

The minority felt that RMCLs should be set for 1,1-dichloroethylene and p-dichlorobenzene due to health effects information and the potential for widespread occurrence of these compounds in drinking water.

Phase IIA: Fluoride

In 1981, the State of South Carolina filed a petition requesting that EPA revoke the fluoride primary regulation. The petition recommended that fluoride be placed in the secondary, non-enforceable regulations based upon aesthetics of drinking water. The Agency began a review of the data and asked the Surgeon General for advice on fluoride in drinking water and its relationship to the health aspects of dental fluorosis. The Surgeon General replied that evidence did not exist showing fluoride in drinking water has an adverse effect on dental health. On October 26, 1982, the Council met to review the drinking water regulations for fluoride. They concluded that both health and cosmetic effects could be associated with excess fluoride intake and recommended a primary MCL based upon non-dental health effects and a secondary MCL based upon dental fluorosis. Due to new issues raised concerning non-dental effects of fluoride, EPA requested a review of these effects by the Surgeon General. In January 1984, a report was submitted on the toxicology of fluoride in which the Surgeon General's committee concluded that adverse health effects, including gastrointestinal irritation and crippling fluorosis were not likely to occur from consumption of drinking water in the United States. The Surgeon General did not consider either dental fluorosis or mild osteosclerosis to be an adverse health effect.

In light of the latest report from the Surgeon General and other new information, the questions listed below revisit some of the same issues that were discussed in the 1982 Council meeting. They are intended to elicit any new comments or recommendations that the Council may have.

Report on Dental Fluorosis by Dr. Edward Collins

Dr. Edward Collins, University of Texas, Health Science Center, San Antonio, Texas, presented the results of his recent work on dental fluorosis to the Subcommittee (see Attachment 3). In this study a panel of dentists from high fluoride areas examined slides of 55 cases for cosmetic and dysfunctional effects and recommended corrective measures.

The specific objectives of this study were to: (1) assess the extent of cosmetic discoloration due to fluoride levels exceeding two times the optimum; (2) evaluate the presence and/or extent of any dental dysfunctional effects resulting from mottling and the potential cost for restoring function; (3) determine the teeth requiring remedial measures

for restoring the cosmetic appearance to a level acceptable in the community; and (4) determine the number of subjects with cosmetic or dental dysfunctional defects for which no feasible method of correction exists.

The following conclusions were made: (1) the dental treatment costs for restoring function in subjects with moderate and severe mottling usually equaled or exceeded the costs required for correcting the cosmetic discoloration; and (2) bleaching, where indicated, is an effective procedure for treatment of the cosmetic discoloration due to mottling.

The Subcommittee invited Dr. Collins to present the report to the full Council on August 2, 1984. The Subcommittee recommended a clinical study investigating the effect of dental fluorosis on the oral health of adults. Also, water chemistry and mineral analysis should be incorporated in the protocol.

The Regulations Subcommittee emphasized that while the Agency has a position on fluoridation of public drinking water supplies, the major fluoride-related issue being addressed by the Subcommittee is health effects of excess natural fluoride in drinking water and not fluoridation. The Subcommittee addressed the different issues as follows:

1. Should dental fluorosis be considered an adverse health effect or a cosmetic effect?

Regulations Subcommittee

The Regulations Subcommittee recommends that moderate and severe fluorosis be considered an adverse health effect since these condition are associated with cosmetic deformity, dental dysfunction, and/or social/behavioral effects.

Council (vote: 6 for, 4 against, 1 abstain)

The Council recommended that moderate and severe fluorosis be considered an adverse health effect.

While four members voted against the Subcommittee recommendation, no clear minority position was expressed. Two concerns were apparent: One member felt that the volume of new information available made an informed decision difficult; another member was concerned about the implications of saying that social and behavioral effects are adverse health effects.

2. Should non-dental effects such as osteosclerosis or crippling fluorosis be considered adverse health effects?

Regulations Subcommittee

The Regulations Subcommittee recommends that non-dental effects of fluoride such as osteosclerosis or crippling fluorosis be considered as adverse health effects.

Council

The Council unanimously adopts the recommendation of the Regulations Subcommittee.

3. Should fluoride be retained in the primary regulations or included in the secondary regulations? On what basis?

Regulations Subcommittee

The Regulations Subcommittee recommends that the standard for fluoride, which is based on dental fluorosis, should be retained in the primary regulations. The basis of this recommendation is that the Subcommittee concluded that moderate and severe dental fluorosis be considered to be adverse health effects in the context of the Safe Drinking Water Act.

Council (vote: 8 for, 1 against, 1 abstain)

The Council believes that fluoride should be retained in the primary regulations on the basis that moderate and severe fluorosis represents an adverse health effect.

4. At what level should the RMCL be set if a primary regulation is written?

Regulations Subcommittee

The Regulations Subcommittee recommends that the RMCL and MCL for fluoride be the same. Also, the Subcommittee recommends that the existing MCL for fluoride which is based on dental fluorosis remain unchanged since the Subcommittee has not been provided with data which support altering this standard. This matter will be reconsidered when EPA's complete analysis is provided to the Council in conjunction with any potential future proposed regulation.

A minority opinion (1 vote) recommended that fluorosis be considered an adverse health effect at 4 mg/l and above and an RMCL and MCL for fluoride be included in the Primary Drinking Water Regulations on that basis. The minority felt that there was sufficient doubt and variability in the range of 2 mg/l to 4 mg/l regarding adverse health effects of fluoride that a secondary MCL should be established for that range of exposures. The

minority recognized that this would in effect allow communities exposed to levels less than 4 mg/l to take action on an individual system basis.

Council (vote: 3 for, 6 against)

The Council discussion of the Subcommittee recommendation in the Subcommittee report on the RMCL and MCL demonstrated much concern over the level of both the RMCL and MCL. Because of these concerns, the motion brought to the Council separated the issues of RMCL and MCLs, and only RMCLs were addressed by the Council. The Subcommittee recommended that the RMCL be set at two times optimum. The Council recommended that the Subcommittee recommendation not be adopted. The basis for the Council recommendation was primarily related to disagreement on the specific level being recommended for the RMCL. Some Council members felt the level should be lower, some felt it should be higher, and there was some feeling that there was insufficient information available at that time upon which to make a judgment.

The minority felt that the recommendations of the Regulations Subcommittee should be adopted.

5. Certain subpopulations may be at increased risk to fluoride toxicity. These include persons with kidney impairment, young children and pregnant women. How should these high risk groups be taken into account in setting the MCL?

Regulations Subcommittee

The Regulations Subcommittee recommends that there is no need to address this issue since it was recommended that the RMCL be set based upon fluorosis and the sensitivity of these subgroups is at higher levels of fluoride exposure than levels associated with adverse health effects attributable to fluorosis.

Council

The Council did not address this issue since it had previously considered fluorosis to be an adverse health effect and high risk groups exhibit sensitivity to fluoride at higher levels than those associated with fluorosis.

6. If significant behavioral effects occurred in children with moderate or severe fluorosis would that be a basis for primary regulation - see NAS definition of health effects.

Regulations Subcommittee

The Regulations Subcommittee recommends that behavioral and social effects of fluoride manifested in children with moderate and severe fluorosis constitute a basis for retaining fluoride in the primary regulations. Behavioral and social effects are felt by the Subcommittee to represent adverse health effects.

Council

The Council did not address this issue since it had previously considered fluorosis to be an adverse health effect on the basis of behavioral effects and dental dysfunction.

1. History & Background

- ° In 1975, EPA promulgated the fluoride MCL as a primary regulation:
 - The 1962 PHS standards for fluoride were based on its potential dental effects, i.e., severe dental fluorosis which involves pitting of the dental enamel as well as brown staining.
 - EPA (following the PHS) regulated fluoride in drinking water at two times the optimum level for the prevention of dental caries. Levels above two times were considered unacceptable in that fluorosis or dental mottling began to appear in the most sensitive 2-3% of the exposed population (children under age 9 are group at risk). Other potential adverse effects of fluoride were known to occur at higher levels of exposure. However, control of fluoride to avoid dental mottling provided a safety factor for these other effects.
 - In 1978, EDF challenged the MCL (twice the optimum protective level) as being too high.
 - In upholding EPA's decision, the Court of Appeals for the District of Columbia Circuit found that EPA struck a proper balance between the level of dental health protection to be provided and the cost to meet that level. EDF v. Costle, 578 F.2d 337 (D.C. Cir. 1977)
 - The Court also noted that "[t]here is serious question as to whether mottling can be regarded as an 'adverse effect on health' within the meaning of the Act."
- ° In 1981, the State of South Carolina Department of Health and Environmental Control, pursuant to the Administrative Procedure Act, filed a petition requesting that EPA exercise its rulemaking authority to revoke the fluoride primary regulation. 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." (Secondary drinking water regulations deal with the esthetic quality of water and are not federally enforceable). The petition has been supported by the States of Arkansas, Illinois, Iowa, Kansas, Kentucky, Maine, Michigan, New Mexico, Nebraska, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, and Virginia.

- ° On December 1, 1981, the Agency acknowledged receipt of the South Carolina petition in the Federal Register. In response to the petition, EPA referenced the ongoing epidemiological studies (new research designed to reinvestigate the original 1940's studies on which the standard was based) and stated that the Agency would review the data submitted by South Carolina along with the completed results of the epidemiological studies in making a final decision. The Surgeon General and other review sources were part of the assessment. Preliminary resolution was anticipated by August 1982.
- ° Since the promulgation of the fluoride primary regulation, a series of epidemiological studies have been funded to try and accurately determine the frequency of occurrence and impact of dental fluorosis at different levels of fluoride.

The new studies reconfirmed the original work and show:

- At 2 to 3 times optimum fluoride levels, over 15% of children have objectionable (moderate to severe) fluorosis.
- At 4 to 5 times optimum fluoride levels, over 30% of children have objectionable (moderate to severe) fluorosis.
- Fluorosis occurrence is comparable to that reported in earlier studies (Dean, 1936 - 1942).
- ° As part of the review, EPA asked the Surgeon General to advise on the relationship of fluoride in drinking water and health aspects of dental fluorosis."
- ° The Surgeon General replied on July 30, 1982, stating among other things 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."

However, the Surgeon General added: "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 a diminished protection against dental caries."

He 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 esthetically objectionable dental fluorosis."

- ° The American Dental Association (ADA) and the American Medical Association (AMA) have addressed the fluoride issue and if dental fluorosis should be considered an adverse health effect:
 - American Dental Association (1979): "natural fluoride levels of drinking water in the United States do not constitute a health hazard."
 - American Medical Association (1982): "the AMA does not believe that the evidence supports a conclusion that tooth mottling is an adverse health effect."
- ° On October 26, 1982, National Drinking Water Advisory Council met in Washington to review the drinking water regulations for fluoride. The result of their deliberations were the following recommendations:
 - The Council heard testimony from the American Medical Association, the American Dental Association, 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. All of the speakers expressed the opinion that dental fluorosis should not be considered as an adverse health effect.
 - Based upon the scientific information which they considered, the National Drinking Water Advisory Council concluded that both health and cosmetic effects could be associated with excess fluoride intake and subsequently recommended to the Administrator:

"A primary MCL based upon (non-dental) health effects and a secondary MCL based upon dental fluorosis."
 - Other discussion by the Council centered upon the appropriate level for an MCL. Levels from 2 mg/l to 8 mg/l

were considered. No consensus was reached and the results of the deliberations were forwarded to the Administrator as follows:

1. "Six members voted for (a primary MCL of) 4 mg/l and six members voted for a value to be determined (by EPA) in the range of 4 to 8 mg/l".
 2. An MCL of not less than 4 mg/l and certainly less than 8 mg/l would appear appropriate on the basis of the scientific evidence available to the NDWAC.
 3. Based upon the comments in the second part of the Surgeon General's letter, a secondary standard of 2 mg/l was also recommended which could be implemented by the States as they desire.
- ° Due to the many questions that surround the non-dental effects of fluoride EPA requested (in January 1983) that the PHS conduct a review to determine the level at which adverse nondental (medical) health effects may result as a consequence of fluoride in natural drinking water supplies and the margin of safety that would be appropriate.
- ° In January 1984 the Surgeon General submitted the long awaited report to EPA on the toxicology of fluoride. His Ad Hoc Committee on the Non-Dental Health Effects of Fluoride in Drinking Water defined adverse health effects as gastrointestinal hemorrhage, gastrointestinal irritation, arthralgias and crippling fluorosis. They concluded that these effects were not likely to occur from consumption of drinking water in the United States. The Surgeon General did not consider either dental fluorosis or mild osteosclerosis (increased bone density) to be an adverse health effect. The Committee concluded that:
1. It is inadvisable for fluoride content in drinking water to be greater than twice optimum for children up to age 9 to avoid dental fluorosis.
 2. Fluoride concentrations should not exceed four times optimum in any community water supply.
 3. Four times optimum would provide "no known or anticipated adverse effect with a margin of safety".
 4. Additional research should be conducted on the relationship of excess fluoride intake and skeletal maturation and growth in children.

- Since the report was received, we have reviewed the issues on several occasions which led up to the meeting with you and the Surgeon General.
- On July 8, 1984 you and the Surgeon General met to discuss the issues raised in the second report. The Surgeon General reaffirmed his position that dental fluorosis was not an adverse health effect. At the end of the meeting a question was raised on the possible psychological and behavioral effects of dental fluorosis.
- On August 3, 1984 the National Drinking Water Advisory Council convened and heard testimony on the issue of the psychological and behavioral effects of fluorosis. The Council concluded that moderate and severe fluorosis should be considered adverse health effects since those conditions are associated with cosmetic deformity, dental dysfunction and social and behavioral effects.
- On October 31, 1984 the EPA assisted by the National Institute of Mental Health convened an ad hoc panel to consider whether dental fluorosis could lead to psychological or behavioral effects. The panel concluded the following:
 - That individuals who have suffered impaired dental appearance as a result of moderate to severe fluorosis are probably at increased risk for psychological and behavioral problems or difficulties.
 - That support was needed for further research on this subject.
 - That techniques be developed for the amelioration or removal of the unaesthetic appearance effects associated with some levels of fluorosis.

2. Issues

Institutional -

- The Agency, by its Federal Register Notice of December 1, 1981, had committed to making a decision on the fluoride standard in the fall of 1982. Due to the need for a more detailed review from the Surgeon General this date has been pushed back. In the last six months the State of South Carolina has brought suit against the Agency over the Agency's failure to establish fluoride standards. The plaintiff has filed for a summary judgement motion. We are seeking to negotiate a settlement for the revised fluoride regulation. An immediate decision is necessary to enable the Agency to adopt a quick schedule which will settle the lawsuit.

Health -

- ° Dental Fluorosis - It is clear that the original work to support the fluoride Interim Drinking Water Standard was valid and that moderate (dark staining) or severe dental mottling (pitting of tooth enamel) will occur in the most sensitive portions of the populations (2 to 3% of children under 9 years of age) at the present level of regulation. Currently available data indicates that, while moderate and severe fluorosis can not be related to loss of function or tooth mortality, the cosmetic effects are potential causes of adverse psychological and behavioral problems. In addition, there is anecdotal evidence of loss of tooth function and tooth mortality in adults.
- ° Skeletal Fluorosis - Osteosclerosis (increased bone density) has been observed in some populations exposed to drinking water concentrations of fluoride ranging from 4 mg/l to 8 mg/l. Crippling fluorosis, rheumatic attacks, pain and stiffness were observed in populations exposed to fluoride concentrations ranging from more than 20 mg/day to 80 mg/day in drinking water.
- ° Other health effects have been identified as being potentially associated with fluoride. These effects include cardiotoxicity effects, thyroid damage, growth retardation, kidney disease and others. These other effects are generally associated with levels of fluoride well above the present regulations.
- ° There are a series of potential health issues that presently are not quantifiable, but which may be fundamentally important. These include the increased susceptibility (to fluoride toxicity) of persons with renal impairment, accelerated transplacental transfer of fluoride in pregnant women, and fluoride induced effects on skeletal maturation and growth in children due to amplification of osteosclerotic effects during periods of high bone remodeling, i.e., ages 0-9.

The health issues can be summarized as follows:

1. The current Surgeon General (using the reports of the dental and medical committees) has "generally" articulated the following positions:
 - a. Dental effects are not "adverse health effects" and while cosmetically undesirable, do not constitute the appropriate toxicological endpoint for standard setting.
 - b. Osteosclerotic effects begin to occur at around 4 mg/l and are pronounced at 8 mg/l. These effects may not necessarily be "adverse health effects" but are indicators of effects such as crippling

fluorosis that occur at higher fluoride levels.

- c. Crippling fluorosis should be the basis for standard setting. His committee concluded that 4 times optimum level (between 2.8 and 4.8 mg/l) protects against these effects with "an adequate margin of safety".
2. Adverse behavioral and psychological effects can be considered to be adverse health effects. These would be projected to be associated with cosmetic objectional dental fluorosis as discussed by the panel of behavioral scientists.
3. There are serious questions regarding what constitutes an "adverse health effect". A protective approach would lead to considering at least severe dental mottling as an "adverse effect". Other interpretations of the statute do not reach the same conclusion.

Exposure

- ° The U.S.P.H.S recommends that fluoride be added to water to about 1 mg/l. Many systems follow this practice and have fluoride levels at .7 to 1.3 mg/l levels. Population wise the occurrence of fluoride at levels in excess of 2 mg/l is not extensive, since small systems or ground water make up virtually all of the exceders. However, some large systems, e.g., Myrtle Beach, S.C., are included.* Preliminary estimates suggest that at least 1300 systems would be required to take some action at a standard of 2 mg/l. At 4 mg/l about 275 systems would need remediation. The majority of these systems are small and would have difficulty installing remedial treatment without external financial and technical support.

Costs

Treatment costs are relatively insensitive to influent concentrations. They range from about \$27.00 per household for activated alumina in large water systems (10000 persons) to about \$73.00 per household for point of use reverse osmosis in small communities (100 to 500 persons).

While the costs of remedial treatment are not extreme under the circumstances, water systems will have extra costs due to site specific conditions such as multiple wells. More important, most of the affected communities are small and voluntary compliance is complicated by the historic inability

*EPA has been informed that Myrtle Beach, SC is now moving from its present water sources to a surface supply which would have low fluoride levels. Whether this change is because of the existing standard or to provide added quantities of water to support development is unclear.

of these small systems to operate treatment facilities. Compliance for most of the smaller communities would probably be by nonconventional solutions such as bottled water or point of use treatment, if these were to be acceptable under the SDWA. See the attached sheets illustrating the costs relative to size of systems for central treatment, complete decentralized treatment, and partial decentralized treatment (only for those residences with children under nine years of age).

There is some risk of a challenge if point of use methods or bottled water were authorized as "generally available technologies". Point of use is a technologically viable approach which is not specifically addressed in the SDWA as a compliance method. However, an argument can be made that under public water system management, this approach can provide equivalent protection for this type of contaminant. Bottled water as a compliance method is more debatable except as an interim measure.

If dental fluorosis were selected as the basis for the standard then one compliance option might include providing lower fluoride water only for the high risk group -- children up to age nine. It is estimated that on average about 30% of the homes in a community would be affected. OGC feels that a limited compliance coverage of that sort would be vulnerable to challenge as not providing protection substantially equivalent to central treatment and that specific health justification would be required.

ODW has been working on mechanisms for dealing with communities which could not raise the economic resources to meet potential standards. We are developing an interpretation of "Generally Available Technology" concept in the SDWA to be sensitive to small community technology and cost problems.

Either of these approaches would provide needed operational flexibility to the States that is not now available with the interim regulations. EPA would have to develop guidance on what a system can afford to pay for improved water quality.

RMCL - Health Goal - Options

Option I - 1 mg/l RMCL based upon protection from the psychological effects of objectionable dental fluorosis.

- Generally considered to be the optimum drinking water intake level to protect against dental caries, but borderline.
- Could be proposed based upon behavioral effects from cosmetic objectional fluorosis as well as objectional fluorosis per se.

- Virtually no water related moderate or severe dental fluorosis would occur
- Probably insufficient to provide significant protection against osteoporosis - which is age-related bone degeneration particularly in women
- Incorporates a safety factor of 5 from the observed no observed effect level for skeletal fluorosis suggested by the Surgeon General's Ad Hoc Advisory Committee, and thus provides additional protection for the "sensitive" population which may be young children and adults with renal impairment
- Most acceptable to antifuoridation groups who feel that adverse effects occur even below 1 mg/l
- Contrary to the stated opinions of the current Surgeon General, AMA, ADA, State Health and Dental Directors
- Would be a complete rejection of the petition from the State of South Carolina
- Significant opposition would be expected from virtually all organized dental and health organizations

An MCL at 1 mg/l would affect about 5000 communities and 6 million persons.

- Very high national costs
- Very high noncompliance would result
- Could have a negative effect on fluoridation for dental health.

Option II - 2 mg/l RMCL based upon protection from objectionable fluorosis.

- Safety factor of 2 added to the recommended no effect level for skeletal fluorosis from the Surgeon General's Ad Hoc Committee
- Could be proposed based upon avoidance of objectionable fluorosis per se as well as possible behavioral effects of cosmetic fluorosis
- This is approximately the current national drinking water MCL
- Twice the optimum level for protection from dental caries

- Probably some additional protection from dental caries
- Provides protection from skeletal fluorosis and dental caries
- Probably an additional slight benefit for those at risk to osteoporosis
- Contrary to opinions of current Surgeon General, AMA, ADA, State Health and Dental Directors, National Drinking Water Advisory Council, and the Ad Hoc Panel on the Psychological and Behavioral Effects
- Would be a rejection of the South Carolina petition
- Would be higher value than 1 mg/l with somewhat higher risk of dental fluorosis but still small
- Would generate continued opposition from State and Dental Groups

An MCL at 2 mg/l would affect about 1300 communities.

- High level of noncompliance however much improved from the current situation if unconventional methods such as bottled water and point of use are legally acceptable.

Option III - 4 mg/l RMCL based upon protection from skeletal effects

- This would be derived directly from the recommended no effect level of the Surgeon General's Ad Hoc Committee
- This is twice the current standard and 4 times the optimum for protection from dental caries
- Caries protection is probably slightly less than at 2 or 3 times optimum
- A very small amount of mild nonsymptomatic skeletal fluorosis would occur
- Very high incidence (up to 40%) of moderate and severe fluorosis, with possible psychological and behavioral effects, would occur in many communities
- Some additional positive effect against osteoporosis would probably occur
- Although this would be argued against by AMA, ADA, State

officials and possibly even the Surgeon General, it might be acceptable to them in the long run because of the lower impact on State Programs

- Would disagree with Ad Hoc Panel on Psychological and Behavioral Effects
- Would probably generate legal action from anti-fluoridation groups.

An MCL at 4 mg/l would affect about 275 communities which are the current worst cases.

- Most of them would probably comply if bottled water and point of use devices were permitted.
- This 4 mg/l MCL could be coupled with an unenforceable Secondary standard (SMCL) of 2 mg/l with a public notification requirement. This could induce parents in communities between 2 and 4 mg/l to take protective action (bottled water or point of use) or some of these communities might also provide water to meet 2 mg/l.

Option IV - Propose to delete fluoride from the Primary Drinking Water Regulations and add to the non federally enforceable Secondary Regulations based upon the esthetics of dental fluorosis.

- Consistent with the recommendations from the Surgeon General and the ADA, State Health and Dental Directors
- Favorable response to the South Carolina petition
- Not consistent with the recommendation of the Surgeon General's Ad Hoc Advisory Panel, the National Drinking Water Advisory Council, and the Ad Hoc Panel on Psychological and Behavioral Effects
- Few States are likely to take any further action to force fluoride reductions.
- Possible lawsuit or other negative reaction from anti-fluoridation organizations on the basis that adverse effects occur.