ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[WH-FRL-2800-2]

National Primary Drinking Water Regulations; Fluoride

April 30, 1985.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rulemaking.

SUMMARY: This rule is proposed under the Safe Drinking Water Act (SDWA) (42 USC 300f *et seq.*) and would establish a Recommended Maximum Contaminant Level (RMCL) for fluoride in drinking water. The RMCL is proposed at 4 mg/L. An RMCL is a *non-enforceable health goal* set at a level which would result in no known or anticipated adverse health effects with an adequate margin of safety. This proposal is the initial stage in rulemaking for the establishment of a primary drinking water regulation for fluoride. When the RMCL is promulgated, EPA will propose a primary drinking water regulation consisting of a Maximum Contaminant Level (MCL) and monitoring/reporting requirements. An MCL is an *enforceable standard* and is set as close to the RMCL as feasible with the use of the best technology generally available taking costs into consideration.

DATES: Written comments should be submitted by July 15, 1985. A public meeting will be held in Washington, D.C. on June 17–18, beginning at 10:00 AM in Room 2126, EPA, 401 M Street SW., Washington, D.C.

ADDRESSES: Send written comments to: Comment Clerk, Criteria and Standards Division, Office of Drinking Water (WH–550), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. A copy of all comments will be available for review during normal business hours at the EPA, Room 2904 (rear), 401 M Street, SW., Washington, D.C 20460. It is requested that anyone planning to attend the public meeting (especially those who plan to make statements) register in advance by calling or writing Ms. Nancy Dillon at (202) 382–3022, EPA, (WH–550), 401 M Street, SW., Washington, D.C 20460. Persons planning to make statements at the hearing are encouraged to submit written copies of their remarks at the time of the meeting.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph. D., Director, Criteria and Standards Division, Office of Drinking Water (WH–550), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C 20460, (202) 382–7575.

Supporting documents cited in Section VIII will be available for inspection at the above address in Room 2904 (rear) in the Public Information Reference Unit and at the Drinking Water Supply Branch Offices in EPA's Regional Offices at the addresses listed below.

I. JFK Federal Bldg., Boston, MA 02203, Phone: (617) 223–6486, Jerome Healy
II. 26 Federal Plaza, Room 824, New York, NY 10278, Phone: (212) 264–1800, Walter Andrews
III. 841 Chestnut Street, Philadelphia, PA 19107, Phone: (215) 597–9873, Bernie Sarnowski
IV. 345 Courtland Street, Atlanta, GA 30365, Phone: (404) 881–3781, Robert Jourdan
V. 230 S. Dearborn Street, Chicago, IL 60604, Phone: (312) 886–1676, Joseph Harrison
VI. 1201 Elm Street, Dallas, TX 75270, Phone: (214) 767–2620, James Graham
VII. 726 Minnesota Ave., Kansas City, KS 66101, Phone: (913) 234–2815, Gerald R. Foree
VIII. 1860 Lincoln Street, Denver, CO 80295, Phone: (303) 293–1413, Marc Alston
IX. 215 Fremont Street, San Francisco, CA 94105, Phone: (415) 974–8076, Leslie Ragle
X. 1200 Sixth Avenue, Seattle, WA 98101, Phone: (206) 442–1225, Jerry Opatz.

Copies of the draft health criteria, occurrence, and treatment/cost documents are available for a fee from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll free number is (800) 336–4700; in Washington, D.C. area: (703) 487–4650.

SUPPLEMENTARY INFORMATION:

I. Statutory Requirements

The Safe Drinking Water Act ("SDWA" or "the Act"), in Section 1401, requires EPA to establish primary drinking water regulations which (1) apply to public water systems; (2) specify contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons; and (3) specify for each contaminant either (a) MCL or (b) a treatment technique. See Section 1401(1), 42 U.S.C. 300f. A treatment technique requirement would only be set if "it is not economically or technologically feasible" to ascertain the level of a contaminant in drinking water. *Id.*

The SDWA includes provision for Interim and Revised Regulations. See Section 1412. Interim Regulations were to be established within 180 days of enactment of the SDWA. They were promulgated in 1975 (40 FR 59566, December 24, 1975). Revised regulations are to be developed in two steps: first EPA (the Agency) is to establish RMCLs and then establish MCLs as close to the RMCLs as feasible. *RMCLs are non-enforceable health goals.* RMCLs are to be set at a level at which, in the Administrator's judgment, "no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety", Section 1412(b)(1)(B). RMCLs have no direct impact on public water systems or the public. By promulgating RMCLs, no system is forced to reduce contaminants to this level or to take other action regarding other contaminants. However, if EPA promulgates an RMCL, the Act requires EPA to eventually promulgate an MCL.

MCLs are the enforceable standards. MCLs must be set as close to RMCLs as is feasible. Feasible means "with the use of the best technology, treatment techniques and other means, which the Administrator finds are generally available (taking costs into consideration)" Section 1412(b)(3).

The SDWA specifies that primary drinking water regulations must contain criteria and procedures to assure a supply of water that complies with the MCLs (i.e., monitoring and reporting

requirements), Section 1401(1)(D). Section 1445(a) also authorizes EPA to require, by regulation, any public water suppliers to keep records, make reports, conduct monitoring and provide such other information as may be required to assist in determining compliance with the SDWA, in evaluating health risks of unregulated contaminants, or in advising the public of such health risks.

National Secondary Drinking Water Regulations (NSDWR) (Section 1412(c)) are also authorized under the SDWA. A secondary drinking water regulation is defined in Section 1401(2) as "a regulation which applies to public water systems and which specifies the maximum contaminant levels which, in the judgment of the Administrator, are requisite to protect the public welfare." The NSDWR "may apply to any contaminant in drinking water (A) which may adversely affect the odor or appearance of such water and consequently may cause a substantial number of persons served by the public water systems providing such water to discontinue its use, or (B) which may otherwise adversely affect the public welfare." In addition, such regulations "may vary according to geographic and other circumstances." NSDWR are not Federally enforceable. Secondary Maximum Contaminant Levels (SMCLs) were established in 1979 for 12 parameters (44 FR 42196 July 19, 1979).

States may assume primary enforcement responsibility (primary) for public water systems under SDWA Section 1413. To assure primacy, States must adopt drinking water regulations that are no less stringent than EPA's National Interim Primary Drinking Water Regulations and other supporting authority. *See* SDWA Section 1413(a). States must, therefore, adopt EPA's primary MCLs but need not adopt the RMCLs or the Secondary MCLs to assume or retain primacy.

II. Regulatory Framework

The issuing of Revised Primary Drinking Water Regulations is a two-step process required by the SDWA.

In the first step, the National Interim Primary Drinking Water Regulations (NIPDWRs) were promulgated for fluoride and other chemicals on December 24, 1975, with an effective date of June 24, 1977. Amendments were issued in 1976, 1979 and 1980. See 40 CFR Part 141. MCLs and monitoring and reporting requirements were set for numerous microbiological, organic, radionuclide, and inorganic contaminants, including fluoride. *See* 40 CFR, Part 141, Subpart B.

As the second step, Section 1412(b)(1) requires EPA to consult with the National Academy of Sciences and to propose and promulgate National Revised Primary Drinking Water Regulations (NPDWR) that include MCLs and monitoring and reporting requirements for those contaminants which may have any adverse effect on human health. This notice initiates the second step for fluoride. NPDWRs for other contaminants in drinking water are being developed in rulemaking separate from fluoride. *See* 48 FR 45502 (October 5, 1983) and 49 FR 24330 (June 12, 1984). An advance notice of proposed rulemaking was issued for fluoride and other contaminants on October 5, 1983 (48 FR 45502, 45514).

This rulemaking will also satisfy a consent decree which settles a legal challenge brought by South Carolina against EPA. On June 4, 1981, the State of South Carolina Department of Health and Environmental Control filed a petition requesting that EPA exercise its rulemaking authority to revoke the fluoride Interim Regulation. The petition contended that (1) fluoride does not pose a public health hazard, and (2) the cost of reducing fluoride concentrations is prohibitively high and not justified by the benefits. The petition recommended "that further study of the medical and economic aspects of fluoride removal be conducted and that, pending results of that study, fluorides be removed to the secondary drinking water regulations."

The Agency responded to the South Carolina petition on December 1, 1981 (46 FR 58345). In this response, the Administrator agreed to make a decision on the South Carolina petition through the Revised Regulation process, "as soon as the current epidemiology studies are completed, reported and reviewed, and revised treatment and economic impact assessments are completed."

In 1984, South Carolina sued EPA seeking faster action in EPA's rulemakings on fluoride (*South Carolina Department of Health and Environmental Control* v. *U.S. Environmental Protection Agency, et al.*, No. 3:84–0676–15 (D.S.C. April 4, 1984). On January 18, 1985, EPA and South Carolina signed a Consent Decree that set forth a schedule for rulemaking on EPA's decision whether to regulate fluoride under the Revised Regulations. Today's notice is the first step towards implementing that decree.

III. Background

A. Interim Fluoride Regulation

In 1975, EPA promulgated the NIPDWR under Section 1412 of the Safe Drinking Water Act. EPA regulated fluoride and set an MCL. The MCL varied from 1.4 mg/L to 2.4 mg/L, depending upon annual average ambient air temperatures. These levels were considered to be twice the optimum level (.7 to 1.4 mg/L); "optimum" is defined as a balance between the prevention of both dental caries and objectionable fluorosis (Mc Clura, 1970). Objectionable fluorosis is a mottling of dental enamel characterized by staining and/or pitting. The Agency set this MCL based on evidence that higher levels of fluoride in drinking water could produce adverse health effects by increasing the occurrence of objectionable dental fluorosis. This MCL was identical to a previous United States Public Health Service Standard that was established in 1962.

The Interim Regulation for fluoride was challenged by the Environmental Defense Fund (EDF) (*EDF* v. *Costle*, 578 F.2d 337 (D.C. Cir. 1977)). EDF believed that the standard was not sufficiently protective of human health since technologies were available to control fluoride to lower levels. In upholding EPA's position, the Court of Appeals for the District of Columbia Circuit found that EPA had struck a proper balance between health protection and the cost of meeting the standard. However, the court also noted that "there is serious question as to whether mottling (dental fluorosis) can be regulated as an 'adverse effect on health' within the meaning of the Act." *Id.* at 347 n. 35.

B. National Academy of Sciences Review

EPA requested the advice of the National Academy of Sciences concerning contaminants for which MCLs had been established. In *Drinking Water and Health*, Vols. I and III (NAS 1977, NAS 1980) the Academy concluded:

- Fluoride "has not been shown unequivocally to be an essential element for human nutrition"; in addition, the Academy estimated adequate and safe daily intakes of fluoride ranging from 0.1 mg for infants less than 6 months old to 1.5 to 2.5 mg fluoride for children from 7 years to adulthood— these levels of fluoride are considered protective against both caries and osteoporosis (reduced bone density) (NAS 1980).
- "Ingestion of drinking water containing excessive fluoride can result in mottling of the teeth and dental fluorosis in children. Increased density and calcification of bone (osteosclerosis) has been associated with chronic ingestion of high-fluoride. . . . At unusually high levels, chronic fluoride ingestion can result in crippling skeletal fluorosis."; "Dental mottling and changes in tooth structure may develop in children when fluoride levels in water exceed approximately 0.7 to 1.3 mg/liter, depending on ambient temperature . . . and diet"; and "a 10 to 20 year daily ingestion of 20 to 80 mg

fluoride could result in crippling skeletal fluorosis." (NAS 1980).

- "Until more precise measures of the margin of safety for the use of fluoride are available," (concerning crippling skeletal fluorosis and other aspects of fluoride toxicity), "the levels of fluoride in drinking water should not exceed the optimal levels for anticariogenic benefits." (NAS 1980).
- The Academy also noted the lack of recent studies on the incidence of mottling, and suggested the need for additonal studies on dental mottling and skeletal fluorosis as well as sociological studies to determine whether mottling was perceived by the public as a health problem. (NAS 1977) Those studies are now completed (Driscoll *et al.* 1983, Segreto *et al.* 1984, Kleck 1984) and the findings are discussed in Section V.

C. The South Carolina Petition

The petition from South Carolina (June 4, 1981) requested that the Agency delete fluoride from the Primary Drinking Water Regulations and set an SMCL for fluoride in the Secondary Drinking Water Regulations. The state argued that dental fluorosis should not be considered an adverse health effect, but should be considered a cosmetic effect. South Carolina contended that cosmetic effects of dental fluorosis (e.g. discoloration and pitting of teeth) are appropriate for regulation in the Secondary and not the Primary Drinking Water Regulations.

A number of other states and professional organizations supported the petition, including such groups as the American Medical Association, American Dental Association, Association of State and Territorial Dental Directors, and the Association of State and Territorial Health Officials. The main concern of the states appeared to be over the costs of the fluoride removal; however, several of the other groups stated that the inclusion of fluoride in the primary regulations as a contaminant that poses health risks to consumers will undermine efforts to promote fluoridation of community water supplies where optimal levels of fluoride do not occur naturally.

Dose-related beneficial and undesirable effects with the same substance are not an unusual occurrence. Certain chemicals are essential nutrients or otherwise beneficial at low levels, but pose health risks at higher levels of consumption. Fluoride is somewhat unique in this circumstance because there is some overlap of the doses at which beneficial and undesirable effects occur.

D. The Surgeon General's Views and National Drinking Water Advisory Council Recommendations

EPA requested that the U.S. Surgeon General examine "the issue of the relationship of fluoride in drinking water and the health aspects of dental fluorosis." The Surgeon General replied on July 30, 1982 (Koop 1982). He concurred with the findings of an ad hoc committee headed by the Chief Dental Officer of the U.S. Public Health Service, which included the following statements (Albertini et al. 1982):

- "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 an adverse effect on general health."
- "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."

The Surgeon General did not consider dental fluorosis to be an adverse health effect. He added (in agreement with the previous Surgeon General):

- "Also, as one concerned about the total well-being of the individual and one dedicated in helping people avoid impediments to their reaching their maximum potential in society, I cannot condone the use of public water supplies that may cause undesirable cosmetic effects to teeth, just as I cannot condone the use of water supplies below the optimum concentrations because of diminished protection against dental caries" (Koop 1982, Richmond 1980).

The Surgeon General also stated:

- "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."

On October 26, 1982, the National Drinking Water Advisory Council (NDWAC) convened in a special session to consider the fluoride issue and to develop recommendations to the Administrator (NDWAC 1982). The Regulations Subcommittee of the Council heard testimony from organizations including the American Medical Association, the American Dental Association, the State of South Carolina, the Association of State and Territorial Dental Directors, the Association of State and Territorial Health Officials, the National Institute for Dental Research and the Chief Dental Officer, U.S. Public Health Service. These speakers supported deleting fluoride from the Primary Drinking Water Regulations and placing fluoride in the Secondary Drinking Water Regulations. The subcommittee also considered other scientific and technical information on fluoride in drinking water and in dental and skeletal fluorosis.

In a letter to the Administrator summarizing their discussions, the full NDWAC concluded that osteosclerosis and other adverse health effects constitute a sufficient basis for a Primary Regulation. The Council also felt that dental fluorosis could be the basis for a Secondary Regulation.

Due to the many questions regarding the non-dental effects of fluoride, in January 1983 EPA requested that the U.S. Surgeon General review the available date on these effects. The review was to include a determination of the levels at which such effects would occur and of a margin of safety that would be appropriate. In April 1983, the Surgeon General convened a committee of health scientists to investigate the non-dental health effects of fluoride. The Surgeon General provided the Agency with a copy of the committee report and his recommendations in January 1984 (Shapiro 1983, Koop 1984).

The Surgeon General emphasized that he did not consider changes in bone density to be adverse health effects. Adverse health effects were defined as death, gastrointestinal hemorrhage or irritation, arthralgias, and crippling fluorisis. The Surgeon General stated that no credible reports exist of cases of death or gastrointestinal effects of fluoride in drinking water in the U.S. and that arthralgias are not likely to occur in patients on therapeutic regimens of less than 20 mg/day. He noted that crippling fluorosis had been detected in some people who have consumed 20 mg/day for 20 or more years.

The Surgeon General repeated his earlier opinion on the advisability of limiting fluoride concentrations to twice the optimum to avoid objectionable dental fluorosis. In conclusion, the Surgeon General said that there is "essentially no likelihood of even non-adverse medical effects where drinking water supplies contain up to four times the optimum concentration of fluoride." In the committee report were the following conclusions:

- "The fluoride content of drinking water should not be greater than four times the optimal level of any community water supply. This conclusion recognizes that, fluoride intake from water between 5.0 and 8.0 mg/L (4 times–10 times optimum) has been associated in a very small number of subjects, with the radiologic appearance of early osteosclerosis which while not an adverse health effect, is however, an indication of demonstrable osseous changes not to be anticipated at lower levels (less than 4 times optimum) of fluoride."
- "... There exists no directly applicable scientific documentation of adverse medical effects at levels of fluoride below 8 mg/L

(ppm). Therefore, it can be concluded that 4 times optimum in the U.S. drinking water supplies is a level that would provide no known or anticipated adverse effect with a margin of safety."

On August 2 and 3, 1984, the NDWAC reexamined the fluoride issues and reports (NDWAC 1984). The Council heard testimony on a recent study in Texas on fluoride in drinking water (Segreto 1984) and held discussions on whether objectionable dental fluorosis which probably results in psychological and behavioral effects should be considered adverse health effects. It was the Council's recommendation that moderate and severe levels of dental fluorosis be considered adverse health effects since "these effects are associated with cosmetic deformity, dental dysfunction, and possible social and behavioral effects, . . ." (NDWAC 1984). This position reflects a conclusion that, as personal appearance is generally considered important by society, the cosmetic effects associated with moderate and severe dental fluorosis may lead to "psychological and behavioral problems or difficulties" that impede an individual from developing to his full potential.

In response to the Council's recommendation, the Agency, with the assistance of the National Institute of Mental Health (NIMH), convened an ad hoc panel of behavioral scientists to evaluate the potential psychological effects of objectionable (moderate and severe) fluorosis. The panel's conclusion (Kleck 1984) was similar to that of the Council. The panel found that "individuals who have suffered impaired dental appearance as a result of moderate or severe fluorosis are probably at increased risk for psychological and behavioral problems or difficulties" (Kleck 1984).

In its meeting of December 6 and 7, 1984, the NDWAC recommended that the RMCL for fluoride be set at 2 mg/L (a minority position—four members of the Council—recommended setting the RMCL at 1 mg/L) (NDWAC 1985).

E. World Health Organization's Fluoride Guidelines

Guidelines were established for fluoride by the World Health Organization (WHO) in 1984. The guidelines are intended "as a basis for development of standards which, if properly implemented, will ensure the safety of drinking water supplies." The fluoride guidelines was set at 1.5 mg/L and was established in the category of "inorganic constituents of health significance" on the basis of mottling of teeth (WHO 1984). The WHO stated:

"At levels above 1.5 mg/liter, mottling of teeth has been reported very occasionally and at 3.0–6.0 mg/liter skeletal fluorosis may be observed; when a concentration of 10 mg/liter is exceeded, crippling fluorosis can ensue." (WHO 1984).

IV. Occurrence/Human Exposure

This section briefly summarizes the available occurrence data in drinking water and food and provides an overview of population exposure estimates. Additional information can be found in the references listed in Section VIII.

A. Occurrence of Fluoride in Drinking Water

Table 1 shows the range and average concentration of fluoride in seawater, surface waters, and ground waters.

TABLE 1.—FLUORIDE IN WATERS

Water Type	Fluoride Content (mg/L)	
	Range	Average
Seawater		1.2
Ground waters from:		
Granitic rocks	0.0–9	1.2
Alkalic rocks	0.7–35.1	8.7
Basaltic rocks	0.0–0.5	0.1
Limestones and dolomites	0.0–1.7	0.3
Shales and clays	0.0–2.8	0.4
Surface water:		
Rivers	0.0–6.5	0.2
Lakes	up to 1,627	

Source: Fleischer *et al.* 1974.

Surface waters generally contain less than 1 mg/L fluoride (WHO 1970), although, as indicated in Table 1, they can contain considerably higher levels. The average concentration of fluoride in U.S. rivers, measured at 343 stations of the National Stream Quality Accounting Network in 1975, was 0.33 mg/L; only six streams had concentrations above 1.4 mg/L, and the highest level was 1.8 mg/L. The higher concentrations were reported for streams in southern Arizona, southern Texas, and the Oklahoma Panhandle region (EPA 1984).

The fluoride content of ground water generally averages around 0.4 mg/L, depending upon the type of rock with which it is associated. Relatively high concentrations of fluoride (5–8 mg/L) are found in ground waters associated with alkalic rocks, and for thermal waters associated with volcanoes and epithermal mineral deposits.

In general, the relatively high concentrations of fluoride in ground waters of the southwestern and western states tend to be dispersed around the geographical distribution of major fluorite mineral deposits although this association does not seem to hold for the eastern United States. High levels of fluoride extend from northwestern Ohio, westward through Iowa and then northwestward through the Dakotas and correlate with the glacial materials that are known to underlie this geographic region (EPA 1984).

Data are available for fluoride from a number of sources including compliance information for NIPDWR standards, the EPA Community Water Supply Surveys, and the EPA Rural Water Survey (EPA 1984). These data are summarized for surface and ground water derived water supply systems in Table 2 and Table 3. These and other data indicate that approximately 5% of surface and ground water systems presently exceed the existing temperature dependent MCL of 1.4 mg/L to 2.4 mg/L (EPA 1984). Most of those systems serve small populations (2,500 or fewer people). Table 4 presents the number of people exposed to various concentrations of fluoride in their drinking water.

TABLE 2.—ESTIMATED NATIONAL OCCURRENCE OF FLUORIDE IN SURFACE WATER DERIVED PUBLIC WATER SUPPLY SYSTEMS

System size (population served)	Systems with fluoride concentrations (mg/L)			
	<1.0	1.0–2.0	>2.0–4.0	>4.0
<500	3,670	117	5	3
500 to 2,500	2,960	265	6	1
>2,500 to 10,000	1,967	174	3	2
>10,000	1,615	148	2	0

TABLE 3.—ESTIMATED NATIONAL OCCURRENCE OF FLUORIDE IN GROUND WATER DERIVED PUBLIC WATER SUPPLY SYSTEMS

System size (population served)	Systems with fluoride concentrations (mg/L)			
	<1.0	1.0–2.0	>2.0–4.0	>4.0
<500	31,931	2,281	833	220
500 to 2,500	8,964	341	165	40
>2,500 to 10,000	2,828	219	44	14
>10,000	1,187	48	6	2

TABLE 4.—POPULATIONS (IN THOUSANDS) EXPOSED TO FLUORIDE

Systems	Fluoride concentrations (mg/L)			
	<1.0	1.0–2.0	>2.0–4.0	>4.0
Ground water derived systems	64,619	3,872	572	176
Surface water derived systems	103,680	22,590	78	8
Total	168,299	26,462	650	184

B. Human Exposure to Fluoride

Fluoride occurs at low levels in food and air as well as in drinking water. Atmospheric levels of fluoride are relatively low and contribute little to the average level of fluoride exposure. Available information suggests that a typical diet may represent a contribution to exposure roughly equivalent to those received from drinking water containing 0.5 mg/L fluoride. For populations

without fluoridated water food is the major route of exposure.

Both natural and man-made processes release fluorine compounds to the air (EPA 1984). Atmospheric emissions of fluorides from certain industries have resulted in serious adverse effects on local vegetation and animals. However, the vast majority of nationwide air measurements have been reported to be below detection limits (0.05 μ/m^3).

Virtually all foods contain trace amounts of fluoride (NAS 1980). Table 5 shows the fluoride content of several foods in its market basket survey taken from four areas in the United States. Very few foods contain more than 1–2 ppm fluoride, and most contain less than 0.5 ppm (dry weight). The notable exceptions are fish, other seafoods, and tea.

Table 6 shows several estimates of the daily dietary intake of fluoride, exclusive of drinking water, in the United States. These estimates generally place fluoride dietary intake in the range of 0.0028–0.011 mg/kg for adults and 0.0024–0.024 mg/kg for infants and children.

TABLE 5.—FLUORIDE CONTENT OF VARIOUS FOODS

Food	Fluoride content (ppm)	
	WHO (1970)	NAS (1980)
Meats	0.2–2.0	0.01–7.7
Offal	2.3–10.1	(1)
Fish	5.8–25.9	<0.10–24
Shellfish	0.7–2.0	(1)
Eggs	1.2	0.00–2.05
Milk	0.07–0.22	0.04–0.55
Cheese	1.62	0.13–1.62
Butter	(1)	0.4
Tea (average, dry weight)	97.0	(1)
Coffee	0.2–1.6	0.2–1.6
Citrus fruits	0.03–0.36	0.04–0.36
Noncitrus fruits	0.11–1.32	0.02–1.32
Cereals and cereal products	0.1–0.7	0.10–20
Vegetables and tubers	0.1–1.0	0.10–3.0
Beer and wine	0.07–0.24	0.0–6.34
Sugar	(1)	0.10–0.32

[1] No data provided.

TABLE 6.—REPORTED DAILY INTAKE OF FLUORIDE (EXCLUSIVE OF WATER)

Source	Category of individual	Daily intake (mg/kg)
WHO (1970)	Ages 1 to 3	0.0024–0.024
	Ages 4 to 6	0.002–0.020
	Ages 7 to 9	0.0019–0.019
	Ages 10 to 12	0.0016–0.016
NAS (1980)	Adult	0.0028–0.0043
Underwood (1973)	do	0.0043–0.0071
Hodge and Smith (1970)	do	0.0043–0.011
Singer et al. (1980) [1]	Young adult male	0.0043–0.0086

[1] Excludes all beverages.

These estimates of dietary exposure to fluoride may overlook some subpopulations with higher intakes. For example, a person drinking 2 cups of tea a day may be receiving as much as 0.008 mg/kg of additional fluoride.

Leverett (1982) has reported that fluoride dietary levels may have increased in the last 30 years and may be higher than the levels reported above. This rise is believed to be due to factors such as the increased use of fluoridated water in food processing and in beverages, and the widespread use of fluoridated dentifrices.

The relative contribution of drinking water as a source of exposure for a formula-fed infant, a 10-year-old child, and an adult is shown in Table 7. The predominant sources of fluoride to individuals in the United States are food and drinking water. Drinking water is the greater source of exposure where levels approach 1 mg/L.

TABLE 7.—ESTIMATED INTAKE OF FLUORIDE RELATIVE TO DRINKING WATER

Source	Daily dose (mg/kg)		
	Infant [1]	Child [2]	Adult [3]
Drinking water consumption (1 mg/L)	(4)	0.051	0.034
Air (0.05 $\mu g/m^3$)	0.00002	0.00002	0.00002
Food (from Table 5)	0.24	0.002–0.02	0.0043–0.011

[1] The infant is assumed to weigh 3.5 kg, consume solely 0.85 L of formula reconstituted with tap water, and inhale 3.4 m^3 a day.
[2] The child is assumed to weigh 33 kg, drink 1.4 L of tap water, and inhale 15 m^3 a day.
[3] The adult is assumed to weigh 70 kg, drink 2 L of tap water, and inhale 23 m^3 a day.
[4] No value is listed since the infant's intake of water is by formula and is counted as food.

While food is a significant source of fluoride, the Agency believes that it is unnecessary to adjust the RMCL to allow for dietary exposure. The health effects associated with fluoride and the doses at which they occur, are based upon epidemiology studies which implicitly incorporate dietary exposures to fluoride.

C. Temperature and Fluoride Intake

The present MCL for fluoride establishes the allowable concentration as a function of the average maximum daily temperature. The MCL ranges from 1.4 mg/L for public water systems serving populations located where the annual average maximum temperature is above 79.3 to 2.4 mg/L for systems serving populations located where temperatures are below 53.7° F. This temperature-dependent component of the regulation, referred to in the National Academy of Sciences Review (NAS, 1977), originated in a series of articles on drinking water consumption among children (Galagan and Lamson 1962, Galagan et al. 1957, Galagan and Vermillion 1957). The major portion of these articles consisted of a survey of children, under the age of 10, in two neighboring communities in California. The survey concluded that water consumption during summer months (80 to 90 ° F) increased by about 50 percent over consumption during winter months (50 to 60 ° F). The survey data indicated, however, that temperature played only a minor role in predicting drinking water consumption. Children of similar ages had drinking water consumptions (on a weight basis) that varied by a factor of 300 to 400%. Due to the limitations of the survey, the effect of humidity on water consumption could not be evaluated.

The findings of the Galagan study is contradicted in part by a recent survey of water consumption in Canada which indicates that among children, in areas where the average daily maximum temperature is below 70 ° F, water consumption is independent of temperature (EHD 1982).

The Agency has concluded that there is insufficient data to quantitatively incorporate temperature in drinking water regulations. The Galagan study, while technically sound, was limited by its restriction to a single location. The study was not able to evaluate the effects of humidity or other effects of climate, nor was it able to evaluate drinking water consumption at temperatures below 60 ° F. Further, because the study was performed over 30 years ago, the increased use of tenperature controls (heating and air conditioning) in homes and schools is likely to have reduced the effects of temperature on drinking water consumption.

V. Physiological Effects of Fluoride Ingestion

EPA has conducted a comprehensive examination of an extensive amount of literature on the potential adverse effects resulting from the ingestion of fluoride. In addition, comments and advice have been received from a wide variety of sources including such groups as the NDWAC, the U.S. Surgeon General, the American Medical Association, the American Dental Association, and the National Academy of Sciences. Based upon an evaluation of all pertinent information, advice and data in both the literature and that provided to EPA, the following statements briefly summarize EPA's findings:

- Exposure to low levels of fluoride (i.e., 1 to 2 mg/L) can contribute to objectionable (moderate and severe) dental fluorosis in a small percentage of persons. The frequency and severity of objectionable fluorosis increases as these levels are exceeded.
- Some individuals with visibly objectionable fluorosis are probably at an increased risk of related behaviorial effects.

- Fluoride at levels of 1–2 mg/L up to 4 mg/L has been shown to contribute to reduced dental caries formation.
- Fluoridation of drinking water is normally practiced around 1 mg/L to reduce dental caries and represents a balance between the benefits of decreased dental caries and the adverse effects of dental fluorosis.
- Exposures greater than 4 mg/L of fluoride can result in asymptomatic osteosclerosis (increased bone density) in a small percentage of individuals.
- Crippling fluorosis, rheumatic attack, pain and stiffness have been observed in populations (not in the U.S.) chronically exposed to fluoride in drinking water at levels of 10 mg/L to 40 mg/L.
- Other effects of fluoride ingestion, which have been suggested by some reports, including cancer or Down's syndrome, have not been found to be scientifically supportable.

This section discusses these findings. Further details can be found in EPA's Draft Fluoride Health Effects Criteria Document (April 1985).

A. Dental Fluorosis

Dental fluorosis results from excess exposure to fluoride during the age of calcification of the teeth (up to about eight years of age for anterior teeth). Dental fluorosis (Dean 1934) in mild form is characterized in part by white opaque areas covering at least 50% of a given tooth; in its severe form, dental fluorosis is characterized by stains (brown to almost black) and severe pitting of the teeth. Anecdotal data suggest that severe dental fluorosis may be associated with abrasive premature loss of enamel, brittle and deformed teeth, and fracture of the teeth as well. However, this anecdotal data has not been sufficiently corroborated or quantified at this time.

Leverett (1982) has reasoned that total fluoride consumption may have increased in the U.S. over the last thirty or so years, thus suggesting that the incidence and severity of dental fluorosis associated with a given level of fluoride in drinking water may have increased. However, the results of studies conducted over the last forty-eight years (1937–1984), suggests that the relationship of objectionable (moderate and severe) dental fluorosis to fluoride levels has not changed appreciably (Albertini et al. 1982, Segreto et al. 1984). While there are factors that would tend to have increased total fluoride consumption, the Agency believes that there are also factors that would tend to have decreased total fluoride consumption such as: the marked increase in the use of air conditioning which would tend to decrease the consumption of drinking water; increased consumption of soft drinks and other beverages, possibly of relatively low fluoride content; increased public awareness of dental fluorosis in high fluoride areas leading to decreased tap water consumption.

Recently, Driscoll et al. (1983) reported the results of a cross-sectional survey of the prevalence of dental fluorosis and dental caries among 807 school children (8 to 10 years old) in seven Illinois communities. Fluoride concentrations in the community drinking water ranged from 1.1 to 4.1 mg/L. As shown in Table 9, Driscoll et al. observed that the combined incidence of moderate and severe dental fluorosis increased from 2.4% at a fluoride level of 1.1 mg/L to 30.2% at 3.8 mg/L (Also see Table 8).

In a separate study, Segreto et al. (1984) investigated the possibility that significant changes in cultural and dietary patterns have altered fluoride intake patterns from those of 20 to 40 years ago. They selected 16 Texas cities and surveyed children (7 to 18 years old) for dental fluorosis. Fluoride levels ranged from 0.2 mg/L to 3.2 mg/L. The combined incidence of moderate and severe dental fluorosis observed (see Table 10; also see Table 8) is in general agreement with the results of Driscoll et al. (1983), ranging from minimal fluorosis at 0.2 mg/L to 31.6 percent moderate fluorosis at 3.2 mg/L. However, Segreto et al. reported only 1 case of severe dental fluorosis. The variation in the combined incidence of moderate and severe dental fluorosis with increasing levels of fluoride reported in Tables 8 and 10, possibly reflects a marked variation in total fluoride ingestion due to different "lifestyles" in the different communities studied or, possibly, due to different susceptibilities of the children examined or other factors.

TABLE 8.—INCIDENCE OF MODERATE AND SEVERE DENTAL FLUOROSIS VS WATER FLUORIDE LEVEL [1]

Water fluoride level, (mg/L)[2]	Number of children	Moderate fluorosis (pct.)	Severe fluorosis (pct.)
0.2	103	0.0	0.0
0.3	126	0.0	0.0
0.4	223	0.0	0.0
0.4	82	0.0	0.0
0.4	263	0.0	0.0
0.5	113	0.0	0.0
0.5	403	0.0	0.0
0.6	614	0.0	0.0
0.7	316	2.0	0.0
0.8	95	2.0	1.0
0.9	361	0.3	0.0
.09	123	0.0	0.0
1.0	50	0.0	0.0
1.1	336	1.8	0.6
1.1	211	0.9	0.0
1.1	187	0.0	0.0

TABLE 8.—INCIDENCE OF MODERATE AND SEVERE DENTAL FLUOROSIS VS WATER FLUORIDE LEVEL [1]—Continued

Water fluoride level, (mg/L)[2]	Number of children	Moderate fluorosis (pct.)	Severe fluorosis (pct.)
1.1	128	1.1	0.0
1.2	70	13.0	3.0
1.2	633	0.0	0.0
1.2	152	0.0	0.0
1.2	171	0.0	0.0
1.3	447	0.0	0.0
1.5	110	0.9	0.0
1.6	301	3.3	0.0
1.8	57	3.5	0.0
1.8	170	1.2	0.0
1.9	273	1.1	0.0
1.9	170	13.5	0.0
1.9	23	13.0	0.0
2.0	109	14.7	0.0
2.0	200	4.0	0.0
2.1	143	8.4	4.9
2.2	179	13.4	0.0
2.2	138	11.0	0.7
2.3	90	6.7	0.0
2.3	67	32.8	0.0
2.4	113	4.4	0.0
2.5	148	14.2	3.4
2.6	404	6.9	1.5
2.9	192	7.8	6.3
2.9	97	23.7	3.1
3.2	190	31.1	0.5
3.6	21	9.0	0.0
3.9	136	7.4	22.8
3.9	289	33.9	13.2
4.0	39	38.0	6.0
4.0	101	40.0	2.0
4.0	59	23.7	11.9
4.2	39	33.0	3.0
4.4	189	46.0	17.9
4.8	36	6.0	0.0
5.7	38	50.0	39.5
7.6	65	10.8	58.5
8.0	21	47.6	42.9
14.1	26	38.5	53.8

[1] The data in Table 8 is from the following references: Driscoll et al. (1983) Segreto et al. (1984) in which actual fluoride concentrations were not reported in article; values given are personal communication of Edward M. Collins; Albertini et al. (1982).

These data have been collected from 5 surveys taken over a 30 year period. While the surveys are believed to be technically sound they varied in procedure, analytical methods, and sample size. The Agency believes it would be inappropiate to merge these findings into a single distribution and therefore no statistical analysis of the information in this table has been made. The information in the table is offered only as a summary of the historical data.

[2] Each value represents a separate city in AR, AZ, CO, IA, IL, KS, NM, OH, SC or TX.

TABLE 9.—RELATIONSHIP OF WATER FLUORIDE LEVELS TO DENTAL FLUOROSIS AND CARIES REDUCTION IN ILLINOIS [1]

Water fluoride level	Number of children	Children with moderate and severe dental fluorosis (pct.)	Decrease in caries score from 1.06 mg/L level [2] (pct.)
1.06 mg/L	336	2.4	
2.08 mg/L	143	13.3	37.3
2.84 mg/L	192	27.6	55.1
3.84 mg/L	136	30.2	35.7

[1] Adopted from Driscoll et al. (1983).

[2] Significantly different ($p < 0.05$) from score at 1.06 mg/L, but not from each other.

TABLE 10.—RELATIONSHIP BETWEEN FLUORIDE LEVELS AND COMBINED INCIDENCE OF MODERATE AND SEVERE DENTAL FLUOROSIS IN TEXAS [1]

Water fluoride (mg/L) [2]	Number of children examined	Combined incidence of moderate and severe dental fluorosis (pct.)
0.2	103	0.0
0.3	126	0.0
0.4	223	0.0

TABLE 10.—RELATIONSHIP BETWEEN FLUORIDE LEVELS AND COMBINED INCIDENCE OF MODERATE AND SEVERE DENTAL FLUOROSIS IN TEXAS [1]—Continued

Water fluoride (mg/L) [2]	Number of children examined	Combined incidence of moderate and severe dental fluorosis (pct.)
0.8	361	0.3
1.1	211	0.9
1.1	126	0.0
1.1	187	1.1
1.6	301	3.3
1.9	170	13.5
1.9	23	13.0
2.0	109	14.7
2.0	200	4.0
2.3	90	6.7
2.3	67	32.8
2.4	113	4.4
3.2	190	31.6

[1] Adapted from Segreto et al. (1984). Only one case of severe fluorosis was reported.
[2] Personal communication from Edward M. Collins (Coauthor with Segreto), actual fluoride concentration not reported in Segreto et al. (1984). Each value represents a separate community in Texas.

In cattle, severe dental fluorosis is associated with more rapid wear of the teeth and, in some cases, an actual erosion of the enamel (NAS 1971). No quantitative human data are currently available as to whether severe dental fluorosis is or is not associated with more rapid enamel wear; and whether this would cause any adverse health effect. A study is being conducted by the National Institute of Dental Health which should provide information on this question.

B. Dental Fluorosis v. Dental Caries

Table 8 summarizes the results of dental fluorosis studies conducted over the last 48 years (1937–1984). Several observations can be made based on this data.

- No moderate or severe fluorosis was observed at levels of 0.6 mg/L or less.
- Moderate fluorosis was observed intermittently at levels of 0.7 to 1.8 mg/L except for one community which had 13% moderate fluorosis at 1.2 mg/L.
- At levels around 1 mg/L and up to 2.2 mg/L, moderate fluorosis was observed in 0–15% of the children examined.
- At levels around 2 mg/L, moderate fluorosis was observed in 1–15% of the children examined.
- A distinct increase in the occurrence of moderate fluorosis is observable at and above approximately 1.9 mg/L.
- Severe fluorosis was consistently observed at levels of 2.5 mg/L and higher. A few cases of severe fluorosis were observed at lower levels.
- At levels of 3 to 4 mg/L moderate fluorosis was observed in 7%–40% of the children.
- At levels between 2.5 mg/L and 14 mg/L, the frequency of severe fluorosis generally increases but varies widely from 0–59%.
- There is a marked variation overall in the incidence of dental fluorosis observed in different cities at essentially the same fluoride level—e.g. 13% moderate fluorosis at 1.2 mg/L vs 0.9% at 1.5 mg/L. This variation could be due to a number of causes such as: different experimental techniques; variation in total fluoride consumption due to different "lifestyles" or economic circumstances and other factors.

As shown in Table 9, fluoride is very effective in reducing dental caries at levels ranging from 1–2 mg/L up to 4 mg/L range. Fluoridation of drinking water at approximately 1 mg/L is believed to be the optimum balance between effective dental caries reduction and the incidence of dental fluorosis.

C. Skeletal Fluorosis

Skeletal fluorosis, which increases in severity with both dose of fluoride and duration of exposure, is characterized in its mildest form by a slight increase in bone density (osteosclerosis) which is detectable only by x-ray examination; there is no evidence that this is an adverse health effect per se. In its most severe form, skeletal fluorosis is characterized by the deposition of irregular bone deposits which, in the case of the joints, results in arthralgia and crippling (EPA 1985).

Though not observed in the United States, crippling skeletal fluorosis has been observed in workers who, due to occupation, were chronically exposed to high levels of fluoride—e.g., cryolite. However, due to improved industrial hygiene, crippling skeletal fluorosis "seldom (if ever) occurs today" (NAS 1971). In addition, crippling skeletal fluorosis has been observed in cattle chronically exposed to high levels of fluoride (McClure 1970).

Skeletal fluorosis in the United States was investigated by Leone et al. (1955, as discussed in EPA 1985) who compared the effects of exposure to fluoride in drinking water in a high-fluoride area (Bartlett, Texas; 8 mg/L) and in a low-fluoride area (Cameron, Texas; 0.4 mg/L). In the groups studied, there were 116 participants from Bartlett and 121 from Cameron, a total of 237 persons. The average length of exposure was 37 years in the Bartlett area and 38 years in the Cameron area.

The authors concluded that fluoride-induced bone changes (i.e., osteosclerosis): (a) occur in approximately 10–15% of those exposed to high levels of fluoride; and (b) are not associated with other physical findings except for dental mottling in persons who resided in Bartlett during the tooth formative period (up to 9 years of age). Independently of the Leone et al. (1955) survey, Stevenson and Watson 1957 (as discussed in EPA 1985), reviewed the medical records on file at the Scott and White Clinic for the 11 year period from 1943 through 1953. The authors noted 23 cases of osteosclerosis from a total of approximately 170,000 x-ray examinations in patients living in Texas and Oklahoma. The earliest bone changes were observed in the pelvis and lumbar spine and consisted of increased bone density with a "ground glass" appearance. Also, the calcification of sacrospinous and sacrotuberous ligaments was apparent. This type of calcification paralleled closely the degree of bone density. Bone changes described in this study were found when the drinking water contained 4–8 mg/L.

Roholm (as quoted in EPA 1985) has characterized three stages of skeletal fluorosis:

Phase I: Osteosclerosis in pelvis and vertebral column. Coarse and blurred trabeculae, diffuse increased bone density to X-ray.

Phase II: Increased density and blurring of contours of pelvis, vertebral column extended to ribs, extremities.

Phase III: Greatly increased density of bone; irregular and blurred contours. All bones affected, particularly cancellous bones. Extremities thickened. Considerable calcification of ligaments of neck and vertebral column.

While the likelihood of crippling skeletal fluorosis increases in the higher phases, crippling skeletal fluorosis is best illustrated by the signs and symptoms presented by an individual who, during his life in India, consumed water at a level of 9.5 mg/L of fluoride. In this individual, the bony contours showed irregular outgrowths and the sites of insertion of muscles and tendons showed excessive periosteal reaction and multiple exostoses. Irregular bone also was laid down in the joint capsules and interosseous membranes. The most pronounced changes were seen in the vertebral column; vertebrae were enlarged and showed marked lipping and some were fused together. The mechanical properties of the left radius and ulna of this subject showed that tensile strength, strain, energy adsorbed to failure and modulus of activity were reduced; compressive strength, strain and energy were increased (EPA, 1985).

It is estimated that the development of crippling skeletal fluorosis, requires the daily consumption of 20 mg or more of fluoride from all sources for 20 or more years. This would correspond to a fluoride drinking water concentration of

10 mg/L. given a 2 L/day drinking water consumption rate and the relatively small exposure contribution of air and food. Although, water related crippling fluorosis has not been diagnosed in the U.S. as it has been in some other countries, it would be expected that a segment of the population in high fluoride communities would likely be consuming more than 20 mg of fluoride per day considering greater than average water consumption and contribution from non-water sources.

D. Other Fluoride Toxicity and Possible Behavorial Effects

Heifetz and Horowitz (1984), in a comprehensive summary of the acute toxicity of fluoride, have characterized the lethal dose of acutely ingested fluoride in man as dependent upon age and ranging from approximately 32–64 milligrams of fluoride per kilogram of bodyweight. In addition, they have described a variety of symptoms associated with acute fluoride intoxication including nausea, vomiting, convulsions, coma and death.

When considered in toto, available evidence leads to the conclusion that the consumption of fluoride at levels found in U.S. drinking water is not associated with scientifically documented allergic or idiosyncratic sensitivity, Down's syndrome, cancer, decreases in longevity or a variety of other toxic effects, notwithstanding the documented effects discussed above (EPA, 1985).

The ad hoc Review Panel on Psychological/Behavioral Effects of Dental Fluorosis stated the following:

> It is concluded that individuals who have suffered impaired dental appearance as the result of moderate to severe fluorosis are probably at an increased risk for psychological and behavioral problems or difficulties. Since this conclusion is based on extrapolations from research on the effects of physical appearance characteristics other than dental fluorosis, it is suggested that investigations be supported to directly assess the social, emotional, behavioral effects, of fluoride induced cosmetic defects.

E. Dental Caries Prevention

There is unambiguous evidence that fluoride, ingested in appropriate amounts, can markedly reduce caries formation (McClure, 1970).

Studies by Dean and others (as discussed in Leverett 1982) established a rationale for setting the "optimum" level in drinking water at approximately 1 mg/L. The "optimum" level was considered to be the concentration of fluoride in drinking water that reasonably maximizes protection against dental caries while minimizing the induction of objectionable dental fluorosis.

The anticaries effect of fluoride is markedly sensitive to the level of fluoride in drinking water. The optimum level of fluoride can provide as much as a 60–65% reduction in caries in some instances, as compared to very low fluoride levels. As shown in Table 9, Driscoll et al. (1983) observed a decrease in caries at fluoride levels of 2.08, 2.84 and 3.84 mg/L over that observed at 1.06 mg/L (optimum). However the decreases in caries scores observed (37.3% at 2.08 mg/L, 55.1% at 2.84 mg/L and 35.7% at 3.84 mg/L) were not significantly different ($p<0.05$) from each other, thus suggesting that the maximum reduction in caries may occur within the range of 2 to 4 mg/L.

VI. Regulatory Options

A. Options

The basic issues regarding the regulation of fluoride in drinking water are the following:

- Should fluoride be included in the Primary Drinking Water Regulations? If so, at what level should the RMCL be set?
- What level of fluoride, if any, would be appropriate for a Secondary MCL?

The SDWA requires EPA to set Primary Drinking Water Regulations for contaminants, "which in the judgment of the Administrator, may have any adverse effect upon the health of persons." Secondary MCLs are to be set for contaminants to protect the public welfare.

The following options have been considered by the Agency for the regulation of fluoride:

1. Propose a Primary Drinking Water Regulation based upon protection from moderate and severe dental fluorosis.

2. Propose a Primary Drinking Water Regulation based upon protection from crippling skeletal fluorosis. Propose a Secondary Drinking Water Regulation to protect against cosmetic effects of dental fluorosis.

3. 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. Propose a Secondary Drinking Water Regulation to protect against cosmetic effects of dental fluorosis.

The Agency has determined that there are insufficient data to quantitatively predict the role of temperature in drinking water consumption, and therefore temperature effects are not considered in the RMCLs or SMCLs in any of these options.

Option 1: Propose a Primary Drinking Water Regulation Based Upon Protection From Moderate and Severe Dental Fluorosis.

This option would set an RMCL for fluoride based upon the effects of moderate and severe objectionable dental fluorosis upon a significant portion of the population.

To support this option, the Administrator would need to conclude that:

(1) Moderate and severe dental fluorosis, which are manifested by yellow/brown staining and/or pitting of the dental enamel, would be adverse effects, per se, and/or

(2) cosmetic effects associated with moderate and severe dental fluorosis would be adverse health effects because they may lead to psychological and behavioral effects that may impede an individual from developing to his full potential.

Regulating to prevent significant dental fluorosis would be consistent with the advice received from the ad hoc Panel on the psychological/behavioral effects of dental fluorosis. The Panel concluded that persons with cosmetically objectionable dental fluorosis are probably at an increased risk for psychological and behavorial problems or difficulties. This option would also be consistent with the recommendation of the NDWAC that fluoride be regulated on the basis that objectionable dental fluorosis is an adverse health effect.

Under this option, EPA would determine that objectionable dental fluorosis is an adverse health effect as it causes; a) physical damage to dental enamel (pits and stain), which due to possible wear and fracturing and, b) the cosmetic effects which may lead to adverse psychological and behavioral effects.

Two sub-options are presented for the RMCL.

Sub-Option A: Propose an RMCL of 1 mg/L.

A level of 1 mg/L would represent a balancing point or trade-off in minimizing the incidence of moderate to severe fluorosis while allowing the prevention of dental caries. The incidence of moderate and severe dental fluorosis would be expected to range from 0–3% at that level. This is essentially the same as the traditional optimum fluoride level widely accepted by dental authorities. About 5,000 communities currently exceed this level.

Sub-Option B: Propose an RMCL of 2 mg/L.

[a very different trade-off between the incidence of moderate to severe fluorosis and prevention of dental caries. This level would provide a greater protection from dental caries than a fluoride level of 1 mg/L. The incidence of moderate and severe dental fluorosis would be expected to range from 0 to 15% at that level. About 1,300 communities currently exceed this level.

Option 2: Propose a Primary Drinking Water Regulation Based Upon Protection from Crippling Skeletal Fluorosis.

EPA would propose an RMCL at 4 mg/L for fluoride based upon a determination that crippling skeletal fluorosis (but not dental fluorosis) is an adverse health effect. A Secondary Drinking Water Regulation would be proposed at 2 mg/L to protect public welfare on the basis that objectionable dental fluorosis is a cosmetic effect. Monitoring and public notice under Sections 1445 and 1450(a)(1) of the SDWA would be proposed for levels of fluoride of 2 mg/L and above to advise the public of the effects of dental fluorosis and to inform the public of alternatives for prevention.

The incidence of objectionable dental fluorosis would range from 10% to 40% in communities at 4 mg/L. About 280 communities currently exceed this level. As guidance for the States and to further protection of public welfare, an SMCL would be proposed for objectionable dental fluorosis at a level of 2 mg/L. This level represents a balance between the incidence of dental fluorosis and prevention of dental caries.

Monitoring and public notification under Sections 1445 and 1450(a)(1) would also be proposed for those public water systems determined to have levels exceeding the SMCL (about 1,300 communities). Public notification would be to physicians, dentists, and public health officials and to the public. Notification would be required when the SMCL had been exceeded, and would include a statement written by the Agency.

This option would be consistent with the recommendations of the Surgeon General who stated that crippling skeletal fluorosis, in his opinion, was an adverse health effect, and is generally responsive to the position of the professional organizations and state commenters. The Surgeon General's committee endorsed a level of 4 mg/L as preventing osteosclerosis and allowing no known or anticipated adverse effects with a margin of safety. A level of 4 mg/L provides an adequate margin of safety against crippling skeletal fluorosis has been seen in individuals with intakes of fluoride of 20 mg/day over long periods. Thus it would be protective for individuals with high water consumption.

Option 3: 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

This option would propose to delete fluoride from the Interim Primary Drinking Water Regulations and propose an SMCL of 2 mg/L for fluoride; the basis of this proposal would be 1) that objectionable dental fluorosis is a cosmetic effect (not an adverse health effect), and 2) that the risks of crippling skeletal fluorosis are minimal because only a small number of communities have natural fluoride levels in drinking water that approach the levels of concern for crippling fluorosis. As in Option 2, monitoring and public notice under Sections 1445 and 1450(a)(1) would be proposed for levels of 2 mg/L and above to advise the public of the effects of dental fluorosis.

Under this option, the Administrator would conclude that human exposure to fluoride in drinking water in the United States would not have "any adverse effect on the health of persons" and would be in agreement with the Surgeon General that at the concentrations of fluoride currently reported in the United States there is "essentially no likelihood of even non-adverse medical effects" (Koop 1984).

This option would be consistent with the recommendations of American Medical Association, American Dental Association, Associations of the State and Territorial Health Officials, Association of State and Territorial Dental Directors, South Carolina, and a number of other States. This option would be inconsistent with the recommendations of the National Drinking Water Advisory Council and the Panel on psychological and behaviorial effects of dental fluorosis.

B. Proposed Approach

1. *RMCL.* The Agency is proposing Option 2 for the regulation of fluoride. Based upon the information available at this time, EPA believes that crippling skeletal fluorosis is an adverse health effect that can be caused by excessive amounts of fluoride in drinking water, and that 4 mg/L is the level below which "no known or anticipated adverse effect on health of persons occur and which allows an adequate margin of safety." Thus an RMCL is proposed at 4 mg/L.

EPA believes that crippling f should be considered an adver effect under the Safe Drinking Act. These arthritic-like effects significant deleterious injuries t body and are irreversible. Altho crippling fluorosis occurs at leve approximately 10 mg/L (20 mg/d SDWA requires the Agency to incorporate an "adequate margin safety" to protect public health. factor of ten or less is generally appropriate when using data from humans to calculate the level at w to regulate.

This level is also appropriate as coincides with a level at which osteosclerosis does not occur. Osteosclerosis is not viewed by E an adverse health effect within the meaning of the act as it does not a to cause clinically significant effec

The Administrator has also conc that cosmetically objectionable den fluorosis is associated with excess fluoride in drinking water above approximately 1 to 2 mg/L. Inadequ evidence exists to determine that objectionable moderate and severe dental fluorosis are adverse health effects per se or that potential behavioral effects from cosmetically objectionable fluorosis, if they occur adverse health effects in the context the SDWA. These cosmetics effects however, should be the basis for secondary regulations intended to protect public welfare.

2. *Secondary Regulation.* At the tim of proposal of the MCL for fluoride, E plans to propose a Secondary MCL at mg/L. Because of the nature of the psychological effect, EPA is consideri proposing monitoring and public notification requirements under Sectio 1445 and 1450 (a)(1) of the SDWA. The actions are intended to assure that the users of public water supplies which a likely to contribute to staining and pitting of dental enamel of children wil be fully aware of the possible effects and the methods for their prevention.

As part of the montoring, the Agency is considering allowing the States discretion in the proposed monitoring requirement. Based upon the fluoride occurrence data presented previously, the Agency expects that the vast majority of public water supplies will not have fluoride concentrations exceeding an SMCL of 2 mg/L. Further, public water supplies currently have information on the levels of fluoride contamination because of the monitoring requirements of the existing interim standard. Where the States have sufficient evidence that fluoride concentrations have not exceeded the

federal standard, the Agency will not require monitoring. The specifics of when monitoring will be required will be given as part of the MCL and SMCL proposals.

3. *Amendment to Interim Regulation for Fluoride.* Under the SDWA, the existing Interim Regulation for fluoride remains in effect until superseded by the Revised Regulation (which takes effect 18 months after the Revised Regulation is promulgated) SDWA Section 1412(b)(5). Therefore, until the Revised Regulation suspersedes the Interim Regulation, the Interim MCL of 1.4 to 2.4 mg/L will be in effect and enforceable. Because the Revised MCL will be 4 mg/L or higher, EPA is concerned that Public Water Systems may be subjected to citizen suit enforcement actions compelling systems to meet the lower, enforceable Interim MCL. (This situation will occur because the Revised MCL must be set "as close to the RMCL as feasible" with the use of best technology, considering cost, and thus cannot be set lower than 4 mg/L).

The public is not served by forcing water systems to meet a lower Interim MCL that EPA has rejected in promulgating the Revised Regulation. To avoid this result, EPA is considering proposing to amend the Interim MCL when it proposes the MCL for the Revised Regulation. A final amended Interim MCL would be promulgated at the same time as the Revised MCL. The Agency would amend the Interim MCL to be identical with the Revised MCL. Although Interim Regulations when first promulgated under Section 1412(a) must have an effective date 18 months after their date of promulgation [Section 1412(a)(3)), amendments to existing Interim MCLs, that are revised upward need not have an effective date of 18 months. Therefore, the Agency would plan to provide a 30 day effective date for the amended Interim MCL. EPA would thereby avoid a substantial period when there existed a lower, enforceable Interim MCL that the Agency had abandoned.

VII. Treatment for Control of Fluoride

While the Agency is not required to present economic or technical information on the removal of fluoride in the development of an RMCL, the following information is provided as background.

A. Treatment Technology

Experience indicates that ion exchange treatment utilizing activated alumina is the most effective method, in the absence of interfering contaminants, to remove fluorides from water. This technology can be implemented effectively for all sizes of treatment facilities including point-of-use applications. This technololgy, when not operated properly, can leach significant quantities of aluminum which can precipitate in the finished water and therefore is not recommended where adequate facilities, manpower, and resources for operation and maintenace are not available. Other materials such as bone char and tricalcium phosphate can be used in a similar fashion. However, the use of bone char as a defluoridation medium is generally not practical for waters than contain arsenic because of irreversible changes in the composition of bone char. Tricalcium phosphate removes fluoride, but excessive attrition of this media makes this process generally not cost effective.

Reverse osmosis has not been used on a full scale basis for fluoride removal alone, but reverse osmosis is a common technology for total dissolved solids removal. Pilot plant studies have demonstrated its effectiveness for simultaneous fluoride removal. This process may be practical in situations where high dissolved solids and other contaminants must be removed in addition to fluoride. Thus, the overall quality of the water would be improved, which is not the case for activated alumina which selectively removes fluoride. As in the case of activated alumina, reverse osmosis can be used in both small and large systems and in point-of-use applications.

Limited experience with electrodialysis indicates that this method may eventually prove to be c effective for removing fluorides when removal of other contaminants is also necessary. Presently, its cost is much greater than other methods (in the absence of an inexpensive source of power).

Alum coagulation can remove limite amounts of fluoride, but this treatment technology is limited to situations whe filtration capability is present and initi fluoride concentrations do not appreciably exceed the desired limit.

Similarly, lime softening can achieve partial removal of fluorides. However, application of this technology is limited to larger systems where softening facilities are already in existence. Construction of a full scale softening plant for the removal of fluoride alone would not generally be cost-effective due to the large capital investment and high operating costs.

B. Cost of Treatment

Preliminary design and cost estimates have been developed for the hypothetical situation where raw water fluoride content is 3.2 mg/L (the present average value for systems in violation of the interim standard) and where 60 percent of the water would be blended with 40 percent of the untreated water to maintain a final fluoride effluent of 2.0 mg/L. These values were selected only to illustrate the economics of treatment. Tables 11 and 12 provide relevant cost information for treatment technologies to remove fluoride from drinking water. These technologies include activated alumina and reverse osmosis (central and point-of-use applications) as well as lime softening. The costs for these technologies are not particularly sensitive to influent fluoride concentration and can be generalized to other influent and effluent situations. In any event, they should be considered to be illustrative and not definitive at this stage. The background information to support these costs can be found in "Technologies and Costs for the Removal of Fluoride, EPA, Sept. 1983."

TABLE 11.—PRELIMINARY SYSTEM COSTS FOR CONTROLLING FLUORIDES IN DRINKING WATER, COST PER THOUSAND GALLONS

[Mid-1982 dollars]

System size—MGD	0.01	0.04	0.14	0.44	0.9	1.55	8.82
(Population served)	(25–99)	(100–499)	(500–999)	(1,000–2,499)	(2,500–4,999)	(5,000–9,999)	(10,000–100,000)
Activated alumina:							
Central mode	$0.84	$0.58	$0.43	$0.32	$0.22	$0.20	$0.15
Point-of-use-mode	2.07	2.07	2.07	2.07	2.07	2.07	
Reverse osmosis:							
Central Mode	2.71	2.19	1.84	1.67	1.28	.92	.79
Point-of-use-mode	3.74	3.74	3.74	3.74	3.74	3.74	

TABLE 11.—PRELIMINARY SYSTEM COSTS FOR CONTROLLING FLUORIDES IN DRINKING WATER, COST PER THOUSAND GALLONS—Continued

[Mid-1982 dollars]

System size—MGD	0.01	0.04	0.14	0.44	0.9	1.55	8.82
(Population served)	(25–99)	(100–499)	(500–999)	(1,000–2,499)	(2,500–4,999)	(5,000–9,999)	(10,000–100,0
Lime softening:							
Central mode [1]					.22	.16	

[1] Modified for fluoride treatment.

TABLE 12.—PRELIMINARY COSTS FOR CONTROLLING FLUORIDES IN DRINKING WATER, CAPITAL COST IN THOUSANDS OF DOLLARS

[Mid-1982 dollars]

System size—MGD	0.01	0.04	0.14	0.44	0.9	1.55	8.82
(Population served)	(25–99)	(100–499)	(500–999)	(1,000–2,499)	(2,500–4,999)	(5,000–9,999)	(10,000–100,0
Activated alumina:							
Central mode	$1.82	$3.73	$7.14	$12.94	$18.75	$15.22	$67
Point-of-use-mode	1.05	3.15	8.41	23.12	55.70	108.25	
Reverse osmosis:							
Central Mode	4.42	10.78	24.23	66.86	107.43	178.72	784
Point-of-use-mode	3.44	10.44	27.28	76.54	184.52	358.50	
Lime softening:							
Central mode [1]					16.77	18.84	25

[1] Modified for fluoride treatment.

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EPA has received comments from the Office of Management and Budget and has placed them in the Public Docket. However, EPA received these comment late in the process of developing this proposal; EPA is, therefore, unable to address those comments in this notice. EPA will address these comments in its final RMCL regulation.

These references are included in the Public Docket together with other correspondence and information. The Public Docket is available for viewing in Washington, D.C. at the address listed at the beginning of this notice. All public comments received on this proposal will also be included in the Docket.

IX. Request for Comments

EPA requests analyses, comments, and general information on all aspects of this notice, including the appropriate balance between public health protection and practical implementation of EPA's drinking water program under

the requirements of the SDWA. The general questions for which comment is particularly solicited are listed below. Comment on any or all of the specific questions will assist EPA in formulating an effective and practical approach to controlling human exposure to fluoride in drinking water.

1. *Dental Fluorosis.* Should moderate and severe dental fluorosis be considered adverse health effects or should these effects be considered cosmetic and aesthetic effects? If the Agency decides not to consider dental fluorosis as an adverse effect, should dental fluorosis be considered an indicator of excess dosages of fluoride which may potentially result in other adverse effects, such as crippling skeletal fluorosis, at sufficient dosages and duration of exposure?

2. *Psychological Effects of Dental Fluorosis.* The Agency requests comments on whether moderate and severe fluorosis are an adverse health effect because of potential psychological and behavioral effects.

3. *Crippling Skeletal Fluorosis.* The Agency believes that crippling fluorosis is an adverse health effect which occurs at approximately 20 mg/day. EPA requests comment on the data supporting this position and the safety factor the Agency has employed.

4. *Use of a Single Standard for Fluoride.* The proposed RMCL for fluoride, unlike the previous MCL, is a single standard independent of temperature. The Agency is interested in receiving comments on its decision not to make the fluoride standard temperature dependent.

5. *Available Technology.* The Agency is interested in receiving technical and economic information on technologies that are currently or likely to be available to reduce the levels of fluoride in drinking water, including information on costs, operating experience, reliability, and disposal of wastes.

6. *Dental Fluorosis.* The Agency is interested in information on the course of dental fluorosis over time. Is it possible for dental fluorosis in an individual to progress beyond cosmetic effects to adverse health effects?

7. *Remedial Treatment for Dental Fluorosis.* The Agency requests information on the feasibility and cost of available treatments for dental fluorosis.

X. Regulatory Analyses

The proposal of an RMCL is different than the proposal of an MCL in that an RMCL is, by law, to be based only on health and safety considerations, while an MCL takes feasibility and cost into consideration. Therefore, this RMCL proposal notice does not include an analysis of the economic impact of various possible MCLs. However, the Agency intends to fully analyze the probable impact of the various alternatives, and will report on them at the time an MCL is proposed.

The report will include an analysis of the impact of the various alternatives on the water supply industry vis-a-vis capital costs of technology, operating and maintenance costs and the feasibility of financing new treatments. Additionally, impact on the consumer and on the nation as a whole will be analyzed.

Under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., I certify that this action will not have a significant impact on a substantial number of small entities. This proposed action will have no economic impact in and of itself because this is a non-enforceable health goal.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This proposed action does not constitute a "major" regulatory action because it will not have a major financial or adverse impact on the community and it is a non-enforceable action. This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

Dated: April 30, 1985.

Lee M. Thomas,

Administrator.

List of Subjects in 40 CFR Part 141

Chemicals, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Waste supply.

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

The authority citation for Part 141 continues to read as follows:

Authority: Safe Drinking Water Act 42 U.S.C. 300f *et seq.*

For the reasons set out in the preamble, it is proposed that a new section be added to proposed Subpart F Part 141, Subchapter D, Chapter I of Title 40, *Code of Federal Regulations* on June 12, 1984 (40 FR 24352):

Subpart F—Recommended Maximum Contaminant Levels

§ 141.51 Recommended Maximum Contaminant Levels for inorganic chemicals.

The following are Recommended Maximum Contaminant Levels for inorganic chemicals. This is a non-enforceable health goal.

(a) [Reserved]

(b) Recommended Maximum Contaminant Levels for the following substances are:

	Milligrams per liter
Fluoride	4

[FR Doc. 85–11491 Filed 5–13–85; 8:45 am]

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