United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 11, 2000 Decided March 31, 2000

No. 98-1627

Chlorine Chemistry Council and
Chemical Manufacturers Association,
Petitioners

v.

Environmental Protection Agency,
Respondent

Natural Resources Defense Council, et al.,
Intervenors

Consolidated with
99-1053, 99-1056

On Petitions for Review of an Order of the
Environmental Protection Agency

Thomas Richichi argued the cause for petitioners Chlorine Chemistry Council, et al. and supporting intervenor Society of

the Plastics Industry, Inc. With him on the briefs were Kathryn Y. Aspegren, David F. Zoll, Katherine L. Rhyne, Paul D. Clement, Richard S. Wasserstrom, Jerome H. Heckman, Peter L. de la Cruz and Komal J. Hershberg.

John F. Cooney and Brock Landry were on the brief for amicus curiae Public Health Scientists.

Karen L. Egbert, Attorney, U.S. Department of Justice, argued the cause for respondent. With her on the brief were Lois J. Schiffer, Assistant Attorney General, and Karen H. Clark, Attorney, U.S. Environmental Protection Agency. Christopher S. Vaden, Attorney, U.S. Department of Justice, entered an appearance.

Alan Charles Raul and David M. Levy were on the brief for amici curiae Congressman Tom Bliley.

Erik D. Olson was on the brief for intervenors Natural Resources Defense Council and Physicians for Social Responsibility.

Before: Silberman, Williams and Ginsburg, Circuit Judges.

Opinion for the Court filed by Circuit Judge Williams.

Williams, Circuit Judge: The Safe Drinking Water Act ("SDWA" or the "Act") directs the Environmental Protection Agency to set standards for the regulation of covered drinking water contaminants. For each EPA sets a "maximum contaminant level goal" ("MCLG"), defined as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 U.S.C. s 300g-1(b)(4)(A). The MCLG is somewhat aspirational. After having set it, EPA is to promulgate an enforceable standard, known as a maximum contaminant level ("MCL"), which takes practical considerations into account while remaining "as close to the [MCLG] as is feasible." Id. s 300g-1(b)(4)(B).

In March 1998 EPA concluded that chloroform, a drinking water contaminant, exhibits a "nonlinear mode of carcinogenic action." Notice of Data Availability: National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts, 63 Fed. Reg. 15,674, 15,686/1 (1998). In other words, exposures to chloroform below some threshold level pose no risk of cancer. But in promulgating the MCLG it retained the existing standard of zero, which was based on the previously held assumption that there was no safe threshold. Final Rule: National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts, 63 Fed. Reg. 69,390, 69,398/3 (1998) ("Final Rule"). EPA justified its action on a variety of grounds, including an alleged need to consult the report of its Science Advisory Board ("SAB"), which would not be available until after the statutory deadline for rulemaking had expired. Petitioners, including the Chlorine Chemistry Council, a trade association comprised of chlorine and chlorine product manufacturers, petitioned this court for review, arguing that EPA violated its statutory

mandate to use the "best available" evidence when implementing the provisions of the Safe Drinking Water Act. 42 U.S.C. s 300g-1(b)(3)(A). We agree.

* * *

Chloroform, a "nonflammable, colorless liquid," Proposed Rule: National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts, 59 Fed. Reg. 38,668, 38,694/2 (1994), is one of four compounds that together are classed as "Total Trihalomethanes" ("TTHMs"). These are byproducts of chlorination, the most widely used technique for ensuring the safety of drinking water. Chlorination plays a significant role in the control of microbial pathogens and in turn in the protection of public health; but on the basis of rodent tumor data the Agency has concluded that chloroform, a byproduct of this process, acts as a probable human carcinogen. Id. at 38,697/2.

On July 29, 1994 EPA issued a proposed rule on disinfectants and disinfection byproducts in water. This included a zero MCLG for chloroform, based on EPA's finding of an absence of data to suggest a threshold level below which there would be no potential carcinogenic effects. Id. The Agency's

default method of inferring risk at exposure levels for which it has no adequate data is linear extrapolation from cancer incidence inferred at exposures for which it does have data. See EPA's Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,968/3 (1996). Thus, either if the evidence supports linearity, or if there is "insufficient" evidence of nonlinearity, EPA assumes that if a substance causes cancer at any exposure it will do so at every non-zero exposure (though with cancer incidence declining with exposure). But EPA acknowledges its authority "to establish nonzero MCLGs for carcinogens if the scientific evidence" indicates that a "safe threshold" exists. See Final Rule, 63 Fed. Reg. at 69,401/2. And petitioners here assume the validity of the linear default assumption.

In 1996 Congress amended the SDWA, enshrining in the statute a timetable previously set by EPA for rules relating to disinfectants and disinfection byproducts associated with water treatment. 42 U.S.C. s 300g-1(b)(2)(C); Proposed Rule: National Primary Drinking Water Regulations: Monitoring Requirements for Public Drinking Water Supplies, 59 Fed. Reg. 6332, 6361 (1994). The relevant deadline here was November 1998. In preparation for the necessary rulemaking EPA formed an advisory group in 1997 whose purpose was "to collect, share, and analyze new information and data, as well as to build consensus on the regulatory implications of this new information." Notice of Data Availability: National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment Rule, 62 Fed. Reg. 59,486, 59,491/1 (1997).

On the basis of the committee's findings and recommendations, EPA in November 1997 published a Notice of Data Availability ("NODA"), 62 Fed. Reg. 59,388 (1997), and in 1998 it published a second NODA specific to chloroform, 63 Fed. Reg. 15,674 (1998). Among the findings it discussed were those arrived at by a panel of experts organized by the International Life Sciences Institute. The panel, whose work was subject to independent peer review and was convened under the auspices of the EPA, concluded on the basis of chloroform's mode of action that although it was "a likely

carcinogen to humans above a certain dose range, [it was] unlikely to be carcinogenic below a certain dose range." Id. at 15,685/1. The panel recommended "the nonlinear [ ] or margin of exposure approach [as] the preferred approach to quantifying the cancer risk associated with chloroform exposure." Id. at 15,686/1.

EPA agreed. It said that "[a]lthough the precise mechanism of chloroform carcinogenicity is not established," nevertheless "the chloroform dose-response should be considered nonlinear." Id. at 15,685/3. Rather than operating through effects on DNA, which is consistent with linearity, chloroform evidently works through "cytotoxicity" (i.e., damage to the cells) followed by regenerative cell proliferation. Id. Employing the threshold approach that it found was entailed by chloroform's mode of action, EPA then calculated an MCLG of 600 parts per billion ("ppb"), based solely on carcinogenicity. Id. at 15,686/2. This level built in a 1000-fold margin of error in relation to the maximum safe dosage implied from the animal studies used by EPA. Id. But because even lower chlorine doses cause liver toxicity (a non-cancer effect), EPA proposed an MCLG of 300 ppb. Id.

When EPA came to promulgate its final rule in December 1998, however, its MCLG was again zero. Final Rule, 63 Fed. Reg. at 69,398/3. It stuck with 1994's zero level despite its explicit statement that it now "believe[d] that the underlying science for using a nonlinear extrapolation approach to evaluate the carcinogenic risk from chloroform is well founded." Id. at 69,401/1. It justified the action on the basis that "additional deliberations with the Agency's SAB on the analytical approach used" and on the underlying scientific evidence were needed "prior to departing from a long-held EPA policy." Id. at 69,399-69,401. It could not complete such additional deliberations by the November 1998 statutory deadline, and, moreover, the rulemaking would not affect the enforceable MCL for TTHMs.

After briefing on the petition for review at issue here, but before oral argument, EPA moved for a voluntary remand to consider the SAB report on chloroform that would soon be

available. But EPA made no offer to vacate the rule; thus EPA's proposal would have left petitioners subject to a rule they claimed was invalid. We denied the motion.

On February 11, 2000, the day of oral argument, EPA released a draft report by the SAB on chloroform. See Draft, Chloroform Risk Assessment Review, February 10, 2000 (visited March 27, 2000) <http: //www.epa.gov/science1/chlod00x.pdf>. The report concluded that chloroform exhibits a "cytotoxic" mode of action. Such a mode of action (unlike a "genotoxic" mechanism, which acts directly on a cell's DNA) involves no carcinogenic effects at low doses; thus a nonlinear approach is "scientifically reasonable." Id. at 17. After consideration of the draft SAB report, EPA stated that it "no longer believes that it should continue to defend its original decision," and moved that this court vacate the MCLG. Motion for Vacatur, at 2 (February 24, 2000).

* * *

EPA in its motion to vacate concedes that "the discussion on standing at oral argument indicates that petitioners may indeed meet minimum requirements for standing," a necessary precursor to our providing any relief beyond the vacatur proposed by EPA. Given our independent duty to be sure of our jurisdiction, Floyd v. District of Columbia, 129 F.3d 152, 155 (D.C. Cir. 1997), we address EPA's now evidently abandoned jurisdictional arguments.

EPA's brief contends that petitioners lack Article III standing because they have not demonstrated injury-in-fact from the MCLG. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992). We have already held, in International Fabricare Inst. v. EPA, 972 F.2d 384, 390 (D.C. Cir. 1992), that an association of dry cleaning businesses had standing to attack EPA's setting of a zero MCLG for a contaminant used in their business. There we pointed to the MCLG's link to risks of "greater liability under the Comprehensive Environmental Response, Compensation and Liability Act ('CERCLA'), 42 U.S.C. ss 9601-9675," id., which under some circumstances may entail remedial action achieving "a level or

standard of control which at least attains Maximum Contaminant Level Goals established under the Safe Drinking Water Act," 42 U.S.C. s 9621(d)(2)(A).

EPA challenges petitioners' theory on several grounds. First, it says, its regulations provide that when a zero MCLG is set, it is the MCL, not the MCLG, that is used to set cleanup standards. 40 CFR s 300.430(e)(2)(i)(C). In this case, says EPA, the MCL set for TTHMs would control. Since there is no suggestion that the effective MCL will imminently be affected by the zero MCLG, and petitioners have not challenged the MCL for TTHMs, EPA argues that they have failed to demonstrate an injury.

But the MCL for TTHMs is in fact not dispositive in setting the cleanup standard for chloroform. EPA has in the past rejected use of the TTHM MCL for that purpose, saying that that MCL is "based on an analysis evaluating the health benefits of chlorinating public drinking water supplies against the detrimental effects of the production of trihalomethanes as a result of chlorinating those supplies." U.S. EPA, Superfund Record of Decision, Stringfellow Hazardous Waste Site, at 25 (Sept. 30, 1990). Instead, EPA has set chloroform cleanup goals as low as 6 ppb (far below the 100 ppb MCL for TTHMs), based on an assumption that chloroform poses a risk of cancer at any dose, but that 6 ppb would yield an acceptable cancer risk of one-in-a-million. Id. Thus EPA's actual practice belies its claims here as to the inconsequentiality of the chloroform MCLG.

EPA also argues that unlike the petitioners in International Fabricare, neither petitioners nor their members here have yet been subjected to cleanup costs for chloroform contamination, and thus have not demonstrated a "genuine threat" of CERCLA liability. EPA's Br. at 21. But in a forward-looking suit the petitioners' subjection to past injury is relevant primarily as it may shed light on whether the challenged action has a "substantial probability" of causing injury. Florida Audubon Soc'y v. Bentsen, 94 F.3d 658, 666 (D.C. Cir. 1996) (en banc). CERCLA imposes joint and several liability on "any person who by contract, agreement, or otherwise

arranged for disposal or treatment ... of hazardous substances owned or possessed by such person." 42 U.S.C. s 9607(a)(3). In light of petitioners' contention that they face liability "for the cleanup of chloroform at Superfund sites across the country," Petitioners' Reply Br. at 16, we find it at least substantially probable that a zero MCLG, as compared with a nonzero one, will expose them to higher cleanup costs.

* * *

Before turning to the merits of petitioners' claim, we note EPA's contention that its motion to vacate obviates the "need for the Court to issue an opinion." Motion for Vacatur, at 3. But we have no reason to believe that mere vacatur provides an adequate remedy if, as we ultimately conclude, EPA's action was unlawful. Petitioners request that we instruct EPA to "promulgate a non-zero MCLG using the best available peer-reviewed science." Petitioners' Initial Br. at 34. But EPA has not indicated an intention to take such action upon vacatur. Moreover, EPA makes no claim that the 1994 zero MCLG would not be automatically revived by vacatur of the 1998 rule. Our agreement with the petitioners on the rule's lawfulness will thus bring issues of remedy into play.

On the merits petitioners argue that EPA's decision to adopt a zero MCLG in the face of scientific evidence establishing that chloroform is a threshold carcinogen was inconsistent with the Safe Drinking Water Act. Section 300g-1(b)(3)(A) of the Act states unequivocally that "to the degree that an Agency action is based on science, the Administrator shall use ... the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." In promulgating a zero MCLG for chloroform EPA openly overrode the "best available" scientific evidence, which suggested that chloroform is a threshold carcinogen.

EPA provides several arguments in defense of its action. First, it argues that to establish a non-zero MCLG would be a "precedential step," that represents "a major change in the substance of regulatory decisions related to chloroform."

EPA's Br. at 28-29. We do not doubt that adopting a nonzero MCLG is a significant step, one which departs from previous practice. But this is a change in result, not in policy. The change in outcome occurs simply as a result of steadfast application of the relevant rules: first, the statutory mandate to set MCLGs at "the level at which no known or anticipated adverse effect on the health of persons occur," 42 U.S.C. s 300g-1(b)(4)(A), as determined on the basis of the "best available" evidence; and second, EPA's Carcinogen Risk Assessment guidelines, stating that when "adequate data on mode of action show that linearity is not the most reasonable working judgment and provide sufficient evidence to support a nonlinear mode of action," the default assumption of linearity drops out. Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. at 17,969/1. The fact that EPA has arrived at a novel, even politically charged, outcome is of no significance either for its statutory obligation or for fulfillment of its adopted policy.

Second, and similarly, EPA supports its action on the basis that "it could not complete the deliberations with the SAB" before the November 1998 deadline. EPA's Br. at 29; Final Rule, 63 Fed. Reg. at 69,399/1. But however desirable it may be for EPA to consult an SAB and even to revise its conclusion in the future, that is no reason for acting against its own science findings in the meantime. The statute requires the agency to take into account the "best available" evidence. 42 U.S.C. s 300g-1(b)(3)(A) (emphasis added). EPA cannot reject the "best available" evidence simply because of the possibility of contradiction in the future by evidence unavailable at the time of action--a possibility that will always be present.

Third, EPA justifies its decision not to adopt a nonzero MCLG on the basis that it had to reevaluate one of its underlying technical assumptions--that ingestion of chloroform in drinking water accounts for 80% of total exposure to chloroform. As it stated in its final rule, EPA is currently considering use of a 20% relative source contribution for drinking water, which would lower the MCLG to 70 ppb. Final Rule, 63 Fed. Reg. at 69,399/3. Along these lines,

EPA's counsel conceded at oral argument that a science-based MCLG would fall into the interval between 70 and 300 ppb. The uncertainty on this issue may have provided support for choosing the lowest nonzero MCLG from within that interval, but none for choosing an MCLG outside the range of uncertainty.

Fourth, EPA argues that since the final MCL for TTHMs is unaffected, the MCLG has no actual effect, and thus EPA's decision to publish an MCLG of zero pending further review of the scientific evidence was entirely reasonable. In light of our analysis of the standing issue, the no-effect premise is plainly incorrect. Even if it were correct, we fail to see why it would justify EPA's disregard of its own scientific findings.

Finally, EPA argues that its statements in the 1998 Notice of Data Availability do not represent its "ultimate conclusions" with respect to chloroform, and thus in adopting a zero MCLG it did not reject what it considered to be the "best available" evidence. In fact, the zero MCLG merely represented an "interim risk management decision" pending the final SAB report. EPA's Br. at 35. We find these semantic somersaults pointless. First, whether EPA has adopted its 1998 NODA as its "ultimate conclusion" is irrelevant to whether it represented the "best available" evidence. All scientific conclusions are subject to some doubt; future, hypothetical findings always have the potential to resolve the doubt (the new resolution itself being subject, of course, to falsification by later findings). What is significant is Congress's requirement that the action be taken on the basis of the best available evidence at the time of the rulemaking. The word "available" would be senseless if construed to mean "expected to be available at some future date." Second, EPA cannot avoid this result by dubbing its action "interim." The statute applies broadly to any "[a]gency action"; whether the action is interim is irrelevant.

* * *

Although we agree with petitioners that the zero MCLG for chloroform is inconsistent with the Safe Drinking Water Act

and that it should be vacated, we are unclear as to what further remedy petitioners seek. In their opening brief petitioners requested that this Court instruct EPA to "promulgate a non-zero MCLG using the best available peer-reviewed science as identified in the March 31, 1998 NODA and the December 16, 1998 Final Rule on an expeditious timetable to be specified by the Court." Petitioners' Initial Br. at 34. At oral argument, however, counsel for petitioners conceded that this request was a misstatement, and that EPA should be allowed, and required, to consider the new SAB report as well. Further, the consequences of simple vacatur are themselves unclear. Accordingly, we will schedule briefing on the parties' positions as to remedy.

Finding the Agency's December 1998 rule adopting a zero MCLG for chloroform to be arbitrary and capricious and in excess of statutory authority, see 5 U.S.C. s 706(2)(A) & (C), we vacate the rule. A separate order on briefing additional remedies will issue shortly.

So ordered.