



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUL 18 1984

OFFICE OF  
GENERAL COUNSEL

MEMORANDUM

TO: Victor J. Kimm  
Director  
Office of Drinking Water (WH-565)

FROM: Kenneth F. Gray *Ken Gray*  
Attorney

THRU: Colburn T. Cherney *CTC*  
Associate General Counsel  
Water Division (LE-132W)

SUBJECT: Definition of Adverse Health Effect

In recent briefings concerning regulation of fluoride under the Safe Drinking Water Act (SDWA), the question arose whether there was legislative history or case law defining "adverse health effect." This question arose because the Office of Drinking Water is considering regulating fluoride to prevent dental mottling and pitting. 1/ The Surgeon General and others believe that mottling and pitting are only cosmetic and are not adverse health effects.

As discussed below, there is no legislative history or case law which provide criteria for determining which effects should be considered adverse health effects. However, cases addressing regulation of adverse health effects under other statutes provide examples of adverse health effects and establish that the Administrator is granted substantial discretion in determining whether an effect is adverse to health.

1/ Mottling and pitting do not result in loss of tooth function or tooth mortality. I understand that the evidence is mixed as to whether fluoride at these levels may lead to an increase in dental caries. There is anecdotal evidence to suggest that fluoride may cause cracked or broken teeth due to increased brittleness.

Discussion

The SDWA authorizes EPA to set recommended maximum contaminant levels (RMCL's) at a level at which, in the Administrator's judgment, no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. Section 1412; 42 U.S.C. §300g-1. RMCL's are to be set as a prelude to promulgating revised "Primary Drinking Water Regulations" which are to control "contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons." Section 1401, 42 U.S.C. §300f. The Act itself does not further clarify or define the terms "adverse effect" or "health."

The Administrator is also authorized to promulgate "Secondary Drinking Water Regulations" which are, in his judgment, "requisite to protect public welfare." Sections 1401(2) and 1412(c); 42 U.S.C. §§300f(2) and 300g-1(c). These MCL's are to be established for contaminants (1) that affect the odor or appearance of water and which may cause a substantial number of persons to discontinue its use or (2) that otherwise adversely affect the public welfare. These regulations are non-enforceable federal "recommendations;" states need not adopt or enforce these requirements. Thus, the Act authorizes two distinct types of limits on contaminants: "Primary" regulations directed at contaminants causing "adverse effects" on "health" and "Secondary" regulations (unenforceable) aimed at contaminants affecting "public welfare." The statute allows both Primary and Secondary Drinking Water Regulations for a contaminant, if justified by the contaminant's effects.

Congress provided examples of adverse health effects in its general discussion of the problems that EPA was expected to control under the Act. For example, Congress was significantly concerned about disease, poisoning, and cancer-causing agents. Statement of Rep. Staggers, Nov. 19, 1974, House Debate on H.R. 13002, reprinted in A LEGISLATIVE HIST. OF THE SAFE DRINKING WATER ACT at 647 (hereafter LEGISLATIVE HISTORY) (1982). These examples were not intended to be inclusive and are therefore not particularly helpful in drawing a clear line between what is and is not an adverse health effect. Congress did make clear that uncertainties regarding health effects were to be resolved on the side of protection of health. Statement of Rep. Rogers, Nov. 19, 1974, House Debate on H.R. 13002, LEGISLATIVE HISTORY at 652-53. The Administrator is only required to make a reasoned and plausible judgment that contaminants may have adverse health effects, not that they will cause such effects. H.R. Rep. No. 93-1185, 93d Cong., 2d Sess. (1974), LEGISLATIVE HISTORY at 542 (emphasis in original). Because Congress has not defined adverse health effect but has called on the Administrator to exercise his judgment, any reasonable interpretation of the term as it applies to fluoride will be

given deference by the courts. Chevron U.S.A., Inc. v. Natural Resources Defense Council, 52 U.S.L.W. 4845, 4847 (U.S. June 25, 1984).

The only case that construes EPA's authority to promulgate Drinking Water Regulations provides little guidance on the issue of defining "adverse health effect." In Environmental Defense Fund v. Costle, 578 F.2d 337 (D.C. Cir. 1978), the D.C. Court of Appeals reviewed Primary Drinking Water Regulations for several contaminants, including fluoride. In its review of EPA's authorities, the court noted that Congress contemplated regulation of contaminants identified as "possibly injurious to health." Id. at 344. Although the Environmental Defense Fund sought a more stringent maximum contaminant level on fluoride, the court approved EPA's regulations. However, the court stated in a footnote:

There is serious question as to whether mottling can be regarded as an "adverse effect on health" within the meaning of the Act. See, e.g., HEW letter of June 4, 1973, to EPA at 2. "We believe that in the context of discussing limits to avoid concentrations of substances that may be hazardous to health, dental fluorosis should not be termed harmful. The more severe dental fluorosis caused by highly excessive concentrations is described in the literature as unesthetic, cosmetically objectionable, or disfiguring, but is not described as hazardous to health."

Id. at 347, n. 35. This "serious question" was not addressed by the parties or resolved by the court.

We have discovered no cases under federal statutes which have directly addressed the question of whether specific effects are "adverse" health effects or "health" effects. However, there are cases decided under the Clean Air Act which address the issue of the Administrator's discretion in regulating adverse health effects.

In Lead Industries Association v. Environmental Protection Agency, 647 F.2d 1130 (D.C. Cir. 1980), the court reviewed a challenge to EPA's lead standards which were promulgated under section 109(b)(1) of the Clean Air Act. These Clean Air Act standards are to be set at levels which, in the "judgment of the Administrator," are "requisite to protect the public health" allowing an "adequate margin of safety." Clean Air Act §109(b)(1); 42 U.S.C. §7409(b)(1). The legislative history of the Air Act explains that this standard is to ensure that the public is protected from "adverse health effects." This standard is similar to the Safe Drinking Water Act standard for RMCL's.

The Lead Industries Association challenged the Administrator's finding that blood lead levels of 30 ug Pb/dl were significant enough to be considered an adverse health effect. EPA relied on studies that showed that at levels of 30 ug Pb/dl there was some indication of physiological impairment (only mild hematological effects). Serious effects--anemia and central nervous system deficits--appeared at levels of 40-50 ug Pb/dl and above. The court upheld EPA's determination of 30 ug Pb/dl as an appropriate level for regulation.

The Lead Industries Association argued that the statute only permitted regulation on a showing that the effects were "clearly harmful or clearly adverse" and only if there is a "medical consensus that [the effects. . .] are harmful. . ." *Id.* at 1154 (emphasis in original). They argued that only anemia and central nervous system deficits were adverse health effects. The court rejected all of these positions. While the court admitted that effects at the lower level were not "identifiable as a sign of disease," the effects were found to be a lead-related interference with basic biological functions (the production of blood). The court noted that the Administrator had been instructed in the statute to use his judgment to determine which levels and effects were harmful to health.

This view of the Administrator's discretion under the Clean Air Act was endorsed in American Petroleum Institute v. Costle, 665 F.2d 1176 (D.C. Cir. 1981), where the court upheld the Administrator's regulation of low levels of ozone as they disrupted normal body functions (causing respiratory effects), even though the Administrator acknowledged that a clear threshold of adverse health effects could not be identified. *Id.* at 1185.

The facts of Lead Industries and American Petroleum do not brightly illuminate a line beyond which effects should be considered adverse to health. Rather, they are properly read as examples of effects that have been considered adverse. <sup>2/</sup> Together, they illustrate the deference that the Administrator is given in exercising his judgment to protect health.

There would be some risks with adopting the position that mottling and pitting of teeth are adverse health effects. The SDWA clearly contemplates two types of standards: one

<sup>2/</sup> A brief search of state statutory and case law was not enlightening, primarily because any such law has no direct bearing on the proper interpretation of federal law. There is a substantial body of case law indicating that "cosmetic" injury or psychological harm is compensable in tort actions. However, the fact that an effect is compensable does not necessarily indicate that it is an "adverse health effect."

based on adverse health effects and the other on effects on public welfare. A good argument can be made that "cosmetic" effects are precisely those intended to be regulated under the latter (unenforceable) regime. 3/ This is the position of the Surgeon General, the American Medical Association, the American Dental Association, and several states. Although the court must look to the Agency with responsibility for implementing the Act -- EPA -- it is unlikely to ignore entirely the views of the Surgeon General. On balance, I believe that a Primary regulation to control the dental effects of fluoride would be upheld because of the substantial deference accorded the Administrator in defining adverse health effects.

3/ Of course, this argument is undermined if the evidence showing dental caries and cracking of teeth is persuasive, or if it is demonstrated that the "cosmetic" effects lead to adverse psychological effects.