

FINAL  
DECISION  
(FOR EPA)

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**United States Court of Appeals**  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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No. 85-1839

NATURAL RESOURCES DEFENSE COUNCIL, INC., PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, and  
LEE M. THOMAS, ADMINISTRATOR, RESPONDENTS

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No. 85-1854

SOUTH CAROLINA DEPARTMENT OF HEALTH AND  
ENVIRONMENTAL CONTROL, PETITIONER

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,  
RESPONDENT

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Petitions for Review of Orders of the  
Environmental Protection Agency

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Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Argued February 2, 1987

Decided February 27, 1987

*Jacqueline M. Warren* for petitioner, NRDC, Inc., in No. 85-1839. *Jane L. Bloom* also entered an appearance for petitioner in No. 85-1839.

*John Harleston*, Staff Counsel, State of South Carolina, with whom *Walton J. McLeod, III*, General Counsel, State of South Carolina was on the brief for petitioner, South Carolina Department of Health & Environmental Control in No. 85-1854.

*John A. Amodeo*, Attorney, Department of Justice, with whom *Francis S. Blake*, General Counsel and *Kenneth F. Gray*, Attorney, Environmental Protection Agency were on the brief for respondents in Nos. 85-1839 and 85-1854.

Before: RUTH B. GINSBURG, BORK and BUCKLEY,  
*Circuit Judges.*

*Opinion Per Curiam.*

PER CURIAM: Natural Resources Defense Council (NRDC) and South Carolina Department of Health and Environmental Control (DHEC) challenge an Environmental Protection Agency (EPA) rule, effective December 16, 1985, establishing a recommended maximum contaminant level (RMCL) under the Safe Drinking Water Act (SDWA) for fluoride in drinking water. EPA set the level at 4 mg fluoride per liter. NRDC contends that the agency shirked its statutory responsibility by failing to adopt a lower maximum level; DHEC claims that EPA should have set no RMCL at all, or a higher one. We have reviewed the record and find that EPA reasonably interpreted the statute, responsibly evaluated the sometimes conflicting evidence in an extensive record, provided rational explanations for its determinations, and responded adequately to the arguments petitioners

now repeat before the court. We therefore uphold EPA's rule as within the bounds of the agency's permissible discretion.

The SDWA, 42 U.S.C. §§ 300f to 300j-10, directs the EPA to prescribe both primary and secondary maximum levels for contaminants in public drinking water systems. Primary regulations specify federally enforceable maximum levels (MCLs) for "contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons." 42 U.S.C. § 300f(1)(B). Secondary regulations (SMCLs), which are enforceable only in the discretion of the states, specify "maximum contaminant levels which, in the judgment of the Administrator, are requisite to protect the public welfare." 42 U.S.C. § 300f(2).

The Act initially directed EPA to promulgate national drinking water standards in stages. Pursuant to this scheme, EPA first adopted interim primary regulations. See *Environmental Defense Fund, Inc. v. Costle*, 578 F.2d 337 (D.C. Cir. 1978). Revised primary regulations, to replace the interim standards, were then developed in two steps: (1) *recommended* maximum contaminant levels (RMCLs), followed by (2) maximum contaminant levels (MCLs). Based on studies arranged with the National Academy of Sciences (NAS), and as required by the Act, EPA endeavored to set RMCLs at levels at which "no known or anticipated adverse effects on the health of persons occur and which allow[] an adequate margin of safety." 42 U.S.C. § 300g-1(b)(1)(B). RMCLs, as the qualification "recommended" implies, are non-enforceable health goals; RMCLs are set without taking feasibility into account. MCLs are the federally enforceable standards. They must be set "as close to the [RMCLs] . . . as is feasible" using the best means "generally available (taking cost into consideration)." 42

U.S.C. § 300g-1(b)(3).<sup>1</sup> EPA proposed an MCL for fluoride, as well as an SMCL, the same day it published its final RMCL rule.

NRDC attacks the RMCL for fluoride on three main fronts. First, NRDC contends that the RMCL is not low enough even to prevent crippling skeletal fluorosis, the adverse health risk EPA identified. NRDC tendered a series of calculations purporting to show that, at an RMCL of 4 mg/L, a large number of people will consume more than the amount of fluoride that EPA believes can cause crippling fluorosis. EPA convincingly explained, however, that NRDC's calculations are suspect. We note, for example, that NRDC used a daily drinking water consumption figure derived from a chart containing a clear caveat that the calculation NRDC attempted would produce an overestimate. See Attachment F to NRDC Brief.

NRDC claims that the RMCL will not adequately protect particularly susceptible individuals, such as those who drink larger than average quantities of water. EPA intelligibly explained the process through which it determined that the RMCL will protect even sensitive subgroups of the population with an adequate margin of safety. Final Rule, Joint Appendix (J.A.) Tab A, 50 FED. REG. 47142, 47144 (1985). Substantial evidence in the record supports that determination. Although a significant number of people in the United States have long been exposed to levels above 4 mg/L, only two cases of crippling fluorosis related to drinking water have ever been documented in this country. *Id.* at 47144, 47147, 47151-52. Both victims had disorders that caused them to drink excessively, and both drank large quantities of tea, a beverage notably high in fluoride content. EPA

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<sup>1</sup> In June 1986, Congress amended the SDWA, eliminating the distinction between interim and revised primary regulations. Safe Drinking Water Act Amendments of 1986, Pub. L. No. 99-939, 100 Stat. 642 (1986).

reasonably concluded that the SDWA does not "require[] protection by national regulation of persons who, through unusual [dietary] practices, may put themselves at risk." *Id.* at 47148.

NRDC's second main attack targets EPA's conclusion that dental fluorosis does not qualify as an adverse health effect under the SDWA, but is rather a cosmetic effect that would adversely affect public welfare. This conclusion placed dental fluorosis in the domain of secondary, not primary, regulation. The interim standard did account for dental fluorosis as an adverse health effect, *id.* at 47142, and NRDC characterizes the changed categorization as dramatic and unexplained. EPA had set the interim standard at the maximum specified by the existing Public Health Service guideline; at that initial stage, the agency essayed no independent investigation or firm judgment on the issue. Indeed, in reviewing the interim regulation on fluoride, this court questioned whether the "cosmetically undesirable mottling of the tooth enamel that results from excessive fluoride" could "be regarded as an 'adverse effect on health' within the meaning of the [SDWA]." *Environmental Defense Fund*, 578 F.2d at 347 & n.35.

EPA decided to define adverse health effects as those resulting in functional impairment. The agency then determined that dental fluorosis, although manifested by unattractive staining and pitting, did not appear to cause loss of function or mortal injury to the teeth. Thus finding the evidence inadequate to conclude that dental fluorosis is an adverse health effect, EPA did not consider the prevention of that condition in setting the RMCL. The appropriate classification of dental fluorosis was extensively discussed in the rulemaking, and EPA explained its decision. *See Responses to Generic Issues*, J.A. Tab D at 5-6; *Final Rule*, J.A. Tab A, 50 FED. REG. at 47143-44.

NRDC asserts that many scientific experts consider dental fluorosis an adverse effect on health. Acknowledging that this aspect of the rulemaking had been controversial, *id.* at 47143, EPA essentially demurred to NRDC's point. Experts can describe what dental fluorosis does to the body; whether that constitutes an adverse effect on health under the SDWA, however, is a question of statutory interpretation. The statute does not define "adverse effect on health," and NRDC does not seriously contest the reasonableness of defining that phrase to mean some functional impairment. The pivotal question, therefore, is whether EPA reasonably concluded that dental fluorosis does not significantly impair the functioning of body or mind.

NRDC features a psychiatric panel's report concerning potential psychological effects of dental fluorosis. EPA reasonably concluded, however, that the possible problems identified by the expert panel, such as loss of self-confidence and dissatisfaction with personal appearance, were not significant enough to rank under the Act as health rather than welfare effects. Final Rule, J.A. Tab A, 50 FED. REG. at 47144.

Finally, NRDC assails as arbitrary EPA's failure to take into account numerous other health risks that may be connected with fluoride. NRDC cites studies purporting to find a link between fluoride and a host of health problems. Under the SDWA, however, the RMCL is to be set with reference to known or anticipated adverse health effects, not merely possible effects. 42 U.S.C. § 300g-1(b)(1)(B).

EPA reviewed and responded to the studies in fair detail and gave reasoned explanations for finding that they did not convincingly establish a cognizable connection between fluoride in drinking water and the various health risks posited. See Final Rule, J.A. Tab A, 50 FED. REG. at 47152; Drinking Water Criteria Document, J.A. Tab C; Summary of Comments and Responses, J.A. Tab D.

Some of the studies, we note, were not conducted in living organisms, used extremely high dosages of fluoride never found naturally in drinking water, or did not follow established scientific methods. EPA, when it evaluated the studies cited by NRDC, also properly considered compelling contrary evidence.

NRDC, in essence, asks the court to substitute that organization's judgment for EPA's. We have no warrant to do so. Our review function is accomplished when we have inspected the agency's action, as we have here, to insure that the action has a rational basis, one that reasonably promotes the legislative design.

DHEC, in stark contrast to NRDC, maintains that EPA should not have established any RMCL for fluoride because the two isolated cases of crippling skeletal fluorosis observed in the United States are insufficient evidence that fluoride in drinking water has any adverse effect on health. As EPA explained, however, the statute requires the agency to take account of adverse effects on health known or anticipated; SDWA does not confine the agency's ken to effects that have occurred widely in the United States.

DHEC stresses that, in responding to NRDC's argument that crippling skeletal fluorosis is known to occur at 4 mg/L, EPA itself remarked on the limited usefulness of foreign studies of that condition. From this, DHEC concludes that the record affords inadequate support for describing crippling fluorosis as an anticipated effect. See DHEC Reply Brief at 4-6. EPA did say that the occurrence of crippling fluorosis at levels below 4 mg/L in India is not predictive of whether crippling fluorosis will occur *at that level* in the United States. Foreign studies remain probative, however, on the question whether fluoride in drinking water is a source from which one can anticipate incidents of crippling fluorosis. Further, numerous studies have documented crippling

fluorosis from sources of fluoride other than drinking water. Response to Generic Issues, J.A. Tab D at 117-31. It was not irrational for EPA to determine that fluoride contained in drinking water could also produce this condition.

The risk of crippling fluorosis from drinking water, DHEC urges, is so slight that, if any RMCL is tolerable, the necessary margin of safety should be negligible. DHEC proposes an RMCL of 8 mg/L, which is less than the 10 mg/L concentration that EPA believes may lead to crippling fluorosis. DHEC Reply Brief at 19. EPA rationally explained that the margin of safety provided by the RMCL of 4 mg/L may be needed to protect those who drink more than average amounts since the 10 mg/L level is based on an average drinking water consumption figure of 2 L per day. Final Rule, J.A. Tab A, 50 FED. REG. at 47147-48, 47151-52. EPA, in sum, made a permissible administrative judgment, and we must "avoid[ ] all temptation to direct the agency in a choice between rational alternatives." *Environmental Defense Fund*, 578 F.2d at 339.

For the reasons stated, the petitions for review are denied and the final rule at issue is affirmed.

*It is so ordered.*