosis can be developed the evidence indicates that at concentrations below 8 mg/l there is little likelihood of crippling fluorosis occurring. About 300 public water systems currently exceed 4 mg/l of fluoride in their drinking water.[1]

As part of Option 2, a secondary MCL of 2 mg/l would be established. Under this option objectionable dental fluorosis is considered to affect the public welfare but not present a health hazard. The secondary MCL would provide guidance to states and utilities and would reflect a balance between the cosmetic effects of fluorosis and the beneficial effects of fluoride in reducing the incidence of caries. About 1300 public water systems exceed 2 mg/l of fluoride. Monitoring would be required. In addition, residents of communities having over 2 mg/l of fluoride in their drinking water would be notified of the effects of dental fluorosis and the alternatives for prevention. Physicians, dentists, and public health officials would also be notified when the secondary MCL is exceeded.

3.3 Option 3

This option would delete fluoride from the Primary Drinking Water Standards on the premise that dental effects are only cosmetic and crippling bone effects are of

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[1]About 30% to 40% of the exposed population in these communities would, however, experience moderate or severe dental fluorosis if the standard was 4 mg/l.

minimal risk given concentrations of fluoride found in drinking water. Only a secondary MCL of 2 mg/l would be published. Monitoring and public notification requirements would still be put in place under this option to advise the public about concentrations of fluoride above 2 mg/l. This reflects the Surgeon General's view[1] that naturally occurring fluoride concentrations in public water systems in the U.S. do not have adverse effects on general health. It also reflects the Surgeon General's concern over aesthetic effects of dental fluorosis: "I encourage communities having water supplies with fluoride concentrations of over two times optimum to provide children up to age nine with water of optimum fluoride concentration to minimize the risk of their developing aesthetically objectionable dental fluorosis."[2]

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[1]EPA, 50 Federal Register, 20166; May 14, 1985.

[2]Quoted in: 50 Federal Register, 20166; May 14, 1985.

Chapter 4

ASSESSMENT OF BENEFITS

Fluoride in drinking water can induce two types of effects as reported in the health literature. One is changes in bones, including osteoclerosis and reduction in the likelihood of osteoporosis. The other is changes in teeth, including mottling and pitting of teeth and, as is well known, prevention of caries. The benefits of reducing fluoride in drinking water then include 1) reduced incidence of osteosclerosis and 2) reduced incidence of dental fluorosis including psychological effects resulting from this disfiguration. This chapter reviews the evidence on the effects of fluoride on bones and teeth.

4.1 Bone Effects

In bone, calcium ions are stored as the salt, hydroxyapatite. Normally the calcium ion concentration in the plasma is in equilibrium with the calcium in bone. In order to maintain this equilibrium calcium ions must be able to travel from plasma to bone and vice versa in response to hormonal signals. Osteosclerosis is a condition where the calcium is trapped in bones of unusually high density. Osteoporosis, on the other hand, is a disease state where calcium is mobilized from the bone. The resulting demineralization results in a loss of integrity. Osteofluorosis, an accumulation of fluoride in the bone, can result in osteosclerosis in normal individuals and can be curative in individuals suffering from osteoporosis.

4.1.1 Osteosclerosis

This section reviews selected literature on the relationship between osteosclerosis and fluoride in drinking water. Fluoride induces new bone formation which results in densification and replacement of healthy. This fluoride induced bone is denser than the bone it replaces due to the presence of fluoroapatite. The Surgeon General has indicated that changes in bone density per se are not adverse health effects but that crippling

fluorosis is an adverse health effect.[1]

Skeletal fluorosis may progress in several stages.[2]

- Slight radiological changes such as enlargement of trabeculae in the lumbar spine; this can be further subdivided into two stages.

- Osteosclerosis in the pelvis and vertebral column.

- Increased density and blurring of contours of the pelvis, vertebral column, ribs, and extremities.

- Greatly increased density of bone with irregular and blurred contours, all bones being affected. Extremities are thickened and considerable calcification of ligaments of the neck and vertebral column occur.

Greater concentration of fluoride in the bone is apparently associated with more severe stages of osteosclerosis.

Several studies provide evidence relating fluoride in drinking water and osteosclerosis. Leone et al. (1955)[3] compared the effects of fluoride exposure from drinking water in 116 long-term residents of a high fluoride area (Bartlett, Texas; 8 mg/l) to 121 residents of a low fluoride area (Cameron, Texas; 0.4 mg/l). In the study, the authors evaluated the effects of fluoride on bone changes as characterized by X-rays taken in 1943 and 1953.

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[1]Cited in EPA, 50 Federal Register, 20166; May 14, 1985.

[2]Described in EPA, "Final Draft for the Drinking Water Criteria Document on Fluoride," TR-540-61F, April, 1985.

[3]Leone, N.C. Stevenson, T. Hilbish, M. Sosman, 1955. "A Roentgenologic Study of a Human Population Exposed to High Fluoride Domestic Water." Am. J. Roentg., Radium Therapy and Nuclear Medicine. 74:874-85.

The authors concluded that fluoride-induced bone changes:

- occur in approximately 10 to 15 percent of those exposed to 8 ppm of fluoride in drinking water;
- are not associated with physical findings other than dental fluorosis;
- cannot definitely be ascribed to fluoride alone;
- may occasionally have a beneficial effect in adult bone, as in counteracting the normal osteoporotic changes in the aged;
- are not deleterious if the concentration in water is less than 8 ppm.

Thus, this study suggests that significant osteosclerosis effects may occur in some individuals exposed to concentrations of fluoride in drinking water of 8 mg/l or more.

In another study, Stevenson and Watson (1957)[1] further evaluated the systemic effects of excessive fluoride in drinking water. In this study, the authors reviewed medical records over the period 1943 to 1953. A roentgenologic (x-ray) diagnosis of fluoride osteosclerosis was recorded on 23 patients' records out of a total of 170,000 x-ray examinations of the spine and pelvis of patients living primarily in Texas and Oklahoma.

The earliest bone changes were noted in the pelvis and vertebral column and consisted of a slightly increased bone density and a "ground glass appearance." Slight roughening of the bones of the forearms or legs was also detected. Of special interest was the finding of calcification of the sacrospinous and sacrotuberous ligaments in 15 of the 23 patients. All of the reported bone changes occurred only among patients who lived in areas with fluoride concentrations from 4 to 8 mg/l in drinking water. Each of

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[1]Stevenson C., A. Watson, 1957. "Fluoride Osteosclerosis" Am. J. Roent., Radium Therapy and Nuclear Medicine. 78: 13-18.

these patients had lived in the same fluoride-bearing area throughout his life. Thus, the study indicates a lowest observed effect level for osteosclerosis of approximately 4 mg/l. However, the authors concluded that the cases of fluoride osteosclerosis which they saw caused no harmful effects.

Alhava et al. (1980)[1] examined post mortem bone specimens from Kuopio, Finland (where fluoridation started in 1959) and from other locations. The fluoride concentration in Kuopio was approximately 0.97 ppm while the water samples from outside the Kuopio area averaged less than 0.1 ppm. The length of exposure to fluoridation prior to death was between 14-18 years. The findings of this study indicate that: a) fluoride concentration in bones increases with the age of the person, b) fluoride concentrations in bone are greater for the Kuopio population which is exposed to higher concentrations of fluoride in their drinking water, and c) fluoride concentrations in the bones of the Kuopio population are slightly higher for women than for men.

Studies in India have recorded some of the most severe forms of skeletal fluorosis. An individual exposed to 9.5 mg/l of fluoride in his drinking water was described as having irregular outgrowths on bony contours, irregular bone in the joint capsules and interosseous membranes, heavier bones than normal, enlarged vertebrae and fusing of some vertebrae, and other health effects in his bones.[2]

Charen et al. (1979)[3] examined a dose response curve showing fluoride in bone as a function of fluoride in drinking water. A linear relationship was found suggesting that 1 ppm of fluoride in drinking water is associated with a fluoride concentration in bones of about 2000 ppm and that 4 ppm of fluoride in drinking water is associated with a fluoride concentration in bones of about 7000 ppm. This should be considered the result of lifetime exposure to fluorides.

On the basis of the studies reviewed it is not possible to develop a dose-response curve for the crippling effects of skeletal fluorosis. For the purposes of this analysis a qualitative relationship is all that can be supported: concentrations of fluoride in drinking water above 8 mg/l are associated with osteosclerosis and possibly with crippling skeletal fluorosis.

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[1]Alhava, E.M., Olkkonen, H., Kauranen, P. and Kari, Tarja. (1980). "The Effect of Drinking Water Fluoridation on the Fluoride Content, Strength and Mineral Density of Human Bone" Acta Orthopedics Scandinavia 51: 413-420.

[2]Cited in EPA, "Final Draft for the Drinking Water Criteria Document on Fluoride," TR-540-61F, April, 1985.

[3]Charen, J., Taves, D.R., Stamm, J.W. and Parkins, F.M., 1979. "Bone Fluoride Concentrations Associated with Fluoridated Drinking Water: Calcified Tissue International 27: 95-99

4.1.2 Osteoporosis

Osteoporosis is an absolute reduction in bone mass resulting from demineralization of bone. While the cause of osteoporosis is unknown, the increase in bone density following administration of fluoride has been used therapeutically, but not without controversy. This controversy concerns whether bone containing fluoroapatite is physiologically equivalent to normal bone. Bernstein et al.[1] (1966), investigated the relationship between drinking water fluoride content and the prevalence of osteoporosis in North Dakota. Fluoride levels were between 4 and 5.8 ppm in the high concentration area and between 0.15 and 0.3 ppm in the low concentration area. Individuals living in the high fluoride areas had less incidence of osteoporosis and collapsed vertebrae than those living in low fluoride areas. The difference in bone density was observed in females over 55 years of age and in males 55 to 64. A lower incidence of collapsed vertebrae was observed only in females.

4.2 Dental Effects

Fluoride has both positive and negative effects on teeth. This section briefly describes these effects. More detail on adverse dental effects may be found in Appendix A.

4.2.1 Adverse Dental Effects

Dental fluorosis has been classified into degrees of severity by Dean.[2] The Dean Index, shown in Table 4-1, describes characteristics of teeth affected by fluorosis. Moderate and severe forms of dental fluorosis result in brown stains affecting all enamel surfaces and pitting in some teeth.

Several studies have indicated that higher concentrations of fluoride in drinking

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[1]Bernstein, D. et al. 1966, "Prevalence of Osteoporosis in High - and Low-Fluoride Areas in North Dakota," Journal of the American Medical Association, vol, 198, October 31, pp. 85-90.

[2]Dean, H.T., 1942. "The Investigation of Physiological Effects by the Epidemiological Method," in F.R. Moulton, ed., Fluorine and Dental Health, American Association for the Advancement of Science, Publication No. 19.

water are associated with a greater proportion of children having moderate or severe dental fluorosis.[1] Very roughly, at least 10 to 20 percent of the children in a community can be expected to suffer from moderate or severe dental fluorosis if the concentration of fluoride in drinking water exceeds 2.5 to 3 mg/l. Appendix A provides a computation of the number of children exposed to various fluoride concentrations who are expected to suffer from moderate or severe fluorosis. Confidence intervals for these calculations are provided in Appendix C.

An alternative to removing fluoride from drinking water is repair of teeth exhibiting moderate or severe fluorosis. A drinking water MCL obviates the need to undertake such repairs. The repair costs avoided by issuing an MCL are estimated in Appendix B.

Dental fluorosis may also result in health impacts of a psychological nature.[2] The disfiguration caused by more serious forms of fluorosis is likely to be disadvantageous to children and adults, affecting self-confidence, social behavior, other people's perceptions of them, their influence on others, and other psychological characteristics. The exact nature of these difficulties has not been studied, however.

4.2.2 Fluoride and Caries

One of the most important public health findings of the twentieth century has been the effect of fluoride on preventing dental caries. Table 4-2 shows how the average

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[1]National Institute of Dental Research, "Prevalence of Dental Caries and Dental Fluorosis in Areas with Optimal and Above-Optimal Concentrations of Fluoride in Their Community Water Supplies"; and University of Texas, Health Science Center at San Antoino Dental School, "A Clinical Study of Dental Effects in a Population Exposed to Water Fluoride Levels in the 'Critical Zone.'"

[2]R. Kleck, Chairperson, Review Panel on Psychological/Behavioral Effects of Dental Fluorosis, Report to Office of Drinking Water, EPA, November 17, 1984.

score for decayed, missing, and filled surfaces per tooth decreases as fluoride concentration in drinking water increases, according to a recent study.[1,2] Analyses conducted over the past fifty years have identified an optimum concentration of fluoride in drinking water to promote dental health. This optimum depends on climate and water intake but is about one part per million. (The reduction of cases of dental fluorosis due to removal of fluoride from drinking water may be offset by increased dental caries as fluoride concentrations drop. Appendix D provides an estimate of the costs of treating additional caries at various MCLs.)

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[1]E. Collins, et al. "Analysis of Costs for the Treatment of Dental Fluorosis," Health Effects Research Laboratory, EPA, Cincinnati, Table 8 (p. 28).

[2]Higher levels of fluoride are associated with lower scores for decayed, missing, and filled surfaces (DMFS) per tooth. However, at concentrations of fluoride above about 4 mg/l, higher scores for decayed, missing, and filled surfaces and higher caries frequency have been observed. (W. Butler, V. Segretto, and E. Collins, 1985, "Dental Mottling and DMFS Among School-Aged Children in Texas;" and B. Forsman, 1974, "Dental Fluorosis and Caries In High Fluoride Districts in Sweden," Community Dent. Oral Epidemiol. 2: 132-148).
As the fluoride concentration in drinking water increases, the proportion of the population with moderate or severe fluorosis increases. Moreover, the DMFS score is sometimes higher for children with moderate or severe fluorosis than for children with lesser degrees of fluorosis. (This relationship between DMFS and severity of fluorosis has not been found consistently at all age groups of children, however.) It is thought, but has not been conclusively demonstrated, that the pitting effects of moderate and severe dental fluorosis lead to the higher DMFS scores observed at higher concentrations of fluoride in drinking water. Hence, at higher fluoride levels, the incidence of caries may increase.

Table 4-1

DEAN'S FLUOROSIS INDEX

Category	Weight	Description
Normal Enamel	0.0	Normal.
Questionable	0.5	Normal translucency varied by a few white flecks or white spots.
Very Mild	1.0	Small, opaque, paper-white areas scattered over the teeth, involving less than 25 percent of the surface. Tips of cusps of bicuspid and second molars are commonly affected.
Mild	2.0	White opaque areas are more extensive but do not involve more than 50 percent of the surface.
Moderate	3.0	All enamel surfaces are involved and brown stain is a frequent disfiguring feature.
Severe	4.0	All enamel surfaces are involved with pitting in many teeth. Brown stains are widespread and teeth often present a corroded - like appearance.

Source: H.T. Dean, "The Investigation of Physiological Effects by The Epidemiological Method." In F.R. Moulton, ed., Fluorine and Dental Health, American Association for the Advancement of Science, Publication No. 19

Table 4-2

Relationship Between Community Fluoride Concentrations and Dental Caries -- Children 7 to 12 Years of Age

Community Fluoride Concentration	Average Score for Decayed, Missing and Filled Surfaces per Tooth
0-0.9 mg/l	.38
1.0-1.9 mg/l	.24
2.0-2.9 mg/l	.16
3.0-3.9 mg/l	.18
4.0-4.9 mg/l	.13

Source: E. Collins, et al., "Analysis of Costs For the Treatment of Dental Fluorosis," Health Effects Research Laboratory, U.S. Environmental Protection Agency, Cincinnati, Table 8 (p. 28).

Chapter 5

ASSESSMENT OF COSTS

This chapter analyzes the costs of removing fluoride from drinking water. The technologies for removing fluoride are discussed in Section 5.1. Section 5.2 addresses the probability of utilities' selecting these various removal measures. Computations of costs to the nation and costs facing individual affected utilities and their customers are presented in Section 5.3, following a discussion of the assumptions used to estimate these costs. Section 5.4 presents an analysis of the costs of monitoring requirements for fluoride.

5.1 Technologies for Reducing Fluoride

EPA has identified seven technologies for reducing fluoride, some of which have several variations.[1] These are:

- Activated alumina in a centralized treatment plant
- Reverse osmosis in a centralized treatment plant
- Optimized lime softening at an existing softening plant
- Bottled Water
  - Used by all households in the community
  - Used by households with small children (30% of households)
- Point of use treatment

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[1]EPA, "Technologies and Costs for the Removal of Fluoride from Potable Water Supplies," prepared by V.J. Ciccone and Associates, May 25, 1985.

- With activated alumina
- With reverse osmosis

- Regionalization (i.e. interconnection with a nearby water system which does not exceed the fluoride MCL).

- Alternate Source (i.e. tapping a new source of water which does not exceed the fluoride MCL).

The point of use, regionalization, and bottled water alternatives apply only to systems serving fewer than 10,000 persons. Centralized treatment is treatment which occurs at the water system treatment plant rather than at each participating dwelling unit.

5.2 Probabilities of Selecting Removal Measures[1]

A water utility finding fluoride in its water supply in excess of a standard could select any of several methods of treatment. EPA considered the following factors in estimating the probabilities of a utility selecting a treatment:

- system size;
- capital and operating and maintenance costs;
- effectiveness in removing fluorides;
- the population at risk (all households or those with small children); and
- likelihood of other inorganic contaminants being present along with fluorides.

On the basis of these considerations, probabilities for selecting treatments were estimated (assuming the MCL were exceeded) as follows:

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[1]The basic methodology used in this section was first developed in EPA, "Water Utility Financing Study," prepared for the Office of Drinking Water by Temple, Barker, and Sloane (n.d.).

- Systems serving fewer than 1,000 people
  - 85% select point-of-use (activated alumina) for 30% of the households (those households with small children)
  - 5% select point-of-use (reverse osmosis) for 30% of the households (those households with small children)
  - 10% obtain a variance
- Systems serving 1,001 to 10,000 people
  - 90% select central activated alumina
  - 5% select central reverse osmosis
  - 5% obtain a variance
- Systems serving more than 10,000 people
  - 90% select central activated alumina
  - 10% select central reverse osmosis

The decision to use reverse osmosis as opposed to activated alumina is likely to depend on the presence of other contaminants in the water supply. Systems with several inorganics, including fluoride, would probably select reverse osmosis whereas systems whose only inorganic contaminant is fluoride would probably select activated alumina.

5.3 Computation of Costs

5.3.1 Assumptions

Several sets of assumptions were adopted to compute the costs of removing fluoride from drinking water. Costs are computed for the nation as a whole and for individual affected utilities and their customers.

The first set of assumptions defines the standards to which water is to be treated. For this calculation, MCLs of 1 mg/l, 2 mg/l, 3 mg/l, and 4 mg/l are assumed. This will provide a range of costs on which judgements about standards can be made.

The second set of assumptions pertains to the presumed behavior of utilities under different regulatory and nonregulatory options. In particular:

- For promulgating an MCL as a primary standard, it is assumed that the regulation would be enforced and that all systems exceeding the MCL would treat their water to meet the MCL. However, some systems can be expected to be granted a variance.

- For a secondary standard of 2 mg/l or for a notification requirement, it is assumed that no additional systems would adopt fluoride removal measures. Systems failing to comply with the current primary standard would probably not undertake the cost of removing fluorides if it were no longer believed that fluorides present a threat to health as a secondary standard would imply.

- For a monitoring and notification requirement, it is unlikely that any additional systems would act to remove fluorides from drinking water. This requirement is already in place. (40CFR 141.32).

To confirm that these assumptions are reasonable, telephone contacts were made with EPA Regional Offices in Regions IV (Atlanta) and VI (Dallas). Apparently no systems have acted to remove fluorides in response to the existing MCL in Region VI but a few have done so in Region IV. A monitoring and notification requirement was thought by the Regional Offices to be unlikely to induce systems to remove fluorides. A secondary standard of 2 mg/l would probably have little effect although both Regions indicated that the states can enforce these standards. Publicity on fluoride contamination in connection with a secondary standard may induce a few systems to remove fluorides. However, because this is likely to be a small number of systems, the costs are not analyzed here and it is assumed that a secondary standard would not lead to fluoride removal actions.

The third set of assumptions is concerned with the characteristics of the treatment technologies adopted by utilities to remove fluorides. EPA's cost and technologies studies to date[1] have been prepared only for reducing an influent concentration of fluoride of 3.2 mg/l to a standard of 2 mg/l. The costs based on these assumptions are applied to all influent and effluent combinations in the calculations presented below, recognizing that these costs may have to be revised as EPA prepares additional cost

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[1]EPA, "Technologies and Costs for the Removal of Fluoride from Potable Drinking Water Supplies," prepared by V.J. Ciccone and Associates, May 25, 1984. This report was updated on September 10, 1985, but the costs did not change.

information.

The specific features of the treatment technologies expected to be adopted are as follows:

- For centralized activated alumina, 60% of the water is treated and blended with 40% of the raw water to reach the MCL.
- For centralized reverse osmosis, 50% of the water is treated and blended with the remaining raw water.
- For point of use treatment all households will receive fluoride removal equipment.

Recall from Section 5.2, that the other possible treatments are not likely to be selected.

5.3.2 Cost of Alternatives

Two types of cost are presented. One is the cost to society of investing in fluoride removal measures. This is the opportunity cost to the nation of purchasing and operating fluoride treatments. Constant 1982 dollars are used. A real social discount rate of 3% over a time horizon of 20 years is used to compute the present value of costs.[1] The real social discount rate reflects the opportunity cost of a risk-free investment in constant dollars.

The other perspective on costs is that of individual utilities. They must pay a market rate of interest and so prevailing nominal discount rates appropriate to various system size categories are used. EPA's Financing Needs Model estimates water rates and the proportion of systems satisfying certain financial criteria for well managed systems adopting various water treatments.

All systems must currently monitor for fluorides and no new monitoring costs would be incurred as a result of the regulatory alternatives unless the monitoring schedules were changed (except that dropping all standards would obviate the need for even monitoring for fluorides). Because the monitoring requirement is now in effect and no new schedule for monitoring is proposed, no costs for monitoring are included in the costing analysis.

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[1]This discount rate represents a long run historical average, not the higher real rates experienced in the 1980s. Real discount rates exclude the effects of inflation and are consistent with the use of constant dollars.

Table 5-1 shows the capital and operating and maintenance costs, the present value of fluoride removal costs, and the annualized value of fluoride removal costs to society for all systems which would act to remove fluoride assuming an MCL were set.[1] The results are shown by system size category. Table 5-2 shows these costs to society per system by system size category. Only systems exceeding the MCL are included in the calculations leading to Table 5-2.

The cost to society of fluoride removal measures drops off quickly as the MCL is relaxed. This is because the number of systems exceeding the MCL declines rapidly as the MCL increased. Per system costs are about the same at each MCL.[2]

The cost estimates shown in Tables 5-1 and 5-2 are based on the assumption that systems serving fewer than 1000 people would install point of use equipment in 30% of the households. This assumption is consistent with the goal of protecting children from dental fluorosis. If instead the goal of fluoride regulation is to protect all individuals from skeletal osteosclerosis, the analysis must reflect 100 percent protection. In particular, systems serving fewer than 1000 persons would install centralized treatment.

Under this assumption, costs for the two smallest system size categories at the MCL level of four mg/l have been estimated as follows. For the category of systems serving populations between 25 and 500, national capital costs would be $3.8 million and O & M costs $0.5 million, for a total annual cost of $0.7 million and a present value of $10.5 million. Social costs per system for the 25-500 size catory are $18,000 capital cost and $2,500 annual O & M cost, giving a present value of $51,700.

For the category of systems serving populations between 501 and 3300, national capital costs would be $4.7 million and O & M costs $0.6 million, for a total annual cost of $0.9 million and a present value of $14 million. Social costs per system for the 501-3300 category are $92,200 capital cost and $11,800 annual O & M cost, giving a present value of $51,700.

These estimates imply changes in the total social costs to the nation as follow:

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[1]These costs consider only the costs of the technologies to remove fluoride. Reduction of fluoride in some drinking water systems will also cause the incidence of caries to increase. Appendix D provides an estimate of the costs of repairing these additional caries.

[2]Differences are largely due to rounding error and the inclusion of very large systems in the size category 50,000 for an MCL of 1 but not for an MCL of 2 since there are no very large systems with fluoride concentrations above 2 mg/l.

Table 5-1

Social Costs to the Nation of Fluoride Removal
(millions of 1982 dollars)

MCL	System Size Category (population served)				
	25-500	501-3300	3301-50,000	50,000+	TOTAL
MCL = 1 mg/l					
• capital costs	19.7	66.8	285.9	595.3	967.6
• annual O&M Costs	5.4	10.9	50.6	201.2	268.0
• present value*	100.0	229.0	1038.7	3588.6	4954.8
• annualized cost*	6.7	15.4	69.8	241.2	333.0
MCL = 2 mg/l					
• capital costs	5.9	16.7	29.9	2.0	54.6
• annual O&M costs	1.7	2.9	5.0	0.5	10.2
• present value*	31.2	59.8	104.3	9.4	206.4
• annualized cost*	2.1	4.0	7.0	0.6	13.9
MCL = 3 mg/l					
• capital costs	2.2	8.6	12.5	0.0	23.4
• annual O&M costs	0.6	1.4	2.0	0.0	4.2
• present value*	11.1	29.4	42.3	0.0	85.9
• annualized cost*	0.7	2.0	2.8	0.0	5.8
MCL = 4 mg/l					
• capital costs	1.3	3.8	6.8	0.0	11.9
• annual O&M costs	0.4	0.6	1.1	0.0	2.1
• present value*	7.3	12.7	23.2	0.0	43.1
• annualized cost*	0.5	0.9	1.6	0.0	2.9

*Computed with a 3% real discount rate over 20 years.

Note: totals may not add due to rounding

Table 5-2

Social Costs Per System For Fluoride Removal
(thousands of 1982 dollars)

MCL	System Size Category (population served)				
	25-500	3301-501-3300	50,000 System	50,000+	Average
MCL = 1 mg/l					
• capital costs	6.1	78.1	693.9	9929.8	213.1
• annual O&M costs	1.7	12.7	122.8	3357.7	59.0
• present value*	31.4	267.0	2520.9	59883.9	1090.9
MCL = 2 mg/l					
• capital costs	6.2	65.2	622.9	3041.4	43.4
• annual O&M costs	1.8	11.3	104.2	760.3	8.1
• present value*	33.0	233.3	2173.1	14352.7	163.9
MCL = 3 mg/l					
• capital costs	6.6	72.9	625.0	NA	49.7
• annual O&M costs	1.8	11.9	100.0	NA	8.9
• present value*	33.4	249.9	2112.7	NA	182.1
MCL = 4 mg/l					
• capital costs	6.4	74.5	581.2	NA	44.8
• annual O&M costs	2.0	11.8	94.0	NA	7.9
• present value*	36.2	250.1	1979.7	NA	162.3

*Computed with a 3% real discount rate over 20 years.

NA means not applicable

NOTE: Systems using purchased water are excluded to avoid double counting since their water would be treated by their suppliers.

capital cost increases from $11.9 to $15.3 million, annual O & M costs rise from $2.1 to $2.2 million, annual total cost increases from $2.9 to $3.2 million and present value rises from $43.1 to $47.7 million. This increase is about 10 percent of previous estimates, and falls within the expected error of the estimates.

Impacts of treatments as perceived by water utilities are shown in Table 5-3.[1] These impacts are expressed as water rates that would have to be charged by utilities under the current status (no fluoride treatment) and assuming they would adopt a fluoride removal measure. Water rates are computed by the Financing Needs Model assuming that a predetermined earnings or operating surplus level must be met (based on a debt service ratio, pretax interest coverage, or return on equity) and that water usage would not go down if costs and prices went up. The impact of fluoride treatment is the difference in water rates between the current status rate and the rate with the treatment in place. For example, in publicly owned systems serving over 50,000 people, the current status rate is $0.86 per thousand gallons and the rate with central activated alumina is $1.07 per thousand gallons. Therefore the impact on a system choosing central activated alumina is $1.07 minus $0.86, or $0.21 per thousand gallons.

The impact of higher water rates resulting from fluoride removal is shown in Table 5-4 in terms of increases in annual household water bills. These increases assume a typical household purchases 100,000 gallons of water per year. EPA's Financing Needs Model provides for no adjustment for decreased use of water as water prices increase.[2]

Another way to view utility level impacts is to estimate the percentage of systems which could pass the following three tests simultaneously.

- a rate increase less than $1.00 per thousand gallons;
- a ratio of new treatment capital costs to assets less than 1.0; and

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[1]Recall that EPA has not yet studied the costs under alternative influent and effluent concentrations. Thus Table 5-3 and others based on the Financing Needs Model pertain to any influent-effluent combination.

[2]The increase in water bills is simply the median water rate with the fluoride treatment minus the current status rate in Table 5-3; this is then multiplied by 100.

Table 5-3

Utility Cost Impacts--
Median Water Rate
($ per thousand gallons, 1982 dollars)

Fluoride Removal Measure	System Size* and Ownership Category							
	Public Ownership				Private Ownership			
	25-500	501-3300	3301-50,000	50,000+	25-500	501-3300	3301-50,000	50,000+
Current Status	3.80	1.47	1.00	0.86	7.50	3.54	1.66	1.35
Central Activated Alumina	4.75	2.19	1.27	1.07	8.81	4.18	1.96	1.53
Central Reverse Osmosis	7.61	4.75	2.42	1.98	11.17	6.50	2.99	2.29
Point of Use (30% of Households)								
o Activated Alumina	4.32	1.98	-	-	8.21	3.94	-	-
o Reverse Osmosis	5.15	2.59	-	-	9.04	4.64	-	-

*Population served.

Source: Financing Needs Model

Table 5-4

Increase in Annual Household Water Bill Attributable to Fluoride Removal*
(1982 dollars)

Fluoride Removal Measure	System Size** and Ownership Category							
	Public Ownership				Private Ownership			
	25-500	501-3300	3301-50,000	50,000+	25-500	501-3300	3301-50,000	50,000+
Central Activated Alumina	$ 95	$ 72	$ 27	$ 21	$ 131	$ 64	$ 30	$ 18
Central Reverse Osmosis	$381	$328	$142	$112	$ 367	$296	$133	$ 94
Point of Use (30% of households)								
o Activated Alumina	52	51	-	-	71	40	-	-
o Reverse Osmosis	135	112	-	-	154	110	-	-

* Assuming 100,000 gallons of water used per household before and after fluoride treatment

** Population served.

- a total cost (rate) less than $3.00 per thousand gallons.

The Financing Needs Model makes such estimates and the results are shown in Table 5-5. The impact of fluoride treatment is the difference between the percentage of systems meeting this test under current status (with no new fluoride treatment) and the percentage of systems meeting the test with a fluoride removal measure in place. For example, 37.0% of public systems serving 25 to 500 people pass the financial tests before fluoride treatment (i.e., with the current status) but only 18.5% pass the financial tests after fluoride treatment with central activated alumina. Thus the impact is that 37.0% minus 18.5% equals 18.5% of these systems would be significantly affected by a fluoride regulation.

From the utility perspective, the following conclusions can be drawn:

- For systems serving fewer than 3,300 people, point of use activated alumina treatment is likely to be least costly assuming that it could be used under conditions specific to such systems.
- Central activated alumina is least costly for larger systems and relatively inexpensive for systems serving fewer than 3,300 people.
- Reverse osmosis is generally more expensive but it may be selected by systems for which activated alumina is ineffective or inappropriate.

5.3.3 Conclusions

For purposes of standard-setting, EPA judges the feasibility and cost of treatments considering the availability of treatments for larger, well-run, metropolitan and regional systems. In the case of fluoride, large systems can meet any MCL under consideration at a cost of $18 to $21 per household per year using centralized activated alumina. If appropriate, optimized lime softening could be used by large systems at a cost of $9 per household per year. Centralized reverse osmosis could also be used by large systems at a cost of about $100 per household per year. The costs of centralized activated alumina and optimized lime softening are clearly affordable. Therefore, feasibility and cost are not, in general, constraints in setting an MCL. However, few large systems are likely to exceed a fluoride MCL.

Table 5-5

Utility Cost Impacts
Percent of Systems Satisfying Financial Criteria*

	System Size** and Ownership Category							
	Public Ownership				Private Ownership			
	25-500	501-3300	3301-50,000	50,000+	25-500	501-3300	3301-50,000	50,000+
Current Status	37.0	70.3	83.3	83.9	20.8	42.9	78.4	73.2
Central Activated Alumina	18.5	59.5	78.2	78.8	8.3	32.1	64.7	68.3
Central Reverse Osmosis	0.0	0.0	6.4	26.3	0.0	0.0	5.9	51.2
Point of Use (30% of Households)								
o Activated Alumina	29.6	64.9	-	-	8.3	39.3	-	-
o Reverse Osmosis	14.8	21.6	-	-	0.0	17.9	-	-

*Rate increase less than $1.00 per thousand gallons, new capital cost to asset ratio less than 1.0, and total cost (rate) less than $3.00 per thousand gallons.

**Population served

Source: Financing Needs Model.

Families served by small systems that are likely to violate an MCL face significantly larger costs. Moreover, some systems may not be able, as a practical matter, to comply. In the case of fluoride, the engineering and cost analysis shows that there are three treatment technologies generally available (taking cost into consideration) even to the smallest systems. These are centralized activited alumina, targetted point-of-use activated alumina, and targetted point-of-use reverse osmosis, where the targetting is to households having small children. Annual per household cost ranges from $52 to $154 for the smallest systems. Assuming that the Administrator makes a finding that such costs are affordable these would be designated as generally available technologies for the smallest systems.[1]

5.4 Monitoring Requirements

Under current regulations (40 CFR 141.23) community groundwater systems must monitor for fluoride every three years and community water systems using any surface water must monitor for fluoride annually. If the MCL is exceeded three additional analyses must be completed within one month. If the average concentration from these four tests exceeds the MCL, a state-designated monitoring frequency is to be followed until the concentration is less than the MCL on two successive samples.

There are approximately 48,854 groundwater systems and 10,958 surface water systems in the U.S. The number of analyses for fluoride each year is therefore about 27,000. This is "baseline" sampling. In addition, those surface water systems exceeding the MCL would have to take at least three additional samples per year and at least one third of the groundwater systems exceeding the MCL would have to take at least three additional samples per year.

Considering this baseline plus the occurrence of fluorides exceeding various MCLs (Table 2-1), the minimum number of samples per year would be:

- For "baseline" sampling — 27,000 plus
- For an MCL of 1 mg/l — 6,400 additional samples, or
- For an MCL of 2 mg/l — 1,400 additional samples, or
- For an MCL of 3 mg/l — 500 additional samples, or
- For an MCL of 4 mg/l — 300 additional samples.

[1]Exemptions would be available where deemed appropriate.

The laboratory cost per analysis is about $6 using the electrode method. This method is the most commonly used one. Thus baseline laboratory costs would be about $162,000 per year. This would be the cost if no systems violated the MCL. At an MCL of 2 mg/l the costs for additional sampling by systems now exceeding the MCL would add at least $8,400 per year to this figure.

Under proposed regulations described in 40 CFR 141.23, systems with fluoride concentrations less than 2 mg/l would be required to monitor one time in each ten year period. Ground water systems that are likely to exceed 2 mg/l would be required to monitor every three years. Surface water systems that are likely to exceed 2 mg/l would be required to monitor every year (Pages 50 - 57, proposed notice.)

	Ground-water Systems	Surface-water Systems
likely to exceed 2 mg/l	1,324	22
not likely to exceed 2 mg/l	47,530	10,936

Under these regulations, 6,310 samples per year would be required at a cost of $37,860 per year.[1]

It should be noted that these are the current analytical requirements. Under the alternatives examined here, no additional monitoring costs would be imposed.

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[1] Systems < 2 mg/l:

Ground-water (.1 x 47,530)	4,753	samples/year
Surface-water(.1 x 10,936)	1,094	
Total	5,847	

Systems > 2 mg/l:

Ground-water (.33 x 1,324)	441	samples/year
Surface-water (1 x 22)	22	
	463	

Chapter 6
REGULATORY FLEXIBILITY ANALYSIS AND PAPERWORK ANALYSIS

6.1 Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) was enacted on September 19, 1980 to require all agencies to explicitly consider small entities in their regulatory design and implementation process. More specifically, regulatory agencies are to try to minimize the disproportionate burden that falls on small entities. The three primary objectives of the RFA are to:

- increase agency awareness of their regulatory impact on small entities;
- compel agencies to explicitly analyze, explain and publish their regulatory impacts on small entities; and
- encourage agencies to provide regulatory relief to small entities, while accomplishing their statutory mandates.

These objectives are accomplished through the requirements of regulatory flexibility analyses for all existing and proposed regulations. If a regulation does not have a "significant" impact on a "substantial" number of small entities, then the regulatory flexibility analysis will consist of a certification to that effect.

Prior to conducting a regulatory flexibility analysis, the agency must define a small entity. The RFA defines small entities to include small businesses, organizations, and governments (PL 96-354, Section 601 [6]). Small businesses are defined as any business which is independently owned and operated and <u>not</u> dominant in its field (15 U.S. Code, section 632). Small organizations are defined as any non-profit enterprise which is independently owned and operated and is not dominant in its field. Lastly, small governments are defined as those city, county, town, township, village, school district or special district governments serving a population of less than 50,000 persons (Regulatory Flexibility Act, PL 96-354, Sections 601[4] and 601[5]). Some public water systems are publicly owned, some are privately owned, and some are ancillary to other enterprises such as hospitals or mobile home parks. According to EPA's 1980 Survey of Operating

and Financial Characteristics of Community Water Systems[1] there are 26,424 publicly owned water systems of which 98% serve fewer than 50,000 persons. See Table 6-1.

For the case of privately owned water systems, firms primarily engaged in water supply (SIC 4941) are small businesses under the Small Business Administration criteria if their annual receipts are less than $3.5 million (Federal Register, vol. 49, no. 28 [Feb. 9, 1984], p. 5035). Applying the Consumer Price Index for water and sewerage maintenance (February 1980/ February 1984) to this figure, the cut-off for a small water utility would be $2.4 million in 1980 dollars. EPA's 1980 Survey of Operating and Financial Characteristics of Community Water Systems indicates that a population of 50,000 persons is about the cut-off for revenues of $2.4 million. For privately owned systems serving 25,000 to 50,000 persons, revenues in 1980 averaged $1,966,900, and for privately owned systems serving 50,001 to 75,000 persons, revenues in 1980 averaged $3,156,000. The number of privately owned small water systems is shown in Table 6-1.

There is some question as to whether privately owned water systems serving fewer than 50,000 persons qualify as small businesses. Some privately owned systems are not independently owned as there are many holding companies in the water supply business; in particular American, Consumers, Continental, and General Water Works Companies own a number of water utilities. In addition, nearly every privately owned water company is a natural monopoly in its market area, thereby bringing into question its dominance in its field. However, the Small Business Administration considers only a national basis for each industry, not a local basis (Federal Register, Vol. 49, No. 28, Feb. 9, 1984, p. 5039), so most water utilities would not be dominant in the entire U.S. marketplace.

All ancillary systems serve fewer than 500 people according to EPA's 1980 survey. These might be small entities although the main part of the activity to which water is supplied could be too large to qualify as a small business or may be owned by a larger organization. Moreover, some of these ancillary systems are not businesses but rather hospitals or schools. There are 16,907 ancillary water systems; see Table 6-1. It is not possible to disaggregate these systems by size of the parent organization, however.

The number of water systems affected by a fluoride MCL is shown in Table 2-1. EPA's guidelines on compliance with the Regulatory Flexibility Act (April 12, 1983)

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[1]EPA, "Survey of Operating and Financial Characteristics of Community Water Systems," prepared by Temple, Barker and Sloane, 1982.

Table 6-1

Number of Water Systems by Population Served

	Population Served				
	25-500	501-3300	3301-50,000	50,000+	TOTAL
Publicly Owned	8,932	11,544	5,455	493	26,424
Privately Owned	12,591	2,239	802	108	15,740
Ancillary	16,907	0	0	0	16,907
Total	38,430	13,783	6,257	601	59,071

Source: EPA, Survey of Operating and Financial Characteristics of Community Water Systems, 1982.

indicate that, in general, a substantial number of small entities is more than 20% of these entities. Tables 6-1 and 2-1 show that fewer than 20% of the systems would be affected by an MCL of 1 mg/l. Even fewer would be affected by an MCL of 2 mg/l or more. By the 20% rule fluoride regulations would not affect a substantial number of small water utilities.

Cost impacts on small water systems are summarized in Tables 5-3 and 5-5. Table 5-5 suggests the magnitude of significant cost impacts. The difference in the percentage of systems passing the financial tests with and without fluoride treatment indicates that some small systems may face financial difficulties as a result of fluoride regulations. For example, in publicly owned systems serving fewer than 500 people, nearly all will select point-of-use activated alumina, and about 7 percent are likely to find this expensive. For privately owned systems serving fewer than 500 people, nearly all will select point-of-use activated alumina and about 12.5 percent are likely to find this expensive.

6.2 Paperwork Analysis

Among the purposes of the Paperwork Reduction Act (Public Law 96-511; 94 STAT 2812) are:

- Minimization of the Federal paperwork burden for individuals, small businesses, state and local governments, and other persons; and
- Minimization of the cost to the federal government of collecting, maintaining, using and disseminating information.

Water utilities and state agencies will be required to maintain records on monitoring for fluoride and this is likely to be the largest component of paperwork associated with fluoride regulations. The Paperwork Reduction Act is intended to minimize the burden imposed on utilities and states while meeting the need to protect the public health and welfare under the Safe Drinking Water Act.

EPA is required to submit to the Office of Management and Budget proposed information collection requests. EPA must also submit a copy of a proposed rule containing an information collection requirement no later than publication of a notice of proposed rulemaking in the Federal Register. In addition, when a final rule is published in the Federal Register, EPA must explain how any collection of information requirements respond to public comments. The Office of Management and Budget

determines the necessity and practical utility of the information being requested and if approval of the request is made, OMB will issue a control number.

In order to determine whether a specific water system exceeds a maximum contaminant level for fluoride, each water system must monitor its water. EPA, the states, water utilities, and the public would use monitoring information to determine whether fluoride exceeds the MCL and to help determine appropriate courses of action if it does.

The monitoring and notification requirements of a fluoride regulation are likely to constitute the paperwork burden of water utilities. As indicated in Section 5.4, the additional monitoring requirements of a fluoride regulation are negligible since fluoride is now regulated and monitoring is already required. Data collection on fluoride is already authorized by OMB. The number of water samples required per year at an MCL of 2 mg/l would be 28,400. The greatest respondent burden would fall on surface water systems exceeding an MCL. They would have to take at least four samples per year. A certified or state laboratory would conduct the analysis for fluorides.

APPENDIX A

COMPUTATION OF NUMBER OF CASES OF SEVERE AND MODERATE DENTAL FLUOROSIS AVOIDED

This appendix provides numerical estimates of the number of cases of severe and moderate dental fluorosis avoided if various MCLs are adopted. The MCLs examined are 1 mg/l, 2 mg/l, 3 mg/l, and 4 mg/l. These provide a range of standards from which to judge some of the benefits of reducing fluoride.

An ad hoc committee headed by the Chief Dental Officer of the U.S. Public Health Service has stated that "No sound evidence exists which shows that drinking water with the various concentrations of fluoride found naturally in public water supplies in the U.S. has any adverse effect on dental health as measured by loss of function and tooth mortality."[1] The Surgeon General also stated that "...I encourage communities having water supplies with fluoride concentrations of over two times optimum to provide children up to age nine with water of optimum fluoride concentration to minimize the risk of their developing aesthetically objectionable dental fluorosis."[2] The data provided in this appendix suggest the magnitude of cases of objectionable dental fluorosis avoided at various MCLs.

It has been conclusively demonstrated that fluoride in drinking water causes dental fluorosis in some portion of the population. In moderate and severe cases, tooth surfaces have brown stains or pitting or both.

The Dean Index, developed in the late 1930s and early 1940s, is the standard system used to classify the degree of fluorosis.[3] The index contains six categories ranging from "normal" and "questionable" to "severe". See Table 4-1. This analysis is limited to

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[1]Quoted in EPA, 50 Federal Register, 20166; May 14, 1985.

[2]ibid.

[3]Dean, H.T., 1942, "The Investigation of Physiological Effects by the Epidemiological Method," in F.R. Moulton, ed., Fluorine and Dental Health, American

evaluation of the two most serious categories - "moderate" and "severe" - as they represent actual destruction of the dental enamel.

Two studies provide data with a sufficiently wide range of fluoride concentrations to permit estimation of dose-response relationships for fluorosis.[1] These relationships are needed to project the number of cases of fluorosis avoided by reducing fluoride concentrations. Both studies evaluated fluorosis in children since fluorosis is most likely to occur before six years of age. In addition, both studies took into account the concentration of fluoride in the drinking water of the towns in which the children lived. In particular, the University of Texas study team evaluated the prevalence of fluorosis in a total of 2,602 children in 16 Texas communities in which fluoride concentrations in drinking water ranged from 0.3 to 4.3 times the dentally-defined optimal level; the NIDR study evaluated 807 children in seven Illinois communities with fluoride concentrations ranging from 1.0 to 4 times optimum. Although the optimum will vary from place to place due to climatic differences, the optimum is about one part per million or slightly less. Thus a community with water having a fluoride concentration of twice the dental optimum would exhibit a fluoride concentration of about two parts per million. Tables A-1 and A-2 present the percentage distributions of children by degree of fluorosis by level of fluoride in drinking water. Note the difference between the dose-response rates for moderate fluorosis between the two studies.

The data from these studies can be used to determine the number of cases of severe or moderate fluorosis avoided in children under six years of age if fluoride concentrations were reduced. It is assumed that fluorosis occurs due to exposure from birth to six years of age.

The empirical data are insufficient to model the form of the mathematical relationship (e.g., linear, log-linear, etc.) between fluoride concentrations in drinking water (dosage) and the proportion of children with fluorosis (response). This analysis assumes that the relationship is linear, a reasonable assumption in the low dose range.

Association for the Advancement of Science, Publication No. 19.

[1]National Institute of Dental Research, "Prevalence of Dental Caries and Dental Fluorosis in Areas with Optimal and Above-Optimal Concentrations of Fluoride in Their Community Water Supplies;" and University of Texas, Health Science Center at San Antonio Dental School, "A Clinical Study of the Dental Effects in a Population Exposed to Water Fluoride Levels in the 'Critical Zone.'"

Table A-1

PERCENTAGE DISTRIBUTION OF MOTTLED ENAMEL SCORES
AMONG TEXAS CHILDREN

Study Community	Water Fluoride (Factor of Optimal)	Number Examined	% of children with Moderate Fluorosis*	% of children with Severe Fluorosis*
New Braunfels	0.3	103	0.0	0.0
San Marcos	0.3	223	0.0	0.0
San Antonio	0.4	126	0.0	0.0
Kingsville	1.0	361	0.3	0.0
Alvin	1.3	211	0.9	0.0
Angleton	1.3	187	1.1	0.0
Kerrville	1.4	128	0.0	0.0
Alpine	2.3	23	13.0	0.0
Littlefield	2.3	109	14.7	0.0
Fort Stockton	2.5	301	3.3	0.0
Hillsboro	2.7	200	4.0	0.0
Monahans	2.7	170	13.5	0.0
Perryton	2.7	90	6.7	0.0
Abernathy	2.9	67	32.8	0.0
Gatesville	3.1	113	4.4	0.0
Taylor	4.3	190	31.1	0.5

*Each subject was classified on the basis of severest form of enamel mottling recorded for two or more teeth.

Classification made according to Dean (1942).

Source: University of Texas, Health Science Center, San Antonio Dental School, "A Clinical Study of the Dental Effects in a Population Exposed to Water Fluoride Levels in the 'Critical Zone'," Table V.C.3.

Table A-2

PERCENTAGE DISTRIBUTION OF MOTTLED ENAMEL SCORES AMONG ILLINOIS SCHOOL CHILDREN

Study Community	Water Fluoride (Multiple of Optimal Dental Level)	Number Examined	Percentage Distribution of Mottled Enamel Sources*					
			Normal (0.0)	Questionable (0.5)	Very Mild (1.0)	Mild (2.0)	Moderate (3.0)	Severe (4.0)
Kewanee	1	336	56.0	29.5	7.4	4.8	1.8	0.6
Monmouth	2	143	18.2	28.7	23.1	16.8	8.4	4.9
Abingdon Elmwood	3	192	22.9	26.0	15.1	19.8	7.8	8.3
Ipava Bushnell Table Grove	4	136	12.5	15.4	16.9	25.0	7.4	22.8

*Each subject was classified according to Dean's Index on the basis of the most severe form of enamel mottling recorded for two or more teeth.

Source: National Institute of Dental Research, "Prevalence of Dental Caries and Dental Fluorosis in Areas with Optimal and Above Optimal Concentrations of Fluoride in their Community Water Supplies."

Scattergrams of the dosage and response variables within the range of data observed do not support a non-linear relationship.

The calculation of the number of cases avoided annually was performed in several steps. In the first step, the percentage of children having a given degree of fluorosis was regressed on the concentration of fluoride in drinking water. Concentration of fluoride is measured as a multiple of the optimal level. Since the University of Texas data indicated a non-zero percentage of "severe" fluorosis in only one of the 16 groups of children studied, no equation was derived for "severe" fluorosis using these data. The regression equations and coefficients of correlation for the two sets of data are presented in Table A-3.

In the second step, two sources of data were combined to estimate the total population exposed to various concentrations of fluoride. The first data source was EPA's estimate of the number of systems by size category by fluoride concentration.[1] To obtain the population served by each system, the average population by system size category was obtained from EPA's 1980 survey of community water systems.[2] The average population was then multiplied by the number of systems in each size category to obtain the total population exposed to a given fluoride concentration. The estimated population exposed to fluoride by concentration category is shown in Table A-4.

In the third step, the regression equations in Table A-3 were used to calculate the percentage of children with severe or moderate fluorosis at various concentrations of fluoride in drinking water. Concentration levels of 1, 1.5, 2, 2.5, . . ., 8.5 mg/l were utilized.

Data from the Bureau of Census indicate that 10.1 percent of the population is under six years of age.[3] Therefore, in the fourth step, the population data presented in Table A-4 were multiplied by .101 to derive the number of children in the age group birth to six.

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[1]EPA report prepared under contract by JRB Associates, "Occurrence of Fluoride in Drinking Water, Air and Food," February 9, 1984.

[2]EPA, "Survey of Operating and Financial Characteristics of Community Water Systems," 1982, Table II-3.

[3]U.S. Bureau of the Census, Current Population Reports. Preliminary Estimates of the Population of the United States by Age, Sex, and Race: 1970 to 1981. Series P-25, No. 917.

Table A-3

DOSE-RESPONSE RELATIONSHIPS FOR FLUORIDE IN DRINKING WATER AND DENTAL FLUOROSIS[1]

Degree of Fluorosis[2]	Study: University of Texas	Study: NIDR
Moderate	y = -5.51+6.79x r=.73	y = 2.30+1.62x r=.68
Severe	see note 3	y = -8.35+7.00x r=.94

[1] y = percentage of children with fluorosis of the degree of severity indicated.
x = fluoride concentration in drinking water, expressed as the number times the dental optimum concentration.
Analysis uses ordinary least squares regressions.

[2] As defined by Dean (1942).

[3] Only one of the 16 exposure groups showed a non-zero percentage of children with "severe" fluorosis. Therefore, no regression analysis was performed.

Table A-4

ESTIMATED POPULATION EXPOSED TO FLUORIDES IN DRINKING WATER

Population Served by Water System	Average Population (per system)	Number of People Exposed at Concentration Indicated (milligrams per liter)			
		> 1 - 2	> 2 - 3	> 3 - 4	> 4
25 - 100	57	73,017	24,168	3,591	5,757
101 - 500	245	273,910	66,395	19,600	29,890
501 - 1000	782	210,358	65,688	25,024	18,768
1001 - 3300	1,819	783,989	78,217	52,751	41,837
3301 - 10,000	5,765	1,723,735	138,360	34,590	57,650
10,001 - 25,000	16,935	1,066,905	50,805	16,935	33,870
25,001 - 50,000	37,157	2,192,263	74,314	37,157	0
50,001 - 75,000	62,830	753,960	62,830	0	0
75,001 -100,000	88,035	528,210	0	0	0
100,001 -500,000	209,950	9,867,650	0	0	0
500,001 -1 Million	706,830	4,240,980	0	0	0
1 Million +	2,342,736	7,028,208	0	0	0
TOTAL		28,743,185	560,777	189,648	187,772

In the fifth step the net reduction in cases of severe and moderate fluorosis was calculated, assuming that the systems exceeding a given standard would reduce fluoride levels to, but not below, the standard. The net reduction in cases is the total number of cases that would occur in the absence of treatment minus the number of cases that would occur at the level set by the standard. This calculation provides the net reduction in cases within the entire six-year age category (ages 0 to 6). To obtain an annual average rate of fluorosis avoided for this age category, the number of cases avoided for the entire age category was divided by six. The results of this calculation are presented in Table A-5.

As can be seen from Table A-5, the number of moderate cases of dental fluorosis avoided per year is between 55 and 230 if the MCL is set at 4 mg/l. The number of moderate cases of dental fluorosis avoided rises to between 4,486 and 18,806 per year if the MCL is set at 1 mg/l. The large jump in the number of cases avoided from an MCL of 2 mg/l to an MCL of 1 mg/l is due to the occurrence of a large number of systems having a fluoride concentration between 1 and 2 mg/l.

Only the NIDR data provide information on severe cases of fluorosis avoided per year; the University of Texas data indicate few severe cases of fluorosis at the observed levels of fluoride concentration. Thus, one must be cautious about accepting the NIDR results as applied to this problem. With this caveat in mind, the number of severe cases of dental fluorosis avoided per year at a standard of 4 mg/l is 237. This rises to 12,641 severe cases avoided per year at a standard of 1 mg/l. The large jump in the number of cases avoided from an MCL of 2 mg/l to an MCL of 1 mg/l is due to the occurrence of a large number of systems having a fluoride concentration between 1 and 2 mg/l.

Confidence intervals for these estimates are derived in Appendix C. These confidence intervals consider only errors in the dose-response curve.

Table A-5

Number of Cases of Severe and Moderate Dental Fluorosis Avoided Annually at Alternate MCLS for Fluoride in Drinking Water

Number of Cases of Fluorosis Avoided per Year	MCL 4 mg/l	3 mg/l	2 mg/l	1 mg/l
Moderate[1]				
• Systems serving 25-500 people	12-55	25-109	54-228	142- 597
• Systems serving 501-3300 people	17-71	44-185	102-426	315-1316
• Systems serving 3301-50,000 people	25-105	62-261	147-617	948-3972
• Systems serving over 50,00 people	0	0	8- 36	3083-12920
• All systems[2]	55-230	132-554	311-1307	4486-18806
Severe[3]				
• Systems serving 25-500 people	56	112	234	502
• Systems serving 501-3300 people	72	188	437	1065
• Systems serving 3301-50,000 people	107	267	635	2860
• Systems serving over 50,000 people	0	0	37	8211
• All systems[2]	237	570	1346	12641

[1]Low value is from NIDR data, high value is from University of Texas data.

[2]Total may not add due to rounding.

[3]Values are from NIDR data.

APPENDIX B

COSTS OF REPAIR OF DENTAL FLUOROSIS

If fluoride MCLs are not promulgated, then the effects of moderate and severe dental fluorosis can be remedied by cosmetic and functional repairs to the teeth of affected children. The children who would have avoided moderate or severe fluorosis if an MCL were promulgated (Table A-5) would thus require tooth repairs to offset the lack of an MCL. Table B-1 shows the average cost for cosmetic and functional repairs for various degrees of fluorosis[1]. These data are from dentists' evaluations of repair costs for minimum care (assuming the patient has a limited budget) and optimum care (assuming no financial restrictions on the patient)[2]. Fifty-five children were used in the study. These cost data must be used with caution because of the small number of children in some fluorosis categories and the wide variance in costs estimated by the dentists.

Minimum repair costs are lower than optimum repair costs for two reasons. First, minimum repair procedures were performed less frequently per subject than optimum repair procedures. Second, one of the most widely used optimum repair procedures is much more expensive than the most commonly used minimum repair procedures. This expensive optimum procedure is a porcelain gold crown.[3]

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[1]Note that avoided costs are not a measure of the economic value of benefits.

[2]Edwin Collins, University of Texas Health Science Center at San Antonio, letter of June 18, 1985, based on data in E. Collins, et al., "Analysis of Costs for the Treatment of Dental Fluorosis," Health Effects Research Laboratory, EPA, Cincinnati.

[3]The distribution of the most common repair procedures and their costs are as follows:

Minimum Repair	Average Number of Procedures per Dentist Performed on 55 Subjects	Standard Cost
Bleach	60.67	$ 50.00
Amalgam - 2 surface (perm)	27.83	30.00
Amalgam - 1 surface (perm)	27.17	22.00
Composite resin-1 surface	24.50	28.50
Acid etch	23.33	28.50

A maximum contaminant level and repairs to teeth can achieve similar dental results. With an MCL, the costs of cosmetic and functional repairs to remedy moderate and severe cases of fluorosis would be avoided, however. These avoided costs for the nation are shown in Table B-2. These costs were estimated by multiplying the number of moderate and severe cases of fluorosis avoided per year if an MCL were promulgated (Table A-5) by the optimum cost for repair of cosmetic and functional damage to teeth due to fluorosis from Table B-1.

In some cases additional future repair measures may be needed. The costs of these measures have not yet been estimated but they are thought to be small for optimum treatment. Only maintenance measures would be needed. For minimal treatment (which was not used in Table B-2), extensive future repairs will be needed over the lifetime of the patient. These future costs have not yet been estimated.

Acrylic lamination	20.17	80.00
Mastique	8.33	80.00
Optimum Repair		
Bleach	89.33	$ 50.00
Porcelain gold crown	75.67	$412.50
Pit and fissure sealant	58.17	5.00
Composite resin	34.83	28.50
Amalgam - 1 surface (perm.)	30.17	22.00
Amalgam - 2 surface (perm.)	30.00	30.00
Acid etch	23.33	28.50

Data are from Collins et al., Table 1 (pp. 19-21) and Table 2 (p. 22)

TABLE B-1

Average Costs for Repairing Cosmetic and Functional Damage to Teeth Due to Fluorosis

Severity of Fluorosis	Minimum Repair Cost	Optimum Repair Cost
Mild	$ 88.80	$ 210.65
Moderate	130.17	481.30
Severe	230.78	$1,063.91

SOURCE: Edwin Collins, University of Texas Health Science Center at San Antonio, letter of June 18, 1985, based on E. Collins, et al., "Analysis of Costs for the Treatment of Dental Fluorosis," Health Effects Research Laboratory, U.S. Environmental Protection Agency, Cincinnati, Appendix H, p. 43.

Costs based on national fee scale.

Severity of fluorosis is based on Dean's Index.

TABLE B-2

Avoided Costs for Remedial Repair of Moderate and Severe Dental Fluorosis if an MCL is Promulgated

MCL	Avoided Annual Costs for Remedial Repair of Dental Fluorosis (millions of dollars)
1 mg/l	$15.6 - $22.5
2 mg/l	1.6 - 2.1
3 mg/l	0.7 - 0.9
4 mg/l	0.3 - 0.4

NOTE: Costs refer to optimal repair using a national fee scale.

APPENDIX C

UNCERTAINTY OF COSTS AND BENEFITS

The estimates of health benefits such as cases of dental fluorosis avoided and of fluoride removal costs are subject to error. There are two ways to incorporate the uncertainty introduced by these errors into the analysis of costs and benefits of fluoride removal. One is a statistical method involving confidence intervals and the other is sensitivity analysis. This appendix indicates how these approaches could be used in the economic assessment of fluoride regulations.

The statistical approach uses confidence intervals based on the sampling distribution of the relvant variables. For health benefits, the number of cases of fluorosis is the product of the probability of fluoride occurring in drinking water in a given concentration interval, the number of water systems in a given size category, the probability of fluorosis occurring given a concentration in drinking water, and the number of people served by a water system of a given size. Occurrence, number of systems, dose-response, and population served are all random variables. In order to determine confidence intervals for the product of these random variables it is necessary to know the sampling distributions of each of the random variables. The status of this information is as follows:

- Occurrence data -- for higher concentrations of fluoride, theoretically all water systems are included in the estimate of occurrence. There is therefore no sampling error, although there is measurement error. A sample was used for lower concentrations and so a sampling error can be estimated for this set of systems.

- Number of systems -- presumably EPA has identified the universe so there is no sampling error.

- Dose-response function--confidence intervals can be calculated for the dose-response function. For instance, the confidence interval of the coefficient of the dosage variable in a regression of proportion of children with fluorosis (response) on the concentration of fluoride in drinking water (dose) is estimated below. There are insufficient date to compute a dose-response function for

osteosclerosis, however.

- o Number of persons served by a water system -- confidence intervals could be calculated from EPA's 1980 survey of community water systems.

A critical component of uncertainty is the dose-response function. The uncertainty associated with the dose-response function is reflected in the 95% confidence intervals of the coefficient of x (fluoride concentration) in the regression equations reported in Table A-3. These are as follows:

Equation	Coefficient of fluoride concentration	Approximate 95% confidence interval of coefficient of fluoride concentration
University of Texas		
• moderate fluorosis	6.79	3.15 to 10.43
NIDR		
• moderate fluorosis	1.62	-3.65 to 6.89
• severe fluorosis	7.00	-0.84 to 14.84

Given the small number of groups of communities in the NIDR data base (4), one would expect a ver large range of uncertainty in the dose-response functions.

The uncertainty of the benefits of reducing fluoride are shown below using the 95% confidence interval for the slopes of the three dose-response functions.

	Range of Cases of Dental Fluorosis Avoided per Year (95% Confidence Interval)		
	Moderate Fluorosis		
	University of Texas Data	NIDR Data (Illinois)	Severe Fluorosis (NIDR data)
MCL			
1 mg/l	730 to 28884	0 to 19079	0 to 41085
2 mg/l	605 to 20004	0 to 1322	0 to 2839
3 mg/l	257 to 849	0 to 560	0 to 1196
4 mg/l	107 to 353	0 to 232	0 to 491

For costs of contaminant removal, there are also several components: cost data for individual systems, probabilities of utilities selecting a given treatment, the number of water systems, and the proportion of water systems exceeding the standard. The status of this information is as follows:

- Cost data for individual systems -- these data are a nonrandom sample of engineering analyses and design rules of thumb which, because they are nonrandom, cannot be expressed in terms of confidence intervals.

- Treatment selection probabilities -- these are based on expert judgement and therefore it is not appropriate to derive statistical confidence intervals.

- Number of water systems -- this is presumably a count of the universe so a confidence interval is irrelevant.

- Proportion of water systems exceeding the standard -- this is based on a

combination of the universe of water systems (for high fluoride concentrations) and a sample of water systems (for lower fluoride concentrations). Thus a confidence interval depends on fluoride concentration.

When multiplied together these data are not appropriate for use in constructing a statistical confidence interval.

A sensitivity analysis may be more appropriate than a statistical analysis to determine the effects of uncertainty in the cost data. Expert judgement could be used to establish a range of costs of fluoride removal for various system size categories and a range of probabilities of utilities selecting various treatments. Thus a range of national costs could be estimated.

APPENDIX D

ADDITIONAL COSTS FOR CARIES TREATMENT IF A FLUORIDE MCL IS SET

Removing fluoride from drinking water may cause an increased incidence of caries in children. This appendix provides a calculation of the costs of treating the expected number of additional caries in children resulting from reducing the concentration of fluoride in drinking water.

The following assumptions were made:

a. The population of interest is children exposed to excess fluoride, ages 7 to 12.[1]

b. The relevant treatment costs are those given by Collins et al.[2]

c. Annual costs to the nation at a given MCL are $\sum_i (C^* - C_i) P_i/6$, where C_i is the caries treatment cost per person at fluoride concentration category i, C^* is the caries treatment cost per person at the fluoride level just below the MCL, P_i is the number of children ages 7 to 12 exposed to fluoride concentration category i[3], and the sum is divided by 6 to annualize the costs over the six years of age included.

For example, the treatment cost for caries if the fluoride concentration is 1.0 to 1.9 times optimal is $101 and the treatment cost for caries if the fluoride concentration is between 4.0 and 4.9 times optimal is $55. There are 17,607 children aged 7 to 12

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[1] U.S. Bureau of the Census, 1980 Census of Population

[2] E. Collins et al, "Analysis of Costs for the Treatment of Dental Fluorosis; Health Effects Research Laboratory EPA, Cincinnati Table 8. The costs are $160 per child if the community fluoride level is 0 - 0.9 mg/l; $101 if fluoride concentrations are 1.0 - 1.9 mg/l, $67 at 2.0-2.9 mg/l, $76 at 3.0-3.9 mg/l and $55 at 4.0 - 4.9 mg/l.

[3] Obtained by multiplying the exposed population from Table A-4 by the proportion of the population in age category 7 - 12.

exposed to fluoride concentrations of 4.0 times optimal or more. The additional cost of treating their increased caries if an MCL of 2 is imposed is ($101-$55) x 17,607 = $809,922. Annualized, this is $134,987.

Carrying out these calculations, the annualized additional costs for caries treatment if a fluoride MCL is established are as follows:

- MCL = 1 mg/l $27,875,000
- MCL = 2 mg/l 507,000
- MCL = 3 mg/l 35,000
- MCL = 4 mg/l 62,000

(The anomalous low value for an MCL of 3 mg/l is due to the lower caries treatment cost reported by Collins et al. for fluoride concentrations of 2.0 to 2.9 times optimal than for a fluoride concentration of 3.0 to 3.9 times optimal. This calculation assumes no increase or decrease in caries treatment costs if the current concentration of fluoride was 3.0 to 3.9 times optimal and the MCL were set at 3 mg/l).

The net result of this exercise is to add only a very small cost to the annualized national costs of fluoride removal, less than 5% for an MCL of 2, 3, or 4 mg/l, but slightly more for an MCL of 1 mg/l.