IN THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC., Petitioner, v. ENVIRONMENTAL PROTECTION AGENCY, and LEE M. THOMAS, ADMINISTRATOR, Respondents.	Civ. No. 85-1839
consolidated with	
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, Petitioner, v. ENVIRONMENTAL PROTECTION AGENCY, Respondent.	Civ. No. 85-1854

BRIEF OF AMICUS CURIAE LOCAL 2050, NATIONAL FEDERATION OF FEDERAL EMPLOYEES

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I. INTRODUCTION

Local 2050 of the National Federation of Federal Employees (hereinafter referred to as "NFFE" or "the Union") is a Union of dedicated professionals at the Environmental Protection Agency (hereinafter referred to as "EPA" or "the Agency") headquarters, including toxicologists, chemists, physical scientists, statisticians, biologists, engineers and attorneys. NFFE is the exclusive representative of scientific and technical employees at EPA in accordance with the Labor-Management Relations Act, 5 U.S.C. §7101 et seq (1978). The Union is committed to "the highest standards of professional conduct in the efficient and truthful pursuit of the mission of the EPA."[1] At the foundation of the Union lies the recognition that

- the mission of EPA as mandated by Congress through law is to protect public health and the environment,
- professionals hired by EPA form a professional community with the legal, scientific, and technical expertise to recognize and help solve environmental problems, and
- sound professional decision making requires the open interchange of ideas and proposals by all parties

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[1] Statement of Purpose, National Federation of Federal Employees, EPA Professionals, Local 2050 (hereinafter referred to as "Statement of Purpose") (See Attachment A).

concerned: EPA management, its professional staff, Congress and the public.[2]

NFFE members are charged with reviewing, evaluating and assessing technical and scientific knowledge in areas relevant to Agency decision making. They are also responsible for producing final Agency science and technical findings which comply with legal requirements, and for presenting such findings to the Agency Administrator, or his or her representative, charged with achieving national objectives. Thus, the reputations of professionals represented by NFFE are dependent upon EPA producing scientifically and technically sound support documents which are consistent with the mission of the Agency.

NFFE is of the opinion that the Recommended Maximum Contaminant Level (hereinafter referred to as "RMCL") for fluoride set by EPA is based on scientific support documents whose purpose, content and interpretation are open to question. NFFE has repeatedly attempted to have the Agency reconsider the scientific assessments and the science based decisions involved in promulgating this fluoride regulation.[3] For example, on October 31, 1985 NFFE wrote to the Administrator and proposed a seminar devoted to the scientific support work

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2 Statement of Purpose.

3 See Attachments B through G.

for the RMCL. In this letter NFFE informed the Administrator that

> National Federation of Federal Employees Local 2050 is concerned about the scientific basis for the newly authorized Recommended Maximum Contaminant Level (RMCL) for fluoride in drinking water. Our concern is based on the possible impact of the RMCL on our professional reputations.[4]

On November 15, 1985, NFFE wrote again to the Administrator, this time setting forth illustrations of major points of concern:

> First, the literature review missed significant reports in the published literature. ***
>
> Second, references were used that did not address the subject as claimed. ***
>
> Third, scientific conclusions were made without appropriate documentation and which contradict the available evidence. ***
>
> Fourth, EPA documents on fluoride appear designed to "support" the Agency position rather than assess the risks from a scientific data base.[5]

On August 26, 1986, NFFE once again informed the Agency of its concern about the scientific basis of the fluoride RMCL. The Union requested that EPA agree with NRDC to postpone the court case pending a review by the EPA Science Advisory Board of the scientific basis of the regulation. In this letter NFFE stated

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4 Letter from Robert J. Carton to Lee M. Thomas (Oct. 31, 1985).

5 Letter from Robert J. Carton to Lee M. Thomas (Nov. 15, 1985).

> The Agency is presently in court and has responded to the NRDC Brief by asserting that the court should defer to the Agency position because of the "Agency expertise." This presents a conflict for NFFE which represents EPA professionals who are the Agency experts and who the public associates with any scientific or technical publication by the Agency. NFFE has to choose between ignoring what it knows full well to be an unsupportable decision and one which injures the reputation of EPA professionals, or take further action.[6]

This letter was the union's "last attempt at finding a way for EPA to honestly reevaluate the decision on fluoride in-house."[7]

Despite numerous attempts by the Union to open the Agency's channels of communication on the fluoride RMCL issue, EPA has never been receptive to NFFE's concerns.

The Union has concluded that the Brief for Respondents (hereinafter referred to as "Respondents' Brief") does not address serious questions raised by NRDC, but instead advocates a deferential standard of review. NFFE believes that serious errors were made by the Agency in setting the fluoride RMCL and that this case should not be dismissed by the invocation of a doctrine of deference to Agency expertise inasmuch as the Agency deliberately chose not to base its decision on relevant expertise.

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6 Letter from Robert J. Carton to Lee M. Thomas (Aug. 26, 1986).

7 Letter from Robert J. Carton to Lee M. Thomas (Aug. 26, 1986).

Thus, the Union is filing a brief as Amicus Curiae to assist this Court in making an informed determination, to further NFFE's goal of professional excellence in conformance with its Statement of Purpose[8] and the Code of Ethics for Government Employees,[9] and to safeguard the professional reputations of Union members.

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8 Through its Statement of Purpose NFFE is dedicated "to the highest standards of professional conduct in the efficient and truthful pursuit of the mission of EPA." This document also provides:

> In order to achieve [its] goals, this organization recognizes that all professional employees have . . . the responsibility to participate in building and improving [the EPA work] environment, making it more efficient and effective for the benefit of the entire EPA community and the public they serve.

Statement of Purpose, supra.

9 The first rule set forth by the Code of Ethics for Government Service is that Government employees should

> I. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

Pub. L. 96-303, §§ 1-4, July 3, 1980, 94 Stat. 855, 856.

II. SUMMARY OF ARGUMENT

The deferential standard of review urged by EPA is inappropriate in this case since EPA failed to base its decision on its technical expertise, which it was required by law to rely upon and since its decision changed an interim standard in effect for over ten years. For these reasons also, the burden of justifying its decision must fall on EPA. The process by which EPA arrived at the RMCL for fluoride is scientifically irrational and displays an unprofessional review of relevant scientific data. The Safe Drinking Water Act requires that an RMCL must be a reflection of the opinion of health professionals as to the level of a contaminant at which no known or anticipated adverse effect on the health of persons will occur, and which allows an adequate margin of safety. However, the final RMCL for fluoride does not represent a determination made on the basis of scientific and technical expertise.

EPA's deliberate choice not to base its decision on expertise is evident by its failure to follow the proper process in order to determine an RMCL, and by its disregard of the opinion of health professionals. First, EPA failed to properly ascertain the Acceptable Daily Dose (ADD) of fluoride. A proper determination of an ADD is an essential step in the process of ascertaining the appropriate level in drinking water. It represents the

theoretical highest allowable intake level of the substance per person per day from any and all sources, at which no adverse health effects in the population will or may result, allowing for an adequate margin of safety. EPA did not properly ascertain this level because it a) did not adequately consider all the known or anticipated adverse effects of fluoride, including dental and non-dental effects, b) did not conduct a professional review of the available literature on crippling skeletal fluorosis, c) did not consider the most susceptible individuals when calculating the level at which no adverse health effect will occur, and d) did not determine an ADD for susceptible individuals with an adequate margin of safety.

Second, EPA did not properly calculate the RMCL to ensure that no one in the population would ingest more than the ADD from a combination of drinking water and all other sources. This figure was not correctly ascertained because EPA a) did not incorporate any figures to reflect exposure to fluoride from sources other than drinking water, and b) failed to take into account all members of the population when calculating drinking water intake figures.

Third, EPA impermissibly applied feasibility and political considerations when calculating the RMCL for fluoride.

III. ARGUMENT

A. The Deferential Standard of Review Urged by EPA is Inappropriate in this Case

EPA urges the Court to treat this case by the deferential standard of review ordinarily accorded to decisions based solely on the technical expertise of an administrative agency. The EPA is absolutely correct in asserting this to be the usual - and proper - standard. The EPA is wholly incorrect, however, in suggesting that this standard of judicial humility should apply here, where the EPA, in accordance with a contradictory interpretation of the statutory requirements for the determination of an RMCL, ignored its expertise and radically changed an interim standard for fluoride previously in effect for over ten years.

While according deference to administrative decision-making, this Court has recognized that it should not apply unless it is clear that "the agency has exercised a reasoned discretion, with reasons that do not deviate from or ignore the ascertainable legislative intent." Lead Industries Assoc. v. EPA, 647 F.2d 1130 (D.C. Cir. 1980), quoting Greater Boston Television Corp. v. F.C.C., 444 F.2d 841, 850 (D.C. Cir. 1970), cert. denied 403 U.S. 923 (1971).

The Supreme Court recently declared:

> . . .the "deference owed to an expert tribunal cannot be allowed to slip into a judicial inertia which results in the unauthorized

> assumption by an agency of major policy decisions properly made by Congress." American Ship Building Co. v. NLRB, 380 U.S. 300, 318, 85 S.Ct. 955, 967, 13 L.Ed.2d 85 (1965). Accordingly, while reviewing courts should uphold reasonable and defensible construction of an agency's enabling Act, NLRB v. Iron Workers, supra, 434 U.S., at 350, 98 S.Ct., at 660, they must not "rubber-stamp . . .administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." NLRB v. Brown, 380 U.S. 278, 291-292, 85 S.Ct. 980, 988-989, 13 L.Ed.2d 839 (1965).

Here even EPA admits that "an RMCL is, by law to be based only on health and safety consideration . . ." (emphasis added).[10] Nevertheless, as the analysis of the EPA decision-making which follows clearly demonstrates, EPA disregarded that mandate. In so doing, it necessarily opened its decision to judicial scrutiny.

The Supreme Court has also wisely cautioned that:

> Expert discretion is the lifeblood of the administrative process, but unless we make the requirements for administrative action strict and demanding, expertise, the strength of modern government, can become a monster which rules with no practical limits on its discretion.

Motor Vehicle Mfns. Ass'n, Inc. v. State Farm Mut. Ins. Co., 463 U.S. 29, 48 (1983), quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 167 (1962) (emphasis in original).

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10 Final RMCL at 47155.

EPA cites Environmental Defense Fund, Inc. v. Costle, 578 F.2d 337 (D.C. Cir. 1978) to support its assertion that the new RMCL for fluoride is subject to great judicial deference.[11] The deference standard employed in Costle has no place in this case. Unlike the Agency determinations passed upon by this Court in Costle, the Agency action challenged in this case was not intended to involve any cost, feasibility or policy determinations.

Costle involved a challenge to interim regulations under the Safe Drinking Water Act. As this Court correctly noted in Costle the interim regulations "set maximum contaminant levels (MCL) . . . . 'intended to 'protect health to the extent feasible, using technology, treatment techniques, and other means, which the Administrator determines are generally available (taking costs into consideration) on the date of enactment of this title.'"[12] Thus, the Agency determinations at issue in Costle necessarily involved considerations of cost, policy and feasibility.

The words omitted from Respondents' quote from Costle on pages 26-27 of their brief make this clear. In its entirety this quote should read:

> Agency expertise and judgment must be applied in determining the optimal balance between

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11 Respondents' Brief at 26-27.

12 Costle, supra, 578 F.2d at 339-340.

promotion of the public welfare and avoidance of unnecessary expense.

When reprinted in Respondents' brief the underlined portion of the latter quote was omitted.

Here, as the Agency recognized, it was charged with determining a level of fluoride which will "result in no known or anticipated adverse health effects and which allow an adequate margin of safety."[13] In other words, its conclusions were to be based solely on scientific and technical considerations. NFFE contends that its conclusions were not founded upon Agency expertise and this standard of deference to expertise must not apply.

B. The Burden of Demonstrating that the RMCL was Derived Solely from Scientific Assessments of Health and Safety Should be Shifted to EPA

Because the "RMCL is by law based only on health and safety considerations while an MCL takes feasibility and cost into consideration,"[14] EPA was able to escape an economic impact analysis and regulatory impact analysis in connection with the RMCL and was able to considerably narrow scrutiny of its determination. Yet the enforceable MCL standard, which takes into account feasibility and cost, and as to which considerably greater scrutiny exists, cannot be any higher than the RMCL since the RMCL is considered to be a

13 Final RMCL at 47142.

14 Final RMCL at 47155.

non-controversial technical assessment made prior to any public (or judicial) intervention. This entire process, however, is based on the supposition that the Agency professionally ascertained the RMCL by objective scientific standards. NFFE asserts that no such professional assessment occurred here. The EPA, without scientific basis, reversed its ten-year standing maximum contaminant level for fluoride in the face of overwhelming scientific evidence to the contrary only a short period after the OMB and South Carolina requested that the previous lower standard be entirely eliminated. NFFE submits that EPA's decision is flawed on its face and that the burden of justification should therefore fall on the Agency.

C. The Process by Which EPA Arrived at the RMCL for Fluoride Is Irrational

This case involves a challenge to the Recommended Maximum Contaminant Level (RMCL) for fluoride promulgated by the EPA as part of the "Revised National Drinking Water Regulations" under SDWA. The promulgation of RMCLs for contaminants of drinking water is an "initial step" in the rulemaking process. RMCLs are to represent non-enforceable health goals which are to be set at a level which assures "that the health of persons will be

protected against known or anticipated adverse effects [of the substance], allowing an adequate margin of safety."[15]

For those contaminants which "may have any adverse effect on the health of persons," RMCLs are to be set at a level at which

> no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.[16]

By requiring the Agency to arrive at two figures for each contaminant -- an RMCL as a health goal and an MCL as an enforceable standard -- Congress intended to ensure that each RMCL be "based solely on considerations of public health and . . . not influenced by political, budgetary or other considerations."[17]

The language of the Act and its legislative history make clear that an RMCL must be a reflection of the opinion of health professionals as to the level of a contaminant at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[18] Therefore, the Court need not give any deference in this case to the Agency's "line-drawing" between "promotion of the public welfare

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15 H.R. Rep. No. 93-1185, 93d Cong., 2d Sess. 18 (1974) (hereinafter referred to as "House Report").

16 § 1412(b)(1)(B), 42 U.S.C. §300g-1(b)(1)(B).

17 House Report at 19.

18 § 1412(b)(1)(B), 42 U.S.C. §300g-1(b)(1)(B).

and avoidance of unnecessary expense."[19] Instead, the only question to be asked is whether the RMCL for fluoride is based on a proper exercise by the Agency of its scientific and technical expertise.

The scientific and technical employees at the EPA submit that the Agency abused its discretion in the process of setting the new fluoride RMCL. The final RMCL does not represent a determination made on the basis of scientific and technical expertise. Instead, it represents an administrative process replete with inaccurate interpretations of the requirements of the Act, inappropriate applications of political and budgetary considerations, and unprofessional scientific support documentation.

In simplest terms, the process by which an RMCL is determined for a given substance should consist of two parts. First, one must come up with a figure which represents the Acceptable Daily Dose (hereinafter referred to as "ADD") for the substance. Second, one must determine the concentration of the substance in drinking water which will ensure no one ingests more than the ADD from all sources of the substance combined. The entire process should be conducted through professional assessment of the relevant scientific and technical

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19 Environmental Defense Fund, Inc. v. Costle, 188 U.S. App. D.C. 95, 578 F.2d 337 (1978).

literature and should not involve feasibility or political considerations.

1. EPA failed to properly ascertain the Acceptable Daily Dose of Fluoride

The first step to arriving at an appropriate RMCL for a substance is to derive a figure which represents the theoretical highest allowable intake level of the substance per person per day from any and all sources. This figure should be set at a level at which no adverse health effects in the population will or may result, allowing for an adequate margin of safety. This figure is referred to as the Acceptable Daily Dose (ADD).[20]

Several determinations must be made in order to come up with an appropriate ADD. These include the following:

> What are the known and/or reasonably anticipated adverse health effects of the substance?
>
> At what daily intake level do such effects occur on the most sensitive individuals in the

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20 See National Primary Drinking Water Regulations; Synthetic Organic Chemicals, Inorganic Chemicals and Microorganisms; Proposed Rule, 50 Fed. Reg. 219, 46944 (1985) (to be codified at 40 C.F.R. Part 141) (proposed Nov. 13, 1985). Here EPA provides that "[f]or toxic agents not considered to have carcinogenic potential, "no effect" levels for chronic/lifetime periods of exposure including a margin of safety are referred to commonly as ADIs or Acceptable Daily Intakes." EPA calculates ADIs in terms of mg/kg/day. In the discussion above, we are simplifying this method by assuming the weight of a 70 kg adult. EPA's ADI, for an assumed 70 kg adult results in what we refer to above as the Acceptable Daily Dose (ADD).

population? (ie. What is the No Observed Effect Level (NOEL)?)

At what daily intake level will all people be protected by an adequate margin of safety? (ie. What is an Acceptable Daily Dose (ADD)?)

a. The EPA did not adequately consider all the known or anticipated adverse health effects of fluoride.

The RMCL for fluoride set by EPA on November 14, 1985 is designed to protect people in this country only from crippling skeletal fluorosis.[21] The Agency declined, however, to calculate an RMCL intended to prevent the occurrence of other effects, including dental fluorosis (mottling, discoloration or pitting of teeth), mutagenic effects, or carcinogenic effects. The procedure by which these effects were dismissed by EPA was unprofessional and was not in compliance with the SDWA.

1) Dental Fluorosis

The Director of the Office of Drinking Water at EPA conveyed information to the Administrator by memo showing that the effects of dental fluorosis are "potential causes of adverse psychological and behavioral problems."[22] The memo also disclosed that

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21 The EPA admits crippling skeletal fluorosis occurs in the population when daily consumption of fluoride exceeds 20 mg/day. See National Primary Drinking Water Regulations; Fluoride, 50 Fed. Reg. 220, 47144 (1985) (to be codified at 40 C.F.R. Part 141) (hereinafter referred to as "Final RMCL").

22 Memorandum from Victor J. Kimm to William D. (footnote continued)

there is anecdotal evidence of loss of tooth function and tooth mortality in adults.[23]

The evidence presented to EPA on dental fluorosis leads the health professionals of the Union to the conclusion that dental fluorosis can reasonably be anticipated to result in adverse health effects.

At EPA's request an independent panel of behavioral scientists convened to study the psychological and behavioral effects of dental fluorosis. This ad-hoc panel concluded that people who have suffered impaired dental appearance as the result of moderate to severe fluorosis are at increased risk for psychological and behavioral problems and difficulties.[24]

EPA also had evidence that a panel of experts in endocrinology, toxicology, pediatrics, bone metabolism and fluoride metabolism, convened by the Surgeon General at EPA's request, concluded that "mottling or pitting of teeth could represent as yet unknown skeletal effects in children and that severe dental fluorosis per se

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(footnote continued from previous page)
Ruckelshaus (undated) (hereinafter referred to as "Kimm Memo") (See Attachment H).

23 Kimm Memo. Another illustration of concern by Agency experts over the dental effects of fluoride is the fact that a reference dose (RfDs) for oral exposure was, in fact, calculated at a level which would protect children from dental fluorosis. See Verified Reference Doses (RfDs) of the U.S. EPA, May 13, 1986 (attached) (hereinafter referred to as "Verified Reference Doses") (See Attachment O).

24 Final RMCL at 47144.

constitutes an adverse health effect that should be prevented."[25]

Such evidence shows that dental fluorosis should, at least, "reasonably be anticipated" to be an adverse health effect of fluoride. In his memo to Ruckelshaus, Kimm acknowledged that

> a protective approach would lead to considering at least severe dental mottling as an "adverse effect."[26]

Yet EPA did not adopt a protective approach. Instead, the Agency declined to set an RMCL for fluoride which is designed to protect children from the effects of mottling, discoloration or pitting of teeth. In so doing the Administrator disregarded the unambiguous opinion of health experts and stated: "the evidence is inadequate to conclude that dental fluorosis is an adverse health effect."[27] With reference to the effects on mental health, EPA arbitrarily dismissed the advice of the panel convened at its own request and decided that "[t]here is inadequate evidence to conclude that dental fluorosis leads to psychological and behavioral effects."[28]

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25 Draft Report to the Surgeon General of the Ad Hoc Panel of the Non-Dental Health Effects of Fluoride in Drinking Water, May 26, 1983 (See Attachment I).

26 Kimm Memo.

27 Final RMCL at 47143.

28 Final RMCL at 47144.

EPA impermissibly applied a conclusive proof standard when confronted with the scientists' opinion on the psychological and behavioral effects of dental fluorosis. The Adminstrator concluded "there is not sufficient evidence that dental fluorosis does lead to any psychological or behavioral effects."[29] Thus EPA articulated its position that proof must be shown that fluorosis does lead to adverse health effects rather than may lead to adverse health effects before the Agency will consider such effect when calculating an RMCL. To require conclusive proof in setting an RMCL is to disregard the Agency's obligation under the Safe Drinking Water Act. The Act provides that the RMCL should be set to protect against "known and anticipated" adverse health effects.[30] Moreover the legislative history makes clear that "the Administrator must decide whether any adverse effects can be reasonably anticipated, even though not proved to exist."[31]

2) Non-Dental Effects

EPA was aware, as Kimm's memo to Ruckelshaus makes evident, that "many questions . . . surround the

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29 Final RMCL at 47144 (emphasis added).

30 § 1412(b)(1)(B), 42 U.S.C. § 300g-1(b)(1)(B).

31 House Report at 20 (emphasis added).

non-dental effects of fluoride."[32] As was pointed out to the Administrator:

> 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.***
>
> There are a series of potential health issues that presently are not quantifiable, but which may be fundamentally important. These include the increased susceptability (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.[33]

Nonetheless, EPA denied that these effects are associated with fluoride exposure. The following discussion provides illustration of EPA's unprofessional review with respect to two important potential adverse effects of fluoride.

a) Mutagenicity

EPA inappropriately omitted mutagenicity as a possible adverse health effect of fluoride when calculating the fluoride RMCL. The Agency declined to consider possible mutagenetic effects of fluoride because it concluded that

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32 Kimm Memo.

33 Kimm Memo.

> an unequivocal determination of the mutagenicity of fluoride cannot be made.[34]

However, as discussed above, the Safe Drinking Water Act does not permit the Agency to apply a conclusive proof standard when determining possible adverse health effects of contaminants. This standard of proof is also inconsistent with the Agency's own interpretation of the Safe Drinking Water Act. Respondents state in their brief that the Act requires EPA to regulate for effects

> 1) which, although not proved, are likely to occur in humans and 2) for which there is equivocal evidence as to whether the effect will occur in humans.[35]

The process by which EPA arrived at the conclusion that fluoride is not a mutagen is suffused with errors which demonstrate a lack of professional review on the part of the Agency. Among these errors are the following:

First, EPA used abstracts of studies in lieu of actual reports. Three out of the 18 documents[36] on

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[34] Final RMCL at 47150.

[35] Respondents' Brief at 59.

[36] EPA mentioned 21 studies in its mutagenicity discussion. However, the following three were mentioned twice: 1) Martin, G.R., Brown, K.S., Matheson, D.W., Lebowitz, H., Singer, L., Ophaug, R., "Lack of Cytogenetic Effects in Mice or Mutations in Salmonella Receiving Sodium Fluoride," Mut. Res., 66:159-157, 1979. 2) Skare, J./A., Wong, T.K., Schrotel, K.R., "Lack or Genotoxic Activity of Sodium Fluoride in an In Vitro DNA Repair Assay and an In Vivo DNA Damage Assay," Environ. Mut. 7:72 (Abstract), 1985.
(footnote continued)

mutagenicity which were cited by the Agency in the Final RMCL[37] for fluoride are abstracts.[38] As EPA has acknowledged in the Response to Comments on its proposed RMCL for fluoride,[39] an abstract "precludes a critical evaluation of these findings due to the lack of details of the experimental methodology utilized."

Second, EPA used studies that were never peer reviewed. An additional three out of the remaining 15 articles used by EPA for its mutagenicity assessment in the final RMCL were unpublished studies.[40]

(footnote continued from previous page)
3) Tsutsui, T., Suzuki, N., Ohmori, M., "Sodium Fluoride-Induced Morphological and Neoplastic Transformation, Chromosome Aberrations, Sister Chromatid Exchanges and Unscheduled DNA Synthesis in Cultured Syrian Hamster Embryo Cells," Cancer Res., 44:938-941, 1984.

37 Final RMCL at 47150-47151.

38 1) Alieve, A.A., Babaev, D.A., "Cytogenetic Activity of Vitamins in Bone Marrow Cells of Rat Femurs in Sodium Fluoride-Induced Mutation Conditions." Chem. Abs. 98:29471p, 1983. 2) Aliev, A.A., Kuligavin, A.E., Sarina, T.N., "Effect of Alpha-Tocopherol on the Level of Chromosomal Abberations Induced by Sodium Fluoride in Rat Femur Bone Marrow Cells," Chem. Abs. 96:5274j, 1982. 3) Skare, J.A., Wong, T.K., Schrotel, K.R., "Lack of Genotoxic Activity of Sodium Fluoride in an In Vitro DNA Repair Assay and an In Vivo DNA Damage Assay." Environ. Mut. 7:72 (Abstract), 1985.

39 Summary of Comments and Responses from the May 14, 1985 RMCL Proposal 101 (hereinafter referred to as "Response to Comments").

40 1) Ved Brat, S., "The Chinese Hamster Ovary Cell Sister Chromatid Exchange Assay on Sodium Fluoride," Unpublished, 1984a. 2) Tong, C., "The Human Skin Fibroblast/DNA Repair Assay on Compound Sodium Fluoride
(footnote continued)

Third, EPA used studies that were clearly deficient. Three and one half[41] of the remaining twelve studies used by EPA in reviewing mutagenicity of fluoride were clearly deficient. One aspect of a report relied on by EPA written by G.R. Martin et al.[42] utilized the results of the "Ames test" in arriving at its findings. The originator of the test (Bruce Ames) has stated that the Ames test is not appropriate for fluoride.[43] Moreover, EPA cited a study written by Kanematsu et al.[44] which it criticized in the Response to Comments document, stating "No dose-response information is provided by the authors which would allow independent evaluation and their

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(footnote continued from previous page)
Using Human Skin Fibroblast in Culture." Unpublished, 1984. 3) Williams, G.M., "Density Gradient Centrifugation to Detect DNA Repair in D550 Cells Exposed to Sodium Fluoride," Unpublished, 1984.

41 One of these studies involved two endpoints, one of which was not deficient.

42 Martin, G.R., Brown, K.S., Matheson, D.W., Lebowitz, H., Singer, L., Ophaug, R., "Lack of Cytogenetic Effects in Mice or Mutations in Salmonella Receiving Sodium Fluoride," Mut. Res., 66:159-157, 1979.

43 See Letter to Arthur Upton from Bruce Ames (Oct. 19, 1977), reprinted in The National Cancer Program (Part 2 - Fluoridation of Public Drinking Water: Hearings Before a Subcomm. of the Comm. on Government Operations, 95th Cong., 1st Sess. 243 (1977) (See Attachment J). Note that the Martin report was not deficient with respect to other tests not related to the Ames test.

44 Kanematsu, B., Hara, M., Kada, T., "Rec Assay and Mutagenicity Studies on Metal Compounds," Mut. Res., 77:109-116, 1980.

[sic] results."[45] In addition, the Slacik-Erben and Obe[46] study should not have been used by EPA because the Agency had previously stated that the study "has several serious deficiencies which make the results questionable."[47] With respect to the study by Vogel[48] EPA acknowledged that "the observations in the [Vogel 1973] study have recently been shown to be artifactual."[49] Thus, none of these studies should have been relied on by EPA.

Out of the remaining 8-1/2 studies used, the Agency has acknowledged that six reports showed fluoride to be a mutagen and 2-1/2 showed fluoride not to have mutagenic effects.[50] Certainly the evidence actually used by EPA in the Final RMCL added up to the conclusion that mutagenicity is an adverse health effect that is, at a minimum, likely to occur from fluoride consumption. To make matters worse, EPA left many important studies out of

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45 Response to Comments at 98.

46 Slacik-Erbin, R., Obe, G., "The Effect of Sodium Fluoride on DNA Synthesis, Mitotic Indicies and Chromosomal Aberrations in Human Leukocytes Treated With Trenimon in Vitro," Mut. Res., (Complete citation not given), 1976.

47 Response to Comments at 99.

48 Vogel, E., "Strong Antimutagenic Effects of Fluoride on Mutation Induction By Trenimon and 1-Phenyl-3.3-Dimethyltriazene in Drosophila Melanogaster," Mut. Res., 20:39-352, 1973.

49 Response to Comments at 99.

50 Final RMCL at 47150.

its analysis.[51] These studies were never appropriately reviewed by the Agency prior to their rejection. EPA only reviewed abstracts of the articles and went no further. As conceded by the Agency, reliance on an abstract "precludes a critical evaluation" of the study involved.[52] EPA stated that the actual studies were never reviewed because they were not available to the Agency.[53] However,

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51 See Response to Comments at 102-105, which cites articles as follows: Akundov VY, et al. 1981, Izv. Akad. Nauk Az. SSR. Ser. Biol. Nuak (4):3-5 (Full citation not available.) (not available to the Agency.); Aliev AA, Babaev DA. 1981. Tsitol Genet. 15(6):19-23 (Full citation not available.) (Not available to the Agency.); Bale SS, Hart GE. 1973. Can. J. Genetics Cytol. 15:695-702 (Full citation not available.) (Not available to the Agency.); He W, et al. 1983. Huanjing Kexue Xuebao 3(2):94-100. (Full citation not available.) (Not available to the Agency.); Jagiello G, Lin J. 1974. Archives of Environmental Health. 29:230-235. (Full citation not available.) (Not available to the Agency.); Mitchell B, Gerdes RA. 1973. Fluoride 6:113-117. (Full citation not available.) (Not available to the Agency.); Mohamad AH. 1966. Genetics Cytol. 8:575-583 (Full citation not available.) (Not available to the Agency.); Mohamad AH. 1970. Can. J. Genetics Cytol. 12:614-620 (Full citation not available.) (not available to the Agency.); Mohamad AH. 1970. Proc. 2nd Int. Clean Air Congr. (IUAPPA), Dec 1970, p. 26 (Full citation not available.) (Not available to the Agency.); Mohamed AH, et al. 1966. Can. J. Genet. Cytol. 8:241-244 (Full citation not available.) (Not available to the Agency.); Ragamova GK, et al. 1973. Izv. Akad. Nauk Az. SSR. Ser. Biol. Nauk (4):21-24 (Full citation not available.) (Not available to the Agency.).

52 Response to Comments at 101.

53 See note _____, supra.

these studies are in fact easily available through the EPA library or the Agency's literature search capability.

When the studies never properly reviewed by the Agency are added to those actually usable, 18 out of the 21-1/2 studies show that fluoride is a possible mutagen. Thus EPA was not justified in declining to include mutagenicity among the adverse health effects associated with fluoride exposure.

An examination of the studies cited in EPA's Response to Comments also reveals a striking lack of professional review by the Agency. Out of the 47 laboratory studies listed, 20 are shown to be either abstracts, not available to the Agency, or unpublished.[54] Moreover, several important studies appear to have never been looked at by the Agency. For example, an article referred to by EPA by Kanematsu, supra, was superseded by a later article showing positive mutagenicity in a more specific study.[55] In addition, EPA failed to acknowledge that a study relied on by it to show negative effects of fluoride on sister chromatid exchange, also concluded that fluoride caused isochromatid gaps and chromosome breaks.[56]

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54 Response to Comments at 102-105.

55 Kanematsu, B., Japanese Journal of Oral Biology, 27:372-374, 1985. "Genetic Toxicity of Bio-Materials 2. DNA Damage Effects of Sodium Fluoride and Other Fluoride Compounds."

56 Kishi, K., Tonomura, A., "Mutagenicity of Sodium
(footnote continued)

b) Carcinogenicity

The Agency's decision not to consider carcinogenic effects of fluoride when calculating the fluoride RMCL was inappropriate. As EPA acknowledged in issuing its final RMCL[57], eleven out of thirteen papers it considered when assessing the cancer risk of fluoride concluded that fluoride is oncogenic. The Agency relied solely on one report, however, in concluding that

> there is not adequate information to conclude that fluoride presents a cancer risk to humans.[58]

EPA never adequately dealt with the eleven studies showing that fluoride is oncogenic. Among the studies which were ignored is a paper showing that fruit flies treated with fluoride had an increased occurrence of cancer.[59] This study was funded by the National Cancer Institute and was conducted by a leading geneticist in the United States who is also an author of several textbooks on genetics. EPA dismissed the findings of this report by concluding that the relevance of data showing incidence of

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(footnote continued from previous page)
Fluoride (NaF) - Review and Human Lymphocyte Assay." Husso Kenkyu 5:35-41, 1984.

57 Final RMCL at 47150.

58 Final RMCL at 47150.

59 Herkowitz, I.H., Norton, I.L., "Increased Incidence of Melanotic Tumors in Two Strains of Drosophila Melanogaster Following Treatment with Sodium Fluoride," Genetics, 48:307-310, 1963.

melanotic tumors in fruit flies as a result of sodium fluoride "has not been scientifically determined."[60] This blanket dismissal of the findings of Herskowitz and Norton is inconsistent with the protective nature of an RMCL and displays a lack of professional review. Certainly the fact that sodium fluoride produced melanotic tumors in fruit flies is not insignificant. A professional charged with assessing human cancer risk of a substance should deem such data relevant enough to produce concern.

Another paper demonstrated an increase in tumor growth in mice who received 1/2 to 1 ppm of fluoride in their drinking water.[61] EPA summarily dismissed these findings and stated that since independent statistical analysis of this data demonstrated that the effects were not dose-related, it was suggested that the effects of this study were not related to the administration of sodium fluoride after all.[62] As a scientific or purely logical matter, however, the fact that the test data do not show a dose-response relationship, does not preclude the possibility that the effect stemmed from the substance administered. Thus EPA's objection to such study does not

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60 Response to Comments at 62.

61 Taylor, A.., Taylor, N.C., "Effect of Sodium Fluoride on Tumor Growth," Proc. Soc. Exp. Biol. Med., 119:252-255. 1965.

62 Response to Comments at 62.

suffice to dismiss its implications in light of the protective purpose of an RMCL.

Still another study suggested that fluoridation of drinking water supplies is responsible for 10,000 to 20,000 excess cancer deaths per year in the United States.[63] EPA inaccurately rebutted the findings of this study by citing Oldham and Newell[64] as a valid criticism of the report.[65] As NFFE has pointed out to the Agency, "The Oldham and Newell study was, however, published one month before the Yiamouyiannis and Burke study and referred to their previous work published in 1975."[66] A report by Strassburg and Greenland[67] is also cited as a criticism. As the Union has previously informed the Agency, the latter article "contained no reference to the Yiamouyiannis and Burke study of 1977."[68]

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63 Yiamouyiannis, J., Burke, D., "Fluoridation and Cancer: Age-Dependency of Cancer Mortality Related to Artificial Fluoridation," Fluoride, 10:102-125, 1977.

64 Oldham, P.D., Newell, D.J., "Fluoridation of Water Supplies and Cancer - A Possible Association?" Appl. Stat. 26:125-135, 1977.

65 Response to Comments at 59.

66 Letter from Robert J. Carton to Michael R. Cook (undated).

67 Strassburg, M.A., Greenland, S., "Methodological Problems In Evaluating the Carcinogenic Risk of Environmental Agents." J. Environ. Health 41:214-217, 1979.

68 Letter from Robert J. Carton to Michael R. Cook (undated).

Finally, one study not used by EPA, by Duffey et al., which appeared in a well respected medical journal, reported that a human patient on sodium fluoride therapy for osteoporosis was found to have giant cells in her bone marrow "suggestive of a reticuloendothelial malignancy . . . . "[69] By way of response to NFFE's objection to the omission of the latter report, the Director of the Office of Drinking Water stated by letter that the Duffey report "is not concerned with cancer or tumor growth."[70] The first page of the article (attached) contains the following sentence:

> A few giant monocytoid cells, suggestive of a reticuloendothelial malignancy were discovered.

Once again the lack of professional review is evident.

b. EPA did not conduct a professional review of the available literature on crippling skeletal fluorosis.

EPA's brief contends that in establishing the RMCL, the Agency "carefully evaluated all the available health evidence relating to skeletal fluorosis."[71] Among the evidence which was not included in this review was a large body of epidemiological research on the skeletal

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69 Duffey, P.H., Tretbar, H.C., Jarkowski, T.L., "Giant Cells in Bone Marrows of Patients on High-Dose Fluoride Treatments," Annals of Internal Medicine, 75:745-747, 1971 (See Attachment K).

70 Letter from Michael B. Cook to Robert J. Carton (Feb. 6, 1986) (See Attachment L).

71 Respondents' Brief at 32.

effects of fluoride in India.[72] As an indication of what EPA had access to but ignored in the rulemaking, a small sample of the extensive Indian epidemiological literature on skeletal fluorosis, which the Agency never cited, is listed at Attachment M. Although EPA asserts that there are only "four studies associating fluoride in drinking water with drippling skeletal fluorosis in India"[73], nine of the Indian studies listed in Attachment M document severe and crippling skeletal fluorosis, with symptoms including rigidity of the spine and joints, inability to close cysts, and crippling deformities. Two of the studies that show severe and crippling skeletal fluorosis are appended to this brief as Attachment N.

c. EPA did not consider the most susceptible individuals when calculating the No Observed Effect Level of crippling skeletal fluorosis.

The Safe Drinking Water Act requires that in setting an RMCL the Administrator must consider "the existence of groups or individuals in the population which

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[72] More than one million people in India are afflicted with various stages of skeletal fluorosis. The maximum permissible level for fluoride in drinking water in India is 1.0 ppm: at least one team of Indian experts on skeletal fluorosis has called for lowering the limit to 0.5 ppm, because, in its view, 1.0 ppm poses an unreasonable risk of skeletal fluorosis. See Teotia, S.P.S. and Teotia, M., "Endemic Fluorosis in India: A Challenging National Health Problem," Fluoride 18-2:125-127, at 125, 1985 (Abstracted from J. Assoc. of Physicians of India, 32:347-52, 1984).

[73] Respondents' Brief at 38.

are more susceptible to adverse effects than the normal healthy adult."[74] The legislative history of the Act states that in calculating the RMCL for a substance even the most sensitive individuals in the population are to receive the protection of an adequate margin of safety. "The incorporation of an adequate margin of safety is not to be confused with the anticipation of adverse health effects."[75] Thus, Congress contemplated a "three-step process".

> First, the known adverse health effects of contaminants are to be compiled.
>
> Second, the Administrator must decide whether any adverse effects can be reasonably anticipated, even though not proved to exist. It is at this point that the Administrator must consider the possible impact of . . . the existence of more susceptible groups in the population.
>
> Finally, the recommended maximum level must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at the zero level.[76]

In order to ensure that all members of the population are protected by a margin of safety it is necessary to determine first the figure at which even the most sensitive persons will not suffer any adverse effects

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74 § 1412(e)(3), 42 U.S.C. 300g-1(e)(3).

75 House Report at 20 (emphasis added).

76 House Report at 20.

(the No Observed Effect Level - or NOEL) before determining what margin of safety should apply to that figure.[77] EPA did not do this calculation in order to arrive at the Acceptable Daily Dose for fluoride. In fact, the Agency never considered sensitive individuals in calculating the fluoride RMCL.

EPA set the NOEL at 20 mg/day and stated: "Crippling skeletal fluorosis is an adverse health effect which results from intakes of fluoride at 20 mg/day over periods of 20 years or more."[78] By the Agency's own admission, this figure is too high. EPA acknowledged that crippling skeletal flourosis has been observed in the United States where daily consumption of fluoride was somewhere between 14.4 and 21 mg.[79] EPA also boldly stated:

> The Agency agrees that certain segments of the general population may be at increased risk from waterborne fluoride.[80]

Thus EPA set the Acceptable Daily Dose at a level at which it knew adverse effects would occur.

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77 This margin of safety is applied in order to compensate for uncertainty in the data.

78 Final RMCL at 47144.

79 "[C]rippling skeletal fluorosis was noted in both a 55 year old male and a 64 year old male. . . . The amount of water consumed is estimated by the EPA to be 6 L per day containing . . . somewhere between 2.4 and 3.5 mg flouride/L in one case . . . ." Final RMCL at 47147.

80 Final RMCL at 47151.

d. EPA did not determine an ADD for susceptible individuals with an adequate margin of safety.

The Administrator belied the mandate of the SDWA when it stated

> The Agency feels that this RMCL provides an adequate margin of safety except in those very extreme cases involving severely renally impaired individuals . . . .[81]

The Agency repeatedly cites the fact that "only two" cases of crippling skeletal flourosis have been observed in this country to support its conclusion that "the population at risk at 4 mg/L is negligible."[82] However, the statute requires that the RMCL be set at a level where no adverse effects occur, allowing for an adequate margin of safety.

EPA stated in the Response to Comments that "a safety factor of 2.5 will provide protection against crippling skeletal fluorosis with 'an adequate margin of safety.'"[83] The Agency does not show how this factor was used in any calculation. The reason for this failure is obvious if the arithmetic is done. A safety factor of 2.5 applied to the 20 mg figure (after which adverse health affects are said to occur) results in an Acceptable Daily

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81 Final RMCL at 47152.

82 Final RMCL at 47144 and 47151.

83 Response to Comments at 11.

Dose of 8 mg/day.[84] This means that at the RMCL of 4 mg/liter, the ADD (which incorporates the safety factor) will be exceeded by anyone drinking over 2 liters per day at the RMCL, without even considering the concentration of fluoride from other sources.

2. EPA did not properly calculate the RMCL

Once the ADD is ascertained it then becomes necessary to determine the RMCL - namely: What is the maximum amount of the substance that should be allowed in drinking water to ensure that no one will ingest more than the ADD from a combination of drinking water and all other sources?

Several important questions must be answered before this assessment can be made. Among these are the following:

> What is the maximum amount of the substance a person might be expected to ingest from sources other than drinking water?
>
> What is the maximum amount of drinking water a person might be expected to consume per day?

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[84] Moreover, EPA scientists have concluded that "0.12 mg fluoride/kg/day is a safe exposure level for [crippling skeletal fluorosis]." For a 70 kg adult, this level amounts to 8.4 mg/day. See Verified Reference Doses at 2.

a. The Administrator did not incorporate any figures to reflect exposure to fluoride from sources other than drinking water.

As the Administrator acknowledged,[85] fluoride is found in virtually all foods. It is also contained in many toothpastes and occurs in unusually high concentrations in tea and fish.

One of the reports considered by the EPA in calculating the fluoride RMCL concludes:

> Certain foodstuffs and beverages are rich in fluoride; e.g. sardines, tea. A 50 gram portion of canned sardines could contribute 0.8 mg fluoride; in Britain particularly, many people receive more than 1 mg fluoride daily from drinking tea.[86]

Moreover, the National Research Council of Canada reported that British teenagers have an estimated mean daily intake of fluoride from toothpaste of .32 mg with "an extreme high of 5.0 mg."[87] The Council recommended that estimates of fluoride intakes by adults in North America from foods should approximate 1.5 to 2.75 mg/day. "Such estimates

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85 Final RMCL at 47145.

86 Smith, G.E., "A Surfeit of Fluoride," Sci. Prog. Oxf. 69:429, 432 (1985).

87 National Research Council of Canada, NRC Associate Committee on Scientific Criteria for Environmental Quality, "Environmental Fluoride, 1977," page 79 (hereinafter referred to as "Canadian Report").

should include the caution that these intakes may be exceeded by . . . copious tea drinkers . . ."[88]

In order to properly decide on a figure which represents the contribution of fluoride from nondrinking water sources, it is necessary to (a) determine the maximum amount of fluoride found in each source, (b) determine the maximum amounts of each source that are being ingested by people in the United States and (c) calculate the total contribution from these sources. However, the EPA did not include these determinations in its calculation of the fluoride RMCL.

Notwithstanding the existence of outside sources of fluoride, as well as wide variations of intake from such sources in the population (due to variations in diet, income and personal habits), the EPA failed to incorporate such data into its calculation of the fluoride RMCL. The Administrator simply concluded

> while food can be a significant source of fluoride in unusual cases, the Agency believes that it is unnecessary to adjust the RMCL because of dietary exposure.[89]

At the same time, the EPA acknowledged "it is estimated that the development of crippling skeletal

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88 Canadian Report at 83.

89 Final RMCL at 47145.

fluorosis requires the daily consumption of 20 mg or more of fluoride from all sources for 20 or more years."[90]

The Agency's failure to adjust for non-drinking water sources is improper and is not in conformance with the mandate of the Act. The statute makes clear that EPA must include an evaluation of exposure to a contaminant in media other than drinking water in calculating an appropriate RMCL.[91] "[T]he Administrator must consider the possible impact of . . . multi-media exposures."[92] The failure to incorporate data for contribution from other sources also runs afoul of the Agency's own statement of appropriate procedure. EPA has stated:

> To determine the RMCL, the contribution from other sources of exposure, including air and food, should be taken into account.
>
> When sufficient data are available on the relative contribution of other sources, the RMCL is determined as follows: RMCL = (AADI) - (contribution from food) - (contribution from air).[93]

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90 National Primary Drinking Water Regulations: Fluoride, 50 Fed. Reg. 93, 20170 (1985) (to be codified at 40 C.F.R. Part 141) (proposed May 14, 1985).

91 Section 1412(e)(3), § 300g-1(e)(3).

92 House Report at 20.

93 National Primary Drinking Water Regulations; Synthetic Organic Chemicals, Inorganic Chemicals and Microorganisms; Proposed Rule, 50 Fed. Reg. 219, 46946 (1985) (to be codified at 40 C.F.R. Part 141) (proposed Nov. 13, 1985).

Even assuming that the Agency is correct in using 20 mg/day as the figure below which no adverse health effects will result[94], and in using a safety factor of 2.5,[95] the RMCL has been set too high. Using EPA's own equation, and assuming a fluoride contribution from other sources at 2.4, anyone drinking over 1.4 liters/day at the RMCL will be consuming more than the Acceptable Daily Dose of Fluoride.

b. EPA failed to take into account all members of the population when calculating drinking water intake figures.

In order to satisfy its obligation to come up with an RMCL which ensures "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" the RMCL must be designed to protect all members of the population. Thus it is necessary to calculate drinking water intake figures on the basis of the maximum amount of water an individual could be expected to consume.

As EPA acknowledges, the drinking water intake figure of 2 liters per day, on which the fluoride RMCL is based, does not represent the maximum intake level in the

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94 This assumption has been criticized at pg. 31-34.

95 This margin of safety has been criticized at pg. 34-35.

population, but what EPA believes to be the "average" amount of water consumption.[96] EPA also states that

> over 95% of the population are believed to consume 4 liters per day or less, over 99% of the population are believed to consume 5.5 liters or less.[97]

These figures are based on an internal memo from Paul S. Price, to Arthur H. Perler, dated March 4, 1985. The Price memo gives the results of a Tolerance Assessment System (TAS) survey of water consumption patterns in the population. The tables from this survey, reprinted in the Price memo, show that approximately 50% of adult males in the population drink more than two liters a day. In fact, one out of every one hundred males consumes over 5.52 liters per day.[98] Nonetheless, EPA concluded that it need not consider individuals who consumed more than the "average" amount of water when calculating the RMCL.[99]

In utilizing a figure which it believes represents the average drinking water intake of the population to compute the RMCL for fluoride, the EPA has

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96 Final RMCL at 47147.

97 Final RMCL at 47147.

98 Memorandum from Paul S. Price to Arthur H. Perler (Nov. 12, 1985). EPA acknowledged elsewhere that there had been at least two cases reported in the United States of daily water intake of 6 liters/day. See Final RMCL at 47147.

99 "EPA does not believe that the SDWA requires protection by national regulation of persons who, through unusual practices, may put themselves at risk." Final RMCL 47178.

failed to follow the requirements of the statute. The statute provides that the RMCL will be set at a level at which no adverse health effects occur. This scheme requires that all people in the population be protected with an adequate margin of safety. However, EPA calculated the RMCL for fluoride on the basis of a water consumption figure which it acknowledges is inaccurate for half of the adult males in the population.

It is inappropriate to dismiss this error, as EPA tries to do, by claiming that persons drinking more than two liters per day are protected by the margin of safety.[100] To do so is to commit just the type of error which Congress warned against:

> The incorporation of an adequate margin of safety is not to be confused with the anticipation of adverse health effects.[101]

Once again, by plugging appropriate figures into EPA's own equation, the inadequacy of the RMCL becomes obvious. One out of every one hundred males in the population who drink water at the RMCL of 4 mg/liter will be ingesting over 22 mg of fluoride from drinking water alone, not even including the estimated 2.4 mg per day they will consume from outside sources. Thus the total

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100 EPA justifies its RMCL by stating "The Agency believes that the margin of safety is adequate for these persons based on lack of detection of crippling skeletal flourosis in any significant portion of the population." Final RMCL at 47148.

101 House Report at 20.

daily consumption of fluoride from all sources for these men will be over 24.4 mg, a level at which adverse health effects are said to occur, and an amount which is more than three times the level EPA has determined to be an Acceptable Daily Dose.[102]

3. EPA impermissibly applied feasibility and political considerations when calculating the RMCL for fluoride.

The SDWA requires that RMCLs be based purely on considerations of health. However, a memo from the Director of the Office of Drinking Water to the Administrator of EPA shows that the determination of the fluoride RMCL by the Agency was imbued with political and feasibility concerns.[103]

The memo requests guidance on whether dental fluorosis is to be considered an adverse health effect of fluoride in light of the determination of an ad-hoc panel of behavioral scientists that mental health problems could be expected due to dental fluorosis.

The memo presents three options to the Administrator:

1. Conclude that no adverse health effects occur from fluoride exposure and drop the MCL; list as a secondary standard and perhaps require monitoring and public notification.

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102 See pg. 34-35, supra.

103 Kimm Memo.

2. Conclude that crippling skeletal flourosis is the adverse health effect and set the RMCL.

3. Conclude that moderate and severe dental fluorosis is an adverse health effect and set the RMCL.

Significantly, the memo also includes a breakdown of the "Impacts" of these alternatives. One table attached discusses the cost implications at various configurations of the RMCL and MCL. Another attached table discusses the "Legal Challenge Potential" at several different levels of RMCL and MCL.

What this memo shows is that in setting the RMCL for fluoride, EPA did precisely that which Congress had directed it should not do -- it applied considerations other than those required for the protection of public health. The legislature did not mean for the RMCL and MCL to be considered together. Its mandate was that the process by which each standard was set should be distinct.

> In the Committee's view, the question of what is necessary for adequate protection of the public health is and ought to be considered <u>separately</u> from the question of what degree of contaminant control is technologically or economically feasible.[104]

As is evident by the above-mentioned memo, the Administrator's decision to set the flouride RMCL at 4.0 mg/liter was made for reasons expressly prohibited by the statute.

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104 House Report at 18-19.

IV. CONCLUSION

For the reasons stated above, the Agency's decision to establish the RMCL for fluoride at 4mg/L should be reversed and the matter remanded with a directive to the Agency to set a new RMCL in a manner consistent with its statutory duties.

Respectfully submitted,

John J. Loflin
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