EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

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APR 26 1985

Honorable Lee Thomas
Administrator
Environmental Protection Agency
Washington D.C. 20460

Dear Lee Thomas:

On March 22, 1985, the Environmental Protection Agency submitted for our review, pursuant to Executive Order No. 12291, a draft notice of proposed rulemaking (NPRM) that would establish a Recommended Maximum Contaminant Level (RMCL) for fluoride in drinking water under the Safe Drinking Water Act (SDWA), 42 U.S.C. 300f et. seq. This NPRM would be the first step in a rulemaking that could establish revised national primary and secondary drinking water regulations for fluoride.

We have reviewed the draft NPRM, discussed the issues with representatives of EPA, and reviewed EPA's background documents concerning this proposal. We conclude that the rule is inconsistent with the policies of Executive Order No. 12291. However, EPA has essentially committed in a consent decree (discussed below) to make its best efforts to issue an NPRM -- by April 30, 1985. Although the April 30 date is "not binding or enforceable" according to the consent decree, this letter is not intended to affect your timely discharge of any obligations it does create. We are therefore submitting these views in accordance with Section 3(f)(2) of Executive Order No. 12291, and asking EPA to respond as required by Section 3(f)(2) and Section 8(a)(2) of the Order as appropriate, in a manner consistent with the consent decree.

Background

EPA set an interim drinking water standard for fluoride in 1975 as part of the initial group of microbiological, organic, and inorganic contaminants regulated under the interim procedures of the Safe Drinking Water Act (SDWA). This interim fluoride standard set an enforceable Maximum Contaminant Level (MCL) that varies from 1.4 to 2.4 miligrams per liter (mg/L), deper ing on average annual ambient temperatures. EPA set the stan[illegible] for fluoride -- and the other substances as well -- pursuant to the provisions and procedures of 42 U.S.C. 300g-1(a). Those provisions and procedures are different from the authority EPA cites as its authority for the draft rule in hand.

Currently, despite the fact that EPA's interim fluoride standard has been in effect for a decade, approximately 1,300 drinking

water systems that are subject to the SDWA (out of approximately 60,000 such systems) are not in compliance with EPA's interim standard.[1] The systems that are not in compliance are generally (1) small, serving fewer than 500 people; (2) rural;[2] (3) have naturally occurring fluoride concentrations, as opposed to levels resulting from society's use of products containing fluoride; and (4) are not subject to active efforts by EPA to enforce compliance with the current interim fluoride standards.

In 1981, the State of South Carolina petitioned EPA to revoke the 1975 interim standard for fluoride. The petition contended that fluoride did not pose any adverse effects upon health and that the costs of compliance with the interim standard (not merely the costs of treatment of systems with fluoride levels exceeding the interim levels, but the costs of monitoring, testing, etc.) were prohibitively high and greatly exceeded the benefits of the interim standard. The Administrator of EPA, in 1981, agreed to make a decision on the South Carolina petition as soon as certain studies were completed.[3] No further regulatory action was taken by EPA. In 1984, suit was brought by the South Carolina Department of Health and Environmental Control seeking to enjoin enforcement of EPA's National Interim Primary Drinking Water Regulations for fluoride and to require the Administrator of EPA to take final action (or decide not to take final action) on an RMCL for fluoride in accordance with the procedures of the Safe Drinking Water Act.[4] On February 11, 1985, a consent decree was filed in which EPA agreed either to propose an RMCL for fluoride by April 30, 1985, or to rescind the existing national interim primary drinking water regulation for fluoride.

EPA's Draft Proposed Rule

The draft NPRM would propose establishing a Revised National Primary Drinking Water Regulation (NPDWR) with a RMCL of 4 mg/L. EPA proposes to base this standard on a belief that crippling skeletal fluorosis is an "adverse health effect" at high concentrations of fluoride and warrants regulation under 42 U.S.C. 300g-1(b). EPA bases this proposal to relax the current standard on its preliminary determination that dental fluorosis (the basis of the current interim standards) is not an adverse health effect.

The draft NPRM also states that EPA would in a later stage of this rulemaking establish a welfare-based secondary standard under 42 U.S.C. 300g-1(c) to address what EPA concludes is the adverse "cosmetic" effect of dental fluorosis. Under this section, EPA can establish secondary standards to protect public

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[1] EPA draft NPRM, page 25
[2] EPA draft NPRM, page 25
[3] 46 Federal Register 58345
[4] South Carolina Department of Health and Environmental Control v. U.S.E.P.A. et.al., No. 3: 84-0676-15 (D.S.C. April 4, 1984).

welfare (e.g., factors affecting the aesthetic properties of drinking water). Secondary standards are not Federally enforceable[5] but are enforceable by the States at their discretion.

Discussion

There are many aspects of EPA's proposal with which we agree. We agree with EPA's decision to relax the interim fluoride standard because of the absence of adverse health effects (albeit seemingly prodded into this by South Carolina's persistence and its recent lawsuit). And we agree with EPA that if a primary standard is promulgated, the costs and burdens that would be imposed on the 99.6% of the drinking water systems that already meet the proposed standard should be reduced to the minimum possible level, if not eliminated altogether.

Our concerns are in three areas: (1) the basis for the finding that fluoride may present an "adverse effect on the health of persons;" (2) the need for national health standards for fluoride in view of the infinitesimal health risk and quite small (less than 0.1%) population exposure; and (3) the need for explicit criteria for the exercise of the discretion afforded to the Administrator under the SDWA.

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[5]Primary enforcement responsibility for primary standards is also vested in a State if the State enacts a law establishing standards at least as stringent as the Federal standards. EPA can enforce a primary standard even if a State has enacted such a standard, however. If a national standard is promulgated, EPA may also enforce the battery of monitoring, testing, and reporting requirements that would automatically apply to every one of approximately 60,000 systems that are subject to EPA's SDWA jurisdication. Under current law, EPA can take action against a system violating the standard only by filing a court suit. EPA can also take indirect action, where the drinking water program has been delegated to the State, by asking the State to take enforcement action. (EPA might even, in an extreme case, withdraw delegation of a program from a State that fails to undertake enforcement action.) Most States have the authority, through State law, to use administrative order and penalty provisions to enforce drinking water standards (instead of seeking a remedy through court action). Even if it weren't for statutory limitations, the States would always be in a better position to take enforcement action because most of the non-compying systems are small and remote.

The Adverse Effects on the Health of Persons.

Under 42 U.S.C. 300g-1(b)(1)(B), the Administrator has the discretion to establish RMCLs "for each contaminant which, in his judgement based on the report on the study conducted pursuant to subsection (e) of this subsection,[6] may have any adverse effect on the health of persons."

Dental Health. At low concentrations, fluoride intake has the beneficial effect of reducing tooth decay. The optimum concentration for this purpose is 1 mg/L. Over 90% of the 60,000 public drinking water systems must add fluoride in order to reach the optimum level needed to prevent tooth decay. But at what levels of concentration does fluoride have an adverse effect on the health of persons?

In 1981, EPA asked the Surgeon General to assess the effects of fluoride. The Surgeon General responded on July 30, 1982. He later summarized his findings of 1982, as follows:

> "On July 30, 1982, I responded to a request from the Environmental Protection Agency (EPA) to review the scientific aspects of epidemiological studies relating to the effects of fluoride ingested through drinking water and to provide advice on the validity and significance of the findings relative to dental fluorosis. My summary conclusion, based on the lack of sufficient scientific evidence to the contrary, was that dental fluorosis, while not a desirable condition, was nevertheless not an adverse health effect. Thus, from an oral health standpoint, fluoride as currently found in U.S. drinking water supplies,[7] does not constitute a hazard."

In 1984, the Surgeon General reaffirmed that dental fluorosis does not present an adverse effect on the health of persons.

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[6]The study by the National Academy of Sciences under subsection (e) was "to determine...the maximum contaminant levels...in order to protect the health of persons form any known or adverse effects..." and was to be the basis for action by the Administrator. The study didn't do this, of course, which in major part accounts for EPA's difficulty in carrying out the SDWA after this critical default in the legislative scheme.

[7]Letter from C. Everett Koop, M.D. Surgeon General, to William D. Ruckleshaus, Administrator of EPA, dated January 23, 1984.

Non-Dental Health. In 1983, EPA requested the Surgeon General to review the medical literature on the non-dental effects associated with elevated levels of fluoride intake. The Surgeon General convened a committee of experts and, on the basis of the conclusions of that committee, the Surgeon General reported in a letter of January 23, 1984, as follows:

> "Adverse health effects were defined by the committee as death (poisoning), gastrointestinal hemorrhage, gastrointestinal irritation, arthralgias, and crippling fluorosis. No record exists of poisoning death from fluorides consumed in drinking water. There are no scientifically credible reports of gastrointestinal effects of levels found in drinking water. Clinical experience suggests that arthralgias are not likely to occur in patients who are on therapeutic regimens of less than 20 milligrams (mg) per day. Crippling fluorosis has been detected in some people who have consumed 20 mg of more of fluoride per day from all sources for twenty or more years. Such a situation does not exist in the U.S. today."

The expert committee convened by the Surgeon General concluded in its report that:

> "The difference between four times and ten times optimum represents an adequate margin of safety unless further research warrants reconsideration of these levels. There exists no directly applicable scientific documentation of adverse medical effects at levels of fluoride below 8 mg/L (ppm)."

In its draft NPRM, EPA confirms this fact -- no cases of water-related crippling fluorosis have been diagnosed in the United States.[8] EPA nonetheless purports to find an adverse effect on the health of persons from fluoride. In its draft NPRM for the primary standard, EPA explained the basis as follows:

> "Based upon the information available at this time, the Administrator has concluded that crippling skeletal fluorosis is an adverse effect on health 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 effects on health of persons occur and which allow an adequate margin of safety. Thus an RMCL is proposed at 4 mg/L."[9]

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[8] EPA draft NPRM, pages 41, 44

[9] EPA draft NPRM, page 56

The Population Exposed to these Risks and the Need for a National Solution

Elevated fluoride levels occur in a relatively small -- and well known -- number of drinking water systems. EPA's draft NPRM reports that 282 systems have fluoride concentrations of 4 mg/L or higher."[10] These 282 systems represent approximately 0.4% of the Nation's 60,000 drinking water systems subject to the SDWA. In other words, 99.6% of the Nation's system have levels that are below the 4 mg/L level that EPA proposes to establish. And yet every one of these 60,000 systems would be subject to the Federal presence that a national health standard for fluoride would bring, complete with requirements to test, monitor, report, etc.[11]

Not only is the number of systems that have levels of concentration greater than the 4 mg/L standard that EPA would propose small -- both in absolute terms and as a percentage of the total number of systems that would be covered in order to reach this small number -- but the population served by these few systems is an even smaller fraction of the whole. EPA estimates that 184,000 people are served by the 282 systems that have fluoride concentrations greater than 4 mg/L.[12] This is less than 0.1% of the total population of 190-200 million served by the 60,000 drinking water systems that are subject to the SDWA.

Even fewer people are served by systems with higher concentrations of fluoride. At levels of concentration of 6 mg/L and higher, 17,000 people are served. At levels of concentration of 8 mg/L and higher, 3,000 - 4,000 people are served.[13] And at all these concentrations, the Surgeon General and his "world class" panels have found no demonstrated cases of adverse affects on the health of persons.

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[10] EPA draft NPRM, page 25

[11] Drinking water systems relying on surface sources of supply are required to monitor once a year; systems relying on groundwater sources of supply are required to monitor once every three years. If the fluoride concentration exceeds the MCL, the system is required to take three additional samples within a month. If the average fluoride concentration exceeds the MCL, the system is out of compliance with the drinking water standard and the system must take the actions necessary to reduce the fluoride levels. The drinking water system must also 1) notify the population it serves that fluoride levels exceed Federal drinking water standards, 2) advise the public of the effects of fluoride, and 3) inform the public of ways to avoid these effects.

[12] EPA draft NPRM, page 26

[13] Only a still smaller group is truly relevant to EPA's risk assessment since the Surgeon General's Reports indicated that whatever effects relatively high concentrations of fluoride may have would occur in children below the age of 9.

Not only is the population served by systems with fluoride concentrations of 4 mg/L and higher quite small, but EPA and the States know which systems these are. EPA, the States, and presumably the people themselves know they are exposed, and they know they have been so exposed for an indeterminant number of years because these levels occur naturally and they are quite stable over time. In fact, for the last decade, they have also known that most of these systems have been in violation of EPA's current interim standard.

What is going to change if EPA relaxes the standard to 4? What will be the adverse effects on the health of persons that would be avoided by EPA's draft NPRM? Stated the other way around, what would be the health benefits of this standard? Is this benefit worth the costs of a national system that apparently necessitates regulating all 60,000 systems even if only a few are a "problem"?

Since there is no evidence of any adverse effect on the health of persons from fluoride consumed in the United States, it is not very helpful to calculate the costs per case avoided, since apparently no cases would be avoided.

On the basis of EPA estimates of treatment cost, the costs of this fluoride standard would be $5 million or more per year. For a family of four in a smaller community, the treatment cost of meeting the standard would increase water bills by roughly $110 per year.

The use of a primary standard means requiring 190-200 million people to bear the costs of absolutely unnecessary regulatory requirements in order to force 184,000 people to pay to reduce the naturally occurring fluoride in their drinking water to less than 4 mg/L. And even if it made sense to impose these nationwide burdens to address a handful of known, local "problems," this approach would still depend upon a counter-intuitive assumption, viz: That EPA or the States would actually enforce the standards against these systems or that the systems would voluntarily comply with this standard. EPA and the States have had an enforceable, and more stringent, fluoride standard in effect for almost a decade, and still 1,300 systems are in violation of it, 282 with concentration levels at 4 mg/L or greater. It is not clear to me why this is going to change under this EPA proposal. Yet if it does not, the effect of the proposal will simply be to impose regulatory burdens on 100% of the systems without any effect on fluoride levels whatsoever -- in 99.6% of the systems because they are already below 4 mg/L, and in 0.4% because they would not come into compliance. All of this would be undertaken moreover, in order to avoid no documented adverse health effects from concentrations of fluoride found in this Nation's 60,000 drinking water systems.

The Need for Criteria for the Exercise of Discretion Afforded to the Administrator by the SDWA

The SDWA, read literally, would appear to vest the Administrator with the discretion to regulate "any physical, chemical, biological, or radiological substance or matter in water" that "may have any adverse effect on the health of persons." The Act does not require that the substance actually occur in any drinking water system, or enough of them to warrant nationwide regulations, nor does the Act limit to concentrations that actually occur the levels that may be used in determining an adverse effect on health.

Our point is not that the Act should answer these questions -- in our view it should not -- but that the agency should state how it intends to exercise this discretion in a reasonable fashion. Although EPA is not proposing to regulate in the outer-most reaches of the Act, and could not reasonably propose to do so, the two regulatory proposals submitted thus far for our review under Executive Order No. 12291 have some common defects. Neither sets forth and applies criteria for exercise of the Administrator's discretion, nor otherwise provides the public with much understanding of how he will exercise the discretion afforded him by the SDWA.

Both proposals would impose nationwide regulatory requirements in order to address a small percentage of "problem" systems. In the NPRM proposing RMCLs for certain volatile organic chemicals (VOCs), published last summer[14] the percentage of all 60,000 systems that exhibited treatable levels of VOCs was less than 4%. In the proposed fluoride NPRM, the corresponding percentage is 0.4%.

Both proposals would impose costs to be borne by 190-200 million consumers in order to address "problems" faced by but a few consumers. In the VOC proposal, if the MCLs were set at the RMCL levels, no more than approximately 10% of drinking water consumers would face concentration levels in excess of the levels that would be regulated. In the proposed fluoride NPRM the corresponding percentage is less than 0.1%.

And both proposals would "solve" very small if not imagined "health" problems. In the VOC proposal, if all of the regulated VOCs were eliminated from the Nation's drinking water systems, approximately two-thirds of one case of cancer would be avoided out of more than 400,000 cancer deaths per year. In the case of the proposed fluoride NPRM, no cancer cases would be avoided, for indeed no adverse health effects of any type would be avoided.

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[14] 49 Federal Register 24330

From the two proposals we have reviewed, we conclude that EPA is not selecting for regulation substances from which there are worthwhile health gains. If these two proposals do address the largest remaining risks in our drinking water, however, perhaps Congress should consider whether national drinking water standards are needed at all.

In the VOCs NPRM published last year, EPA identified general criteria that it purports to consider in determining whether regulations establishing national primary drinking water standards are appropriate.

- whether the frequency of occurrence, the concentrations detected, and the extent of the population exposed warrant regulation;
- whether available health evidence (or toxicological data) warrants a determination that adverse health effects would occur (or are anticipated) at levels found in drinking water; and
- the possibility that future contamination of drinking water supplies from spills or improper disposal may warrant regulation (even though these substances have not been found to date at high levels or frequencies).

We agree that these are among the important factors to be considered in deciding whether to proceed with the regulation of a substance. The agency has not specified how these general factors are used to evaluate individual contaminants, however. For example, EPA has not identified any explicit standards -- de minimis level of risks, population at risk, etc. -- that might be used to identify substances where national regulation is or is not warranted. Nor is it clear how these criteria could possibly have been used to arrive at the current NPRM. In our letter of May 9, 1984, we expressed our concern with this aspect of EPA's draft rule for VOCs. The same issue now arises in the context of the draft NPRM for fluoride.

Conclusion

In its petition and lawsuit South Carolina suggested rescinding the present interim fluoride standard and issuing a secondary standard instead. In our view, this has advantages. It would avoid the difficulty of searching for an adverse health effect because a health standard would not be set; it would set a secondary standard to deal with dental fluorosis, recognizing that dental fluorosis is not a health problem. It would not impose burdens or costs on everyone in order to deal with a few,

and it would leave to the affected States the choice of whether to deal with the secondary standard, effectively the same choice they would have (and now have) under delegated authority to enforce a health-based fluoride standard.

Sincerely

Douglas H. Ginsburg
Administrator Office of Information
and Regulatory Affairs