United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 20, 2002 Decided February 25, 2003

No. 01-1028

CITY OF WAUKESHA, *ET AL.*,
PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

VILLAGE OF SUSSEX WATER COMMISSION, *ET AL.*,
INTERVENORS

No. 01-1033

RADIATION, SCIENCE & HEALTH, INC.,
PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

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

No. 01-1034

NUCLEAR ENERGY INSTITUTE, INC.,
PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

No. 01-1037

NATIONAL MINING ASSOCIATION,
PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

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

John C. Martin, *Michael B. Wigmore*, *Curt R. Meitz*, and *David C. Lashway* argued the cause for the petitioners. *John N. Hanson*, *Brian L. Doster*, *Justin A. Savage*, *Jean V. MacHarg*, *Susan M. Mathiascheck*, *Donald P. Gallo*, *H. Stanley Riffle*, *Phillip J. Eckert*, *Paul F. Reilly*, *John S. Noble*, *Richard M. Glidden*, *Anthony J. Thompson*, *Robert W. Bishop*, *James B. Harvey*, *Suzanne K. Schalig*, *William Von Arx*, and *Dennis M. Duffy* were on brief.

Daniel M. Flores and *Christopher Peak*, Attorneys, United States Department of Justice, argued the cause for the

respondent. *Karen Clark*, Attorney, United States Environmental Protection Agency, was on brief.

Before: HENDERSON, ROGERS, and GARLAND, *Circuit Judges*.

Opinion for the court filed *PER CURIAM*.

PER CURIAM: The petitioners—the City of Waukesha and its water utility customer Bruce Zivney, trade associations Nuclear Energy Institute ("NEI") and National Mining Association ("NMA"), and advocacy group Radiation, Science & Health ("RSH")—seek review of regulations promulgated by the Environmental Protection Agency ("EPA") pursuant to the Safe Drinking Water Act of 1970 ("SDWA" or "Act"), 42 U.S.C. §§ 300f *et seq*. The challenged regulations establish standards governing radionuclide levels in public water systems. Specifically, they set the maximum contaminant level goal ("MCLG") and the maximum contaminant level ("MCL") for radium-226 and radium-228, naturally occurring uranium, and various beta/photon emitters. Petitioners contend the regulations violate the SDWA and the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq*., ("APA") because in setting the radionuclides standards EPA did not (1) properly conduct required cost-benefit analyses; (2) use the "best available science" to determine the appropriate MCLGs and MCLs; or (3) adequately respond to comments submitted during the rulemaking. For its part, EPA contests petitioners' standing to challenge the regulations and defends the standards on the merits. We conclude that all petitioners except RSH have standing and that EPA complied with the requirements of the SDWA and the APA.

I. BACKGROUND

The SDWA generally applies to "each public water system in each State," 42 U.S.C. § 300g, and authorizes EPA to set standards for drinking water contaminants therein, 42 U.S.C. § 300g-1(b). For a given contaminant the Act directs that EPA first establish an MCLG which is "the level at which no known or anticipated adverse effects on the health of persons

occur and which allows an adequate margin of safety." *Id.* § 300g-1(b)(4)(A). EPA is then to set an MCL "as close to the [MCLG] as is feasible." *Id.* § 300g-1(b)(4)(B).

In 1976 EPA promulgated interim regulations that established MCLGs and MCLs for radionuclides, which are materials that emit radiation as they decay from one elemental form to another. The regulations established an MCL of 5 picocuries/Liter (pCi/L)[1] for the isotopes radium-226 and radium-228; a combined MCL of 4 millirems (mrem)[2] for all beta/photon emitters; and no MCL for naturally-occurring uranium. *See* National Interim Primary Drinking Water Regulations, 41 Fed. Reg. 28,402, 28,404 (July 9, 1976).

In 1991 EPA proposed new MCLs for the radionuclides: 20 pCi/L for radium-226 and -228; 4 mrem effective dose equivalent ("ede") for the beta/photon emitters;[3] and 20 micrograms per liter (μg/L) or 30 pCi/L for naturally occurring uranium. *See* National Primary Drinking Water Regulations; Radionuclides, Notice of Proposed Rulemaking, 56 Fed. Reg. 33,050, 33,051 (July 18, 1991).

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[1] The curie measures the rate at which a given radioactive compound disintegrates. One curie is equivalent to 3.7 x 10^{10} disintegrations per second. A picocurie is a millionth millionth of a curie. National Primary Drinking Water Regulations; Radionuclides, Advance Notice of Proposed Rulemaking, 51 Fed. Reg. 34,836, 34,850 (Sept. 30, 1986).

[2] The rem measures the dose of radiation an individual receives from a certain type of exposure. EPA, *Radionuclides Notice of Availability, Technical Support Document* at I-5 (March 2000). A rem takes into account not only the number of radioactive emissions that are present (i.e., the curies) but also the energy of the radiation and the types of particles that are emitted. 51 Fed. Reg. at 34,849–50.

[3] The effective dose equivalent measures the amount of radiation distributed to an individual. The radiation amount is first estimated for each individual organ and the result is adjusted by a "weighting factor" to reflect the radiosensitivity of the particular organ. The sum of the ede of each organ provides an estimate of the total effect on the entire body. 51 Fed. Reg. at 34,843.

In 1996 the Congress amended the SDWA to, *inter alia*, add an "anti-backsliding" provision requiring that any water regulation revision "maintain, or provide for greater, protection of the health of persons," 42 U.S.C. § 300g-1(b)(9), and to require the agency to consider the relative costs and benefits in setting each MCL, *id.* § 300g-1(b)(3)(C), (4)(C).

In April 2000 EPA issued a "Notice of Data Availability" ("NODA") proposing that the 1991 radionuclide MCLs be revisited in light of "new information" and the 1996 amendments. National Primary Drinking Water Regulations; Radionuclides, 65 Fed. Reg. 21,576 (Apr. 21, 2000).[4] The 2000 NODA proposed maintaining the 1976 MCLs for radium-226 and -228 and for beta/photon emitters and set MCLs for naturally occurring uranium at either 20, 40, or 80 μg/L. EPA further proposed revising the 1976 radium monitoring regimen—which required public water systems to test for radium-228 only if the radium-226 level exceeded 3 pCi/L—to require separate testing for each of the two isotopes. The NODA further set June 20, 2000 as the deadline for submitting comments on the proposed rule and its underlying data and analysis.

In December 2000 EPA issued the final radionuclides rule, National Primary Drinking Water Regulations; Radionuclides, 65 Fed. Reg. 76,708 (Dec. 7, 2000) (Final Rule). As it had proposed, EPA retained the 1976 standards for radium-226 and -228 and for beta/photon emitters and instituted the separate radium isotope monitoring requirement. *Id.* at 76,710–11. For uranium, however, the final rule set the MCL at 30 μg/L. *Id.* at 76,710. Petitioners filed timely petitions for review of the final rule.

Petitioners bring several challenges to the 2000 final rule. First, they argue that EPA failed to publish a cost-benefit analysis for the radium and beta/photon MCLs as required by SDWA § 1412(b)(3)(C)(i), and that the agency's cost-benefit analysis of the uranium MCL fell short of the requirements of

[4] EPA agreed to review and take final action on the radionuclides standards by November 21, 2000 in a consent agreement it executed with a private litigant. 65 Fed. Reg. at 21,579.

the SDWA and the APA. We discuss those arguments in Parts III and IV, respectively. Petitioners also attack the radium, uranium, and beta/photon MCLs on their merits, and we consider those challenges in Parts V, VI, and VII, respectively. Finally, petitioners assert that EPA, in violation of the APA, failed adequately to respond to comments in promulgating the 2000 final rule. We discuss that assertion in Part VIII. EPA defends against each of petitioners' arguments on the merits, and in turn, contests petitioners' standing to bring their petitions, an argument to which we now turn.

II. STANDING

First, we address the threshold issue of our jurisdiction, specifically, whether petitioners have standing to raise their claims. *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002). In analyzing whether a party has standing, the court must determine whether there is "(1) injury-in-fact, (2) causation, and (3) redressability." *Id.* In alleging an injury-in-fact, petitioners must show that "EPA's alleged failings have caused a traceable 'concrete and particularized' harm . . . that is 'actual or imminent.' " *Id.* (quoting *Am. Petroleum Inst. v. United States Envtl. Prot. Agency*, 216 F.3d 50, 63 (D.C. Cir. 2000)). To establish this, petitioners "must demonstrate that there is a 'substantial probability' that local conditions will be adversely affected." *Id.* In addition, in evaluating the standing of an association to sue on behalf of its members, the court must determine that

> (1) at least one of [the association's] members would have standing to sue in his own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires that an individual member of the association participate in the lawsuit.

Id.

The burden of making these showings rests on the petitioner in an agency review case. *Id.* at 899. "In such cases . . . the petitioner ordinarily will have participated in the proceed-

ings before the agency," and therefore the administrative record will establish the relevant facts for the petitioner to show standing. *Id.* The petitioner must "either identify in that record evidence sufficient to support its standing to seek review or ... submit additional evidence to the court of appeals," *id.*, although additional evidence is unnecessary if its "standing to seek review of administrative action is self-evident," *id.* at 899–900. In explaining how petitioners should satisfy that burden, *Sierra Club*, decided June 18, 2002, announced that "henceforth" petitioners must include in their opening briefs sufficient evidence to demonstrate their standing. *Id.* at 900. "Absent good cause shown, ... a litigant should not expect the court" to allow petitioners to submit affidavits post-oral argument in order to support their standing arguments. *Id.* Because the opening briefs in this case were filed before our decision in *Sierra Club*, and EPA has not objected to the filing of supplemental affidavits, our resolution of the question of standing is based on the submissions in petitioners' opening briefs as well as on the supplemental affidavits submitted, with the permission of the court, after oral argument. *See, e.g.*, *United States Telecom Ass'n v. FCC*, 295 F.3d 1326, 1330 (D.C. Cir. 2002).

A.

The administrative record shows that the City of Waukesha would face substantial costs if it was required to comply with the 1976 radium-226 and -228 regulations. EPA has not disputed that record evidence. This is sufficient for injury-in-fact. Moreover, Waukesha has shown, and EPA does not dispute, that maintenance of the 1976 regulations will cause Waukesha's injury. EPA contends, however, that, to the extent that Waukesha and the other utility petitioners base their challenge on EPA's failure to properly conduct a cost-benefit analysis, there is no standing because there is no redressability. In particular, EPA maintains that even if it did not properly develop cost-benefit analyses for the radium regulations, it could not have used those analyses to raise the numerical limits, because the SDWA prohibits the use of cost-benefit analyses to weaken standards in place at the time of

the 1996 amendments to the SDWA. Waukesha responds that the court could order the agency to properly follow the relevant procedural requirements, and it alleges that EPA's failures to follow those requirements are the injuries that it has suffered.

A violation of the procedural requirements of a statute is sufficient to grant a plaintiff standing to sue, so long as the procedural requirement was "designed to protect some threatened concrete interest" of the plaintiff. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 573 n.8 (1992). As explained in *Florida Audubon Society v. Bentsen*, 94 F.3d 658, 665 (D.C. Cir. 1996), a plaintiff must show "not only that the defendant's acts omitted some procedural requirement, but also that it is substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest." There are "at least two links" in an "adequate causal chain" between a procedural violation and injury-in-fact, "one connecting the omitted [procedure] to some substantive government decision that may have been wrongly decided because of the lack of [the procedure] and one connecting that substantive decision to the plaintiff's particularized injury." *Id.* at 668. The second link requires a showing that "the particularized injury that the plaintiff is suffering or is likely to suffer is fairly traceable to the agency action that implicated" the procedural requirement in question. *Id.* at 669.

Here, the procedural requirements for a cost-benefit analysis are related to the threatened interest of Waukesha. The cost-benefit analysis would examine whether the drinking water regulations are overly costly compared to the health benefits they would provide, resulting in increased and unjustified costs for water suppliers. *See* 42 U.S.C. § 300g-1(b)(3)(C), (b)(6)(A). Moreover, the harm suffered by Waukesha—increased water treatment costs—is fairly traceable to the substantive action of EPA that is challenged by petitioners—the maintenance of the 1976 radium regulations. EPA challenges the first causal link connecting the procedural requirement—the cost-benefit analysis—and the substantive actions of EPA. EPA essentially contends that there is no chance that performing the cost-benefit analysis, as requested

by Waukesha, will alleviate the harm suffered by Waukesha, namely, overly strict water-quality standards.[5] Although some sort of connection between the procedural requirement at issue and the substantive action of the agency must be shown, *see Fla. Audobon*, 94 F.3d at 668, the Supreme Court has held that this requirement is not very stringent.

> Thus, under our case law, one living adjacent to the site for proposed construction of a federally licensed dam has standing to challenge the licensing agency's failure to prepare an environmental impact statement, even though he cannot establish with any certainty that the statement will cause the license to be withheld or altered.

Lujan, 504 U.S. at 572 n.7. In fact, "[a]ll that is necessary is to show that the procedural step was connected to the substantive result." *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 94–95 (D.C. Cir. 2002); *see also Fla. Audubon*, 94 F.3d at 669. Indeed, in reviewing the standing question, the court must be careful not to decide the questions on the merits for or against the plaintiff, and must therefore assume that on the merits the plaintiffs would be successful in their claims. *Warth v. Seldin*, 422 U.S. 490, 502 (1975); *Am. Fed'n of Gov't Employees v. Pierce*, 697 F.2d 303, 305 (D.C. Cir. 1982). Consequently, because we assume that Waukesha is correct when it contends that the SDWA does not prohibit the Secretary from raising the relevant standards based on a cost-benefit analysis, there is some connection between the procedural right (the cost-benefit analysis) and the substantive decision (the decision not to relax the drinking water standards). Thus, EPA's redressability argument fails.

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[5] In their reply brief, petitioners argue that they were also harmed by the failure to conduct a cost-benefit analysis because of the lack of "consistent, predictable" clean-up standards. Petitioners' Reply Br. at 5. Nothing in the attached affidavit or in the brief itself shows how a failure to perform the cost-benefit analysis will harm petitioners other than the possibility of setting stricter standards than otherwise might have been imposed.

Having concluded that the City of Waukesha has standing to challenge the radium regulations, it is unnecessary for the court to evaluate standing for Bruce Zivney or any of the remaining utilities who are parties to this case. *See Envtl. Action v. FERC*, 996 F.2d 401, 406 (D.C. Cir. 1993).

B.

NEI contends that it has standing to challenge the beta/photon emitter standard because "[i]ts members' facilities are potential sources of beta/photon radionuclides," which are also "potentially subject to the beta/photon MCLs at decommissioned facilities under CERCLA [Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. §§ 9601–9675]." Petitioners' Br. at 12. EPA maintains that NEI has failed to demonstrate standing because NEI has only stated that its members may be "potentially" subject to the MCLs, which does not meet the requirement that injury-in-fact be concrete and particularized. Respondent's Br. at 27.

With its reply brief, NEI submitted an affidavit stating that EPA "will impose CERCLA requirements (including the SDWA MCLs) at those [NEI member] sites where groundwater is a current or potential drinking water source." Petitioners' Reply Br. Tab A at 2. NEI further avers in the affidavit that decommissioned nuclear industry sites have residual radioactive material that "typically consists of a mixture of different radionuclides" that will be covered by the beta/photon MCL. *Id.* at 4. The affidavit concludes that "application by EPA of the 2000 SDWA beta/photon MCL will in some cases result in increases to NEI members' regulatory compliance costs." *Id.*

To the extent that the demonstration of standing requires substantial specificity and particularity on the part of plaintiffs seeking to establish injury-in-fact, *see, e.g.*, *Am. Petroleum Inst.*, 216 F.3d at 63–68, it is arguable that NEI's initial affidavit falls short. "Bare allegations are insufficient . . . to establish a petitioner's standing to seek judicial review of administrative action." *Sierra Club*, 292 F.3d at 898. Fur-

ther, plaintiffs must show a "substantial probability" that the agency action will cause the alleged injury-in-fact, *Am. Petroleum Inst.*, 216 F.3d at 63–68, and plaintiffs must also show that "local conditions will be adversely affected," *Sierra Club*, 292 F.3d at 898. At no point in its initial affidavit does NEI state that any particular site owned by any of its members had radionuclides that might be covered by the rule, nor does it ever state that a particular site would be decommissioned and therefore become subject to CERCLA. Further, NEI's claims as to future coverage by CERCLA are hedged with qualifiers such as "typically" and "in some cases." Petitioners' Reply Br. Tab A at 4. NEI never states that there is a substantial probability that EPA would require a particular site to be cleaned-up to the SDWA MCL standards for beta/photon emitters.

A supplemental affidavit provided after oral argument, however, reveals that at least one of NEI's members owns a nuclear power plant that has begun the process of decommissioning, and that plant also has identified at least one beta/photon emitter that is present at levels higher than the MCL at issue. At oral argument, EPA conceded that its current regulations and enforcement policy would result in the application of the beta/photon emitter MCL to decommissioned nuclear power plants. As a result, that particular plant faces a substantial probability of higher site investigation and remediation costs under CERCLA as a result of the beta/photon emitter MCL at the present time. Whether, as EPA suggested at oral argument, EPA chooses to change the regulations in the future so that MCLs would no longer apply to decommissioned nuclear power plants under CERCLA, or so that the MCLs are altered significantly, presents only a speculative possibility that does not eliminate the current circumstances faced by the NEI-member plant that is undergoing decomissioning. Thus, at least one member of NEI has shown injury-in-fact caused by the application of the beta/photon SDWA MCL to CERCLA clean-up standards. *See Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1289–90 (D.C. Cir. 2000). And, as noted, NEI has shown that

its injury could be redressed either through a new cost-benefit analysis, or overturning of the regulations on their merits.

The remaining associational requirements are easily fulfilled by NEI: NEI seeks injunctive relief, which does not require the participation of particular individuals, *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 344 (1977), and the goals of the lawsuit are germane to NEI's overall purpose of advancing the interests of the nuclear power industry, *Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 636–37 (D.C. Cir. 2000). Because NEI has standing to challenge the beta/photon emitter provisions, it is unnecessary for the court to address the standing of any other party with respect to the beta/photon emitter provisions.

C.

NMA challenges both the uranium and radium-226 and -228 regulations. NMA's initial showing of its standing was set forth in a conclusory statement in the administrative record that it may be harmed by the proposed regulations:

> The proposed [regulations] for radionuclides (specifically uranium and radium-226 and -228) may impact NMA member companies to the extent they provide water supply services to communities associated with mining and mineral processing facilities. In addition, NMA member companies also may be impacted by the application of [the regulations] as limits on groundwater at mining and mineral processing facilities under other "contamination" regulatory programs.

Letter from Nat'l Mining Ass'n to EPA (June 20, 2000). The statement does not identify any NMA members that own or operate particular water supply services that would be affected by the proposed rule or that own particular sites that might be covered by other " 'contamination' regulatory programs," and states only that the proposed regulations "may impact" its members. *See Sierra Club*, 292 F.3d at 900. NMA's supplemental affidavits filed after oral argument cure any deficiency, however, by identifying an NMA member that

operates a community water system subject to regulation under the SDWA, and by averring that there is a substantial probability that this water system will have uranium levels above the MCL provided for by EPA's new regulations, resulting in significant monitoring, compliance, and disposal costs for that member. This is sufficient to demonstrate injury-in-fact and causation on the part of NMA. The injunctive relief sought by NMA would redress these harms.

Because NMA, like NEI, has shown that at least one of its members has standing to sue, because NMA seeks injunctive relief such that the participation of individual members in the litigation is not required, and because the purpose of the litigation is related to NMA's overall goals of promoting the interests of the mining industry, we conclude that NMA has standing to pursue the challenge to the uranium standards.

D.

RSH, much like NEI and NMA, did not make an initial showing that it has standing. Rather it relied on its comments in the administrative record that do not establish that any of RSH's members have suffered any type of injury from the proposed regulations. While stating in its brief that "its members would be injured based on the likelihood of increased drinking water costs resulting from this regulation," Petitioners' Reply Br. at 5, RSH, unlike NEI and NMA, has provided no affidavit that establishes with specificity and concreteness any particular member of RSH that is likely to suffer increased drinking water costs. Thus, RSH does not have standing to challenge the proposed regulations.

To the extent that RSH seeks to challenge EPA's responses to comments attacking EPA's reliance on the linear nonthreshold model, we note that the City of Waukesha and NMA also raise this challenge. Because the linear nonthreshold model is relevant to the setting of the MCLG and MCL for all of the contaminants, the City of Waukesha and NMA have standing to raise this claim.

III. THE APPLICABILITY OF THE COST-BENEFIT REQUIREMENTS TO THE RADIUM AND BETA/PHOTON MCLs

Petitioners attack EPA's final radium and beta/photon MCLs on the ground that § 1412(b)(3)(C)(i) of the SDWA, 42 U.S.C. § 300g-1(b)(3)(C)(i), allegedly required EPA to conduct a cost-benefit analysis for each MCL, which EPA failed to do.[6] EPA responds that no cost-benefit analysis was

[6] Section 1412(b)(3)(C)(i) provides, in relevant part:

> When proposing any national primary drinking water regulation that includes a maximum contaminant level, the Administrator shall, with respect to a maximum contaminant level that is being considered in accordance with paragraph (4) and each alternative maximum contaminant level that is being considered pursuant to paragraph (5) or (6)(A), publish, seek public comment on, and use for the purposes of paragraphs (4), (5), and (6) an analysis of each of the following:
>
> (I) Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level.
>
> (II) Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the maximum contaminant level, excluding benefits resulting from compliance with other proposed or promulgated regulations.
>
> (III) Quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the maximum contaminant level, including monitoring, treatment, and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations. . . .

42 U.S.C. § 300g-1(b)(3)(C)(i)(I)–(III).

required for these MCLs because the SDWA exempts pre-1986 MCLs from its cost-benefit requirements, and the agency left the pre-existing MCLs for radium and beta/photon emitters unchanged. Unless "Congress has directly spoken to the precise question at issue," we must uphold the agency's interpretation of the SDWA as long as it is "based on a permissible construction of the statute." *Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842–43 (1984).[7]

In 1996, Congress amended § 1412 of the SDWA. *See* Safe Drinking Water Act Amendments of 1996, Pub. L. No. 104-182, 110 Stat. 1613. As amended, § 1412(b)(3)(C)(i) provides that, "[w]hen proposing any national primary drinking water regulation that includes a maximum contaminant level," EPA must publish and seek public comment on an analysis of the health risk reduction benefits and costs associated with the proposed MCL. 42 U.S.C. § 300g-1(b)(3)(C)(i). EPA is to use that analysis "for the purposes of paragraph[ ] (4)," subparagraph (C) of which states:

> At the time the Administrator proposes a national primary drinking water regulation under this paragraph, the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C).

Id. § 300g-1(b)(4)(C). However, amended § 1412(a)(1) also includes a grandfather clause:

> Effective on June 19, 1986, each national interim or revised primary drinking water regulation promulgated under this section before June 19, 1986, shall be deemed to be a national primary drinking water regulation under subsection (b) of this section. *No such regulation shall be required to comply with the standards set forth in*

[7] All parties agree that *Chevron* governs our review of EPA's interpretation of the statute, *see* Petitioners' Br. at 13; Respondent's Br. at 34, an interpretation that was developed in the NODA, *see* 65 Fed. Reg. at 21,579, and in the notice of the final rule, *see id.* at 76,737.

> *subsection (b)(4) of this section unless such regulation is amended to establish a different maximum contaminant level after June 19, 1986.*

Id. § 300g-1(a)(1) (emphasis added).

EPA argues that § 1412(a)(1) exempts the radium and beta/photon MCLs from the cost-benefit determination required by § 1412(b)(4)(C), because they do not establish different contaminant levels from those first promulgated in 1976. EPA further reasons that because the purpose of the cost-benefit analysis required by § 1412(b)(3)(C)(i) is to inform the cost-benefit determination required by § (b)(4)(C), and because that determination is not required for the pre-existing MCLs, no cost-benefit analysis was required for those MCLs. In Part III.A we consider petitioners' attack on EPA's view that cost-benefit analyses are not required when the agency decides to retain pre-existing MCLs. In Part III.B we consider petitioners' claim that EPA did not in fact retain the pre-existing MCLs for radium and beta/photon radionuclides, but instead issued new standards.

A.

Petitioners raise three challenges to EPA's view that cost-benefit analyses are not required when it retains pre-1986 MCLs.

First, petitioners contend that the declaration of § 1412(a)(1)'s grandfather clause, that pre-existing MCLs are not "required to comply with the *standards* set forth in subsection (b)(4) of this section," 42 U.S.C. § 300g-1(a)(1) (emphasis added), is not a reference to § (b)(4)(C)'s cost-benefit determination requirement because that requirement is not a "standard." Rather, petitioners contend that the only "standards" in § (b)(4) are those in § (b)(4)(A) and (B), which apply to "maximum contaminant level goals" and "maximum contaminant levels," respectively. *Id.* § 300g-1(b)(4)(A), (B).[8]

[8] These subsections provide, in relevant part:

> (A) Maximum contaminant level goals

EPA, however, correctly counters that the term "standards" is ambiguous; indeed, the term serves as the title for all of § 1412(b), and "[g]oals and standards" is the title for all of § (b)(4). There is nothing unreasonable about the agency's view that whether the benefits of an MCL justify its costs qualifies as a "standard" by which the MCL may be measured.

Second, petitioners contend that even if the grandfather clause does apply to the cost-benefit *determination* requirement of § 1412(b)(4), it does not expressly apply to the cost-benefit *analysis* requirement of § (b)(3)(C)(i). Although the observation is correct, the agency is justified in describing this as an instance where "the statute is silent . . . with respect to the specific issue," and hence where judicial deference to the agency's interpretation is warranted. *Chevron*, 467 U.S. at 842. Because the statute provides that the § (b)(3)(C)(i) analysis is to be "used for the purposes of paragraph[ ] (4)," 42 U.S.C. § 300g-1(b)(3)(C)(i),[9] it is reason-

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> Each maximum contaminant level goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.
>
> (B) Maximum contaminant levels
>
> Except as provided in paragraphs (5) and (6), each national primary drinking water regulation for a contaminant for which a maximum contaminant level goal is established under this subsection shall specify a maximum contaminant level for such contaminant which is as close to the maximum contaminant level goal as is feasible.

42 U.S.C. § 300g-1(b)(4)(A), (B).

[9] In full, this sentence of § 1412(b)(3)(C)(i) states that the cost-benefit analysis is to be used "for the purposes of paragraphs (4), (5), and (6)." 42 U.S.C. § 300g-1(b)(3)(C)(i); *see supra* note 6. Neither paragraph (b)(5) nor (b)(6) is applicable here, as both are exceptions to the requirements of paragraph (b)(4), from which pre-existing MCLs are exempt by virtue of the grandfather clause.

able for the agency to regard such an analysis as unnecessary in situations in which a § (b)(4) determination will not be made.

Third, petitioners argue that, because EPA could not have known when it published its 2000 proposal to retain the pre-existing MCLs that it would ultimately decide to keep them, the grandfather clause of § 1412(a)(1) did not exempt the agency from conducting a cost-benefit analysis at that time. But since § (a)(1) states that "no" pre-existing regulation is required to comply with the standards of § (b)(4) "unless such regulation *is* amended," *id.* § 300g-1(a)(1) (emphasis added), it is reasonable for the agency to conclude that the cost-benefit requirement is not triggered by a proposal to do nothing more than retain, unamended, pre-existing MCLs. Petitioners stress that § 1412(b)(3)(C)(i) states that the agency is to produce a cost-benefit analysis "[w]hen proposing *any*" MCL. *Id.* § 300g-1(b)(3)(C)(i) (emphasis added). But EPA correctly notes that the rest of the sentence provides that the analysis is to be produced only "with respect to a [MCL] that is being considered in accordance with paragraph (4) and each alternative [MCL] that is being considered pursuant to paragraph (5) or (6)." *Id.*; *see supra* note 6. Due to the grandfather clause, none of the MCLs at issue here were being "considered in accordance with paragraph (4)." Nor were they being considered "pursuant to paragraph (5) or (6)." *See supra* note 9.

EPA bolsters its position on all of these points by reference to another statutory provision, § 1412(b)(9), which it aptly

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Paragraph (b)(5) authorizes EPA to establish an MCL at a level other than the feasible level required under paragraph (b)(4) if the "means used to determine the feasible level would result in an increase in the health risk from drinking water" for specified reasons. 42 U.S.C. § 300g-1(b)(5)(A). Paragraph (b)(6) permits the agency to promulgate an MCL that is not as close to the MCLG as is feasible if EPA determines that the benefits of the feasible level would not justify the costs of compliance. *Id.* § 300g-1(b)(6)(A).

refers to as the SDWA's "anti-backsliding" provision. That section states:

> The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this subchapter. *Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.*

42 U.S.C. § 300g-1(b)(9) (emphasis added). EPA notes that § (b)(9) bars it from revising an MCL unless the revision at least maintains the existing MCL's level of health protection, and reasonably concludes that this means the agency may not raise an existing MCL on the basis of a cost-benefit analysis alone. That conclusion is supported by the legislative history, which states: "Section 1412(b)(9) precludes the use of this new cost-benefit standard-setting authority as the sole basis to relax any existing maximum contaminant level." S. Rep. No. 104-169, at 35 (1995). Accordingly, where the agency proposes to retain an existing MCL, and where (as here) there is no evidence that raising the MCL would provide equivalent health protection, a cost-benefit analysis would have no consequence and the agency is justified in concluding that Congress did not intend to require it to undertake such a futile exercise.

For the foregoing reasons, we conclude that EPA's reading of the SDWA as not requiring the production of a cost-benefit analysis when the agency decides to retain pre-1986 MCLs is a reasonable statutory interpretation to which this court is obligated to defer.[10]

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[10] Petitioners further contend that, because EPA "repromulgated" the existing rules only after public comment and reevaluation, those rules are subject to challenge as though they were new, citing *Public Citizen v. NRC*, 901 F.2d 147, 150 (D.C. Cir. 1990). Because this argument was raised for the first time in petitioners' reply brief, we decline to entertain it. *See, e.g.*, *McBride v. Merrell Dow & Pharm., Inc.*, 800 F.2d 1208, 1210–11 (D.C. Cir. 1986) ("We

B.

Petitioners next contend that even if the SDWA exempts EPA from producing a cost-benefit analysis when it leaves in place pre-existing MCLs, the 2000 beta/photon and radium MCLs are in fact different from the 1976 standards and hence not subject to § 1412(a)(1)'s exemption. We disagree.

With respect to beta/photon emitters, petitioners note that improved scientific methods have led EPA to conclude that the 1976 MCLs generally ensure greater health protection (and less risk) than the agency had originally anticipated. From this fact, petitioners assert that, by retaining the 1976 MCLs, the agency "effectively issue[d] a different standard than the one issued in 1976." Petitioners' Reply Br. at 14. This assertion is unjustified. As we have discussed, EPA reasonably interprets § (a)(1) to exempt a pre-1986 regulation from the statute's cost-benefit determination provision "unless such regulation is amended to establish a different maximum contaminant level after June 19, 1986." 42 U.S.C. § 300g-1(a)(1). Because the SDWA defines "maximum contaminant level" as "the maximum permissible *level of a contaminant* in water which is delivered to any user of a public water system," *id.* § 300f(3) (emphasis added), EPA is right to focus on the level of contaminant set by the original MCL rather than the degree of protection that such a level was anticipated to provide. Since EPA's 2000 beta/photon MCLs neither "amended" the 1976 MCLs nor "establish[ed] . . . different maximum contaminant level[s]," *id.* § 300g-1(a)(1), the exemption of § (a)(1) is plainly applicable.

Nor does petitioners' argument weaken the support that the anti-backsliding provision gives to EPA's conclusion that the 2000 beta/photon MCLs are exempt from the cost-benefit requirements. As we have discussed, § 1412(b)(9) provides

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generally will not entertain arguments omitted from an appellant's opening brief and raised initially in his reply brief. . . . Considering an argument advanced for the first time in a reply brief . . . is not only unfair to an appellee, but also entails the risk of an improvident or ill-advised opinion on the legal issues tendered." (citations omitted)).

that any revision of an MCL "shall maintain, or provide for greater, protection of the health of persons." *Id.* § 300g-1(b)(9). Petitioners contend that this provision does not prohibit EPA from revising an MCL upward when (as here) scientific advances show that a contaminant poses less risk than previously believed, and that in those circumstances the agency may consider a cost-benefit analysis in determining whether to raise the MCL. This argument requires inferring the following bracketed and italicized qualification to the actual language of § (b)(9): "[E]ach revision shall maintain, or provide for greater, protection of the health of persons *[than the agency initially thought it was providing]*." *Id.* But there is nothing unreasonable about EPA's decision to decline to read such a qualification into the section, and instead to regard it as a straightforward instruction to maintain the level of protection that the initial MCL *actually provides*.[11]

With respect to the radium MCL, petitioners argue that the 2000 radium standard is new because, although it retains the same 5 pCi/L level as the original MCL, it requires separate radium-228 monitoring regardless of the concentration of radium-226. *See* 65 Fed. Reg. at 76,712, 76,719. The original regulation required radium-228 monitoring only if the level of radium-226 exceeded 3 pCi/L. *See* 41 Fed. Reg. at 28,404. As discussed above, the agency reasonably interprets § 1412(a)(1) to provide an exemption from cost-benefit requirements for a pre-existing regulation unless EPA chooses to establish a *different maximum contaminant level*. In this case the maximum contaminant level has remained the same, and we agree with EPA that the fact that the agency has changed its monitoring technique, thereby tightening enforce-

[11] In further support of their argument, petitioners cite the following statement in the legislative history: "If new science shows that a less stringent standard would provide the same level of health protection, the MCL may be revised upward." S. Rep. No. 104-169, at 33 n.4. But this citation adds nothing to their case. Just as above, to carry petitioners' meaning, the phrase "that the agency initially thought it was providing" would still have to be inserted before the comma in the cited statement.

ment of compliance with the original level, does not take the 2000 radium regulation out of the statutory exemption. Accordingly, EPA was not required to produce a cost-benefit analysis with respect to the 2000 MCLs for either radium or beta/photon radionuclides.[12]

IV. THE ADEQUACY OF THE COST-BENEFIT ANALYSES PERFORMED FOR THE URANIUM MCL

By contrast to the 2000 radium and beta/photon regulations, the uranium MCL issued in that year represented a "new" standard, as there was no pre-existing MCL for uranium. *See* 65 Fed. Reg. at 76,708. Section 1412(b)(3)(C)(i) therefore required EPA to prepare and publish a cost-benefit analysis, and it did so. Petitioners contend that EPA's analysis failed to satisfy the requirements of that section and the APA.

A.

Petitioners' first argument is that EPA failed to comply with § (b)(3)(C)(i) because it did not analyze the costs and benefits associated with compliance with the uranium MCL in contexts other than the SDWA.[13] In particular, petitioners

[12] Given this conclusion, it is unnecessary for the court to consider arguments relating to the specific costs and benefits that petitioners contend EPA failed to consider with respect to the radium rule.

[13] Petitioners also argue that EPA failed to comply because it did not consider disposal costs for waste-stream residuals from the operation of uranium water-treatment systems, or health risks that those residuals pose to water-treatment workers and the general public. The record reflects that EPA did adequately consider those issues. *See* Office of Ground Water and Drinking Water, EPA, *Economic Analysis of the Radionuclides National Primary Drinking Water Regulations* 4-3 (2000) (explaining that "total treatment costs include the capital and operations and maintenance costs associated with residuals handling and disposal"); Office of Ground Water and Drinking Water & Office of Radiation and Indoor Air, EPA, *Preliminary Health Risk Reduction and Cost Analysis* 4-4

assert that EPA failed to evaluate the costs and benefits arising from compliance with the MCLs at hazardous waste sites governed by CERCLA. EPA counters that the SDWA does not require it to analyze such costs.

EPA again has the better of the argument. Section (b)(3)(C)(i)(III) requires EPA to analyze:

> Quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur *solely as a result of compliance with the maximum contaminant level*, including monitoring, treatment, and other costs *and excluding costs resulting from compliance with other proposed or promulgated regulations.*

42 U.S.C. § 300g-1(b)(3)(C)(i)(III) (emphasis added). EPA reasonably reads the italicized words, particularly the phrase "excluding costs resulting from compliance with other . . . regulations," as excluding costs associated with compliance with regulatory regimes other than the SDWA itself. As EPA argues, the purpose of the MCLs is to protect the public, as much as feasible, from the adverse health effects of drinking contaminated water. *See id.* § 300g-1(b)(4)(A), (B). That purpose would be undermined if the cost-benefit balance were skewed by consideration of the additional costs imposed by other uses of the MCLs, unrelated to protecting consumers of drinking water.

Petitioners attack EPA's view on a number of grounds. First, they note that the cited exclusion refers only to costs resulting from compliance with other "regulations." CERCLA, they correctly point out, is not a regulation but a

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(2000) (hereinafter "PHRRCA") (same); *see also* EPA, *Comment-Response Document* 20-4 to 20-5, 20-7 to 20-21 (2000) (response to comments 20.A.4, 20.B.1 to 20.B.22) (noting that the risks that waste-treatment residuals pose to water-treatment workers and the public were analyzed in draft guidelines issued in 1994) (hereinafter "Comment-Response Document"); Office of Ground Water and Drinking Water, EPA, *Draft Suggested Guidelines for Disposal of Drinking Water Treatment Wastes Containing Radioactivity* (1994).

statute—one that specifically instructs that the clean-up of hazardous waste sites must satisfy contamination standards promulgated under the SDWA. *See* 42 U.S.C. § 9621(d)(2)(A). But EPA, equally correctly, points out that like most statutes, CERCLA's mandate is implemented by regulations, which, among other things, set forth the circumstances under which MCLGs and MCLs of the SDWA are to be used as clean-up standards, as well as the circumstances under which compliance with them can be waived. *See* 40 C.F.R. § 300.430(e), (f); *see generally* 40 C.F.R. pt. 300. Moreover, as EPA further notes, CERCLA itself imposes no requirement that EPA consider the costs and benefits of compliance with MCLs as an element of clean-up standards, and certainly no requirement that the agency do so as part of its obligations under a separate statute like the SDWA.

Second, petitioners contend that the legislative history of the SDWA indicates that the exclusion of consideration of the costs of compliance with other regulations applies only to those regulations that are themselves the product of cost-benefit analysis. This argument relies on a single sentence from a Senate report: "[T]he Administrator is not to consider the benefits (or costs) that are attributable to compliance with other proposed or promulgated regulations, if those benefits and costs are considered in a determination as to whether benefits justify costs under those regulations." S. Rep. No. 104-169, at 29–30. But as EPA notes, while this passage mandates that the agency *may not* consider benefits and costs under such circumstances, it does not state that the agency *must* do so under all other circumstances. Since the statute itself contains no such qualification on its exclusion of the consideration of the costs and benefits of other regulations, that is hardly an unreasonable view for the agency to take.

Third, petitioners assert that even if the SDWA does exclude consideration of the *costs* associated with the application of MCLs in other contexts, the Act does not also exclude consideration of the *benefits* of applying MCLs under other regulatory regimes. In support, petitioners point to the benefits provision of § 1412(b)(3)(C)(i)(I), which, unlike the

costs provision of § (b)(3)(C)(i)(III), contains no exclusion relating to compliance with other regulations. *See supra* note 6. Without qualification, the benefits provision requires an analysis of "[q]uantifiable and nonquantifiable health risk reduction benefits . . . likely to occur as the result of treatment to comply with each level." 42 U.S.C. § 300g-1(b)(3)(C)(i)(I). But while it is true that § (b)(3)(C)(i)(I) contains no exclusion, in context it is also clear that the section's use of the phrase "the result of treatment" refers to *drinking water* treatment, and not to treatment of contaminants for other purposes. *See id.* § 300g-1(b)(3)(C)(ii); *id.* § 300g-4(e)(3). Moreover, we do not understand what petitioners hope to gain by requiring EPA to add further to the benefits (but not to the costs) of MCLs in conducting its cost-benefit analysis; such a calculus would only increase the justification for the MCLs actually promulgated by EPA, as compared to the higher levels favored by petitioners.

Finally, petitioners contend that EPA has itself "acknowledged the necessity of evaluating benefits and costs of MCLs at CERCLA sites." Petitioners' Br. at 26. It is true that EPA's preliminary cost-benefit analysis stated that "the impact of the regulations on other programs, such as the use of MCLs in site clean-up decisions," was a "factor[ ] . . . of interest to decision-makers and will be taken into account in the final selection of the regulatory options to be implemented." PHRRCA, at 6-8. But regarding something as a factor "of interest" is not the same as regarding it as a statutory obligation, and nothing else in the agency's statements suggests that EPA has regarded the consideration of CERCLA costs and benefits as mandatory.

For the foregoing reasons, we reject petitioners' contention that EPA's cost-benefit analysis failed to analyze costs and benefits as required by § 1412(b)(3)(C)(i).

B.

In conducting the cost-benefit analysis for the uranium regulations, EPA published both an initial cost-benefit analysis, issued before the NODA, and a final cost-benefit analysis,

issued about a month before the final regulations were published in the Federal Register. The initial cost-benefit analysis, for which EPA requested comments, provided discussion of the 20, 40, and 80 μg/L standards. The final cost-benefit analysis also included a discussion for the 30 μg/L standard that EPA ultimately promulgated; that discussion was based in large part on an interpolation by EPA from the analyses for the other proposed levels.

Petitioners contend that (1) EPA failed to comply with the SDWA's requirement that a cost-benefit analysis be performed for the 30 μg/L uranium standard that EPA implemented in the final rule, and (2) EPA failed to comply with the APA with respect to both the cost-benefit analysis and the issuance of the 30 μg/L rule. EPA responds that it did not violate the SDWA provisions or the APA because it "provided ample opportunity for public comment on the uranium MCL, conducting a cost-benefit analysis for several possible uranium MCLs in the range of 20 to 80 μg/L." Respondent's Br. at 43. According to EPA, its final 30 μg/L rule was a "logical outgrowth" of the proposed rule, such that the notice and opportunity to comment on the original three proposed MCLs incorporated the final 30 μg/L rule. *Id.* Petitioners reply that the "logical outgrowth" test is inapplicable because the plain language of the SDWA requires that EPA "shall, with respect to . . . *each* alternative maximum contaminant level that is being considered . . ., publish, seek public comment on, and use for the purposes of paragraphs (4), (5), and (6) an analysis" of the costs and benefits of that alternative. 42 U.S.C. § 300g-1(b)(3)(C)(i) (emphasis added); Petitioners' Reply Br. at 9-10.

The traditional APA "logical outgrowth" test applies where an agency changes its final regulation in some way from the proposed regulation for which it provided notice and requested comment, as required under the APA. As this court has recognized:

> EPA undoubtedly has authority to promulgate a final rule that differs in some particulars from its proposed rule. As we noted in *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 632 n.51 (D.C. Cir. 1973), "[a]

> contrary rule would lead to the absurdity that . . . the agency can learn from the comments on its proposals only at the peril of starting a new procedural round of commentary." However, if the final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal.
>
> Courts have devised various verbal formulas for the extent to which an agency can make changes in the final rule that were not clearly presaged by the notice of proposed rulemaking. This court has held, both under the APA and under Clean Air Act § 307(d), that the final rule must be a "logical outgrowth" of the proposed rule.

Small Refiner Lead Phase-Down Task Force v. United States Envtl. Prot. Agency, 705 F.2d 506, 546–47 (D.C. Cir. 1983) (alterations in original). Under the "logical outgrowth" test, then, the key question is whether commenters "should have anticipated" that EPA might use a 30 μg/L standard when it first provided notice of its proposals. *Id.* at 549.

Contrary to petitioners' position, the fact that the SDWA establishes a somewhat different notice-and-comment format for new regulations than the standard APA procedures does not necessarily mean that the "logical outgrowth" test is inapplicable. Under other statutes that have altered the notice-and-comment format for rulemaking, such as the Clean Air Act, the court has held that the "logical outgrowth" test is applicable. *See, e.g.*, *Husqvarna AB v. EPA*, 254 F.3d 195, 203 (D.C. Cir. 2001). Further, strictly applying the plain language of the SDWA, as petitioners advocate, would lead to the absurd results that the doctrine is intended to avoid in the first place. Without a "logical outgrowth" test, EPA would be prevented from issuing a final MCL of 20.1 μg/L, even where it had conducted a cost-benefit analysis for 20 μg/L and EPA had decided that a slight shift in the MCL would be advantageous. Indeed, petitioners conceded at oral argument that their position would have required EPA to conduct an entirely new cost-benefit analysis in order for it to adopt the MCLs that petitioners themselves had suggested to EPA in their comments.

Turning then to consider whether the "logical outgrowth" test was satisfied by EPA, we bear in mind that the doctrine must be considered in the context of this specific statute, where its applicability may be somewhat stricter than in the generic APA case. *Cf. Nat'l Constructors Ass'n v. Marshal*, 581 F.2d 960, 970-71 & n.27 (D.C. Cir. 1978). As noted, in making that determination the court must consider "whether the party, ex ante, should have anticipated" the changes to be made in the course of the rulemaking. *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000) (quotation omitted). Thus, one factor is "whether a new round of notice and comment would provide the *first* opportunity for interested parties to offer comments that could persuade the agency to modify its rule." *Id.* (emphasis in original) (quotation omitted). At oral argument, petitioners conceded that there were no additional comments or evidence they could have proffered for the record during the administrative proceedings as to how the costs and benefits would have differed for an MCL at 30 μg/L as opposed to 20 μg/L or 40 μg/L. Aside from a cursory statement that interpolation does not constitute the required "best available methods," 42 U.S.C. § 300g-1(b)(3)(A)(ii), for the cost-benefit analysis, petitioners have not suggested any criticism they would have raised concerning EPA's method of interpolation of the data.

Of course, the failure of an interested party to show how their comments would have been different had adequate notice been provided does not necessarily preclude a successful claim of inadequate notice-and-comment or a lack of a "logical outgrowth" connection between the proposed and final rule. The APA requires petitioners to show prejudice from an agency procedural violation. *See* 5 U.S.C. § 706. In making such a showing in the context of a violation of notice-and-comment requirements, petitioners may be required to demonstrate that, had proper notice been provided, they would have submitted additional, different comments that could have invalidated the rationale for the revised rule. *See Shell Oil Co. v. EPA*, 950 F.2d 741, 752 (D.C. Cir. 1991) (citing *Air Transport Ass'n of Am. v. CAB*, 732 F.2d 219, 224 n.11 (D.C. Cir. 1984)). On the other hand, there are also situations where prejudice need not be shown by petitioners

in a notice-and-comment rulemaking challenge, "where the agency has entirely failed to comply with notice-and-comment requirements, and the agency has offered no persuasive evidence that possible objections to its final rules have been given sufficient consideration." *Id.* at 752. Either way, a rule requiring petitioners in all "logical outgrowth" cases to show what additional comments they would have submitted had notice been adequate would improperly merge the analysis on the merits of whether the final rule is a "logical outgrowth" with any applicable prejudice analysis. We therefore leave open the possibility that there may be situations where a petitioner who challenges an agency "logical outgrowth" argument is unable to provide a proffer of additional comments for valid reasons, but note that in the instant case petitioners have not offered any such reason.

We nonetheless consider petitioners' failure to suggest how their comments would have been different as a factor in our "logical outgrowth" analysis, separate from any analysis as to whether petitioners were prejudiced by any alleged procedural flaws. We do this because where the final rule falls within the range of the alternatives addressed in the agency's initial cost-benefit analysis, such a failure shows that for notice-and-comment purposes, the initial proposal and the final rule were essentially the same. Given the proximity, both higher and lower, of the adopted MCL to the proposed MCLs, the fact that petitioners were unable to present any additional and new comments that would have been raised had they been aware of the 30 μg/L proposal, and the fact that petitioners have not identified any comment they would have presented regarding EPA's interpolation method, the court has no basis on which to conclude that EPA failed to comply with the SDWA's cost-benefit analysis requirement or violated the notice-and-comment requirements of the SDWA and the APA.

V. THE MERITS OF THE RADIUM MCLs

Next, petitioners challenge the MCLs EPA set for radium-226 and radium-228. We review the rulemaking proceeding and the final rule under the APA and "will reverse an EPA action only if it is 'arbitrary, capricious, an abuse of discre-

tion, or otherwise not in accordance with law.' " *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (quoting 5 U.S.C. § 706(2)(A)). Further, we "will give an extreme degree of deference to the agency when it 'is evaluating scientific data within its technical expertise.' " *Huls Am., Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir. 1996) (quoting *Int'l Fabricare Inst.*, 972 F.2d at 389; citing *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 377 (1989)). Nonetheless, our review must "ensure that the EPA has examined the relevant data and has articulated an adequate explanation for its action." *Int'l Fabricare Inst.*, 972 F.2d at 389.

As noted above, EPA set interim MCLs for each isotope at 5 pCi/L in 1976 and in 1991 proposed a new MCL of 20 pCi/L for each. *See* 56 Fed. Reg. at 33,082. The agency based the 1991 MCLs on the "RADRISK" risk assessment model, with adjustments to conform with data from epidemiological studies. *See id.* at 33,056, 33,073-74. In the 2000 Final Rule the agency used a newer risk assessment model, set out in "Federal Guidance Report No. 13," Keith F. Eckerman et al., EPA, *Federal Guidance Report No. 13: Cancer Risk Coefficients for Environmental Exposure to Radionuclides* (1999) (hereinafter "FGR-13"), *see* 65 Fed. Reg. at 76,735, and, based thereon, decided to retain the original 1976 MCLs of 5 pCi/L, *see id.* at 76,712, 76,748 (codified at 40 C.F.R. § 141.66). Petitioners contend that EPA's decision to retain the lower MCLs violates the SDWA because it is not based on the "best available science," as required by the 1996 amendments to the SDWA which state that:

> In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

42 U.S.C. § 300g-1(b)(3)(A). We disagree.

Petitioners' primary contention is that EPA ignored the epidemiological studies on which it relied in 1991 and failed to

reconcile the results of the FGR-13 model with the data therefrom. Specifically, petitioners point to studies of watch dial painters who, in the early 20th century, ingested radium-226 and radium-228 when they inserted luminescent paint brushes into their mouths to sharpen the tips. In 1991 EPA modified the results of the RADRISK assessment in response to concerns expressed by EPA's Science Advisory Board ("SAB"), based on epidemiological evidence that included the dial painter data, that the results overstated the risk of leukemia and understated the risk of head cancer. Petitioners contend the agency arbitrarily ignored the dial painter data. Contrary to petitioners' claim, the record reveals that the agency did rely in part on the dial painter data which are reflected to some degree in the FGR-13 model. In other respects the agency adequately explained its reasons for rejecting the data.

First, the FGR-13 model's coefficients for both leukemia and bone cancer were adjusted to compensate for their over- and under-prediction, respectively, based on the results of the dial painter studies. *See* FGR-13 at 174 (citing as basis for FGR-13 leukemia "relative biological effectiveness" factor 1994 EPA document "Estimating Radiogenic Risks," which, in turn, explains that factor was adjusted because of evidence it was too high, citing 1991 proposed rulemaking); 65 Fed. Reg. at 76,722 (citing dial painter data as basis for doubling risk coefficient for head and bone cancer combined).[14] In

[14] As part of this challenge, petitioners also contend that EPA failed its obligation under § 1412(b) to explain "the methodology used to reconcile inconsistencies in the scientific data" in a "comprehensive, informative, and understandable manner." Petitioners' Br. at 40, 44. After EPA pointed out that the 1991 RADRISK corrections for leukemia and head cancer were included in FGR-13, Respondent's Br. at 69–70, petitioners stated that, even if true, this was not obvious from the EPA documents and therefore not presented in a "comprehensive, informative, and understandable manner," Petitioners' Reply Br. at 36–37. However, because RADRISK and FGR-13 are consistent and because petitioners never raised the issue of the analysis of leukemia and head cancer by FGR-13 in their comments before the agency, *cf. Northside*

large part, however, the FGR-13 model relies on alternative epidemiological data from studies of Hiroshima and Nagasaki atomic bomb survivors and, to a lesser extent, studies of medical exposure to radium-224, FGR-13 at 173, and provides substantial reasons for doing so. The Final Rule sets forth specific grounds for downplaying the dial painter studies: (1) "no one knows the quantity of radium ingested in those studies, so dose estimates are speculative" and (2) "the high mortality in some groups, and the small numbers of subjects in all exposure groups, would impair use of the data to develop dose response relationships." 65 Fed. Reg. at 76,721; *see also* Comment-Response Document 3-11 to 3-13 (response to comment 3.B.3). In addition, the FGR-13 model identifies a number of advantages to the alternative epidemiological data, in particular the bomb survivor studies: the "large, relatively healthy population at the time of exposure," "wide range of reasonably well established doses to individual subjects," "large, well matched control group," and "detailed, long-term epidemiological follow-up." FGR-13 at 173.

Without contesting the factual bases for EPA's preference, *see* Petitioners' Br. at 40 ("[T]hese observations may be accurate."), petitioners point to disadvantages they see in the alternative data: the bomb studies also involve estimates, the bombing contamination was not limited to radium-226 and -228 and the contamination was largely external exposure rather than ingestion. Given the relative advantages EPA found in the bomb survivor studies, however, we defer to its decision to use the FGR-13 model because it bears a "rational relationship to the characteristics of the data to which it is applied." *See Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 565 (D.C. Cir. 2002) ("We may reject an agency's choice of a scientific model 'only when the model bears no rational relationship to the characteristics of the data to which it is applied.' ") (quoting *Appalachian Power Co. v. EPA*, 135 F.3d 791, 802 (D.C. Cir. 1998) (citing *Am. Iron & Steel Inst. v.*

Sanitary Landfill, Inc. v. Thomas, 849 F.2d 1516, 1521 (D.C. Cir. 1988), there was no need under the statute for EPA to "reconcile" any "inconsistencies" pursuant to § 1412(b)(3)(B)(v).

EPA, 115 F.3d 979, 1005 (D.C. Cir. 1997); *Chem. Mfrs. Ass'n v. EPA,* 28 F.3d 1259, 1265 (D.C. Cir. 1994))); *cf. Am. Forest & Paper Ass'n, Inc*, 294 F.3d 113, 121 (D.C. Cir. 2002) (applying "rational relationship" standard and upholding EPA's reasoned preference for one methodology of calculating safe exposure levels over alternative methodology). We also conclude that EPA adequately responded to comments critiquing its reliance on the bomb studies.

Petitioners further contend that the dial painter data require the use of a quadratic dose-response curve for bone cancer, that is, one based on " 'a model which assumes that the excess risk is proportional to the *square* of the dose, meaning that low dosage presents no appreciable cancer risk,' " Respondent's Br. at 68 n.32 (quoting Nat'l Acad. of Scis. Comm. on the Biological Effects of Ionizing Radiation, *Health Risks of Radon and Other Internally Deposited Alpha-Emitters* IV (1988)) (emphasis added), rather than the linear, non-threshold ("LNT") model used by EPA, which assumes that the risk is directly proportional to the dosage and that there is no threshold dosage below which there is no risk, *see* FGR-13 at v. Here, again, the agency sufficiently justified its choice of model to satisfy the "rational relationship" standard.

First, while acknowledging that the dial painter data suggest a quadratic, rather than linear, dose response curve, EPA concluded that the data are "of limited value for the estimation of risk" because the various reliability problems noted above ("radium dosimetry, the high mortality in some groups, and the small numbers of subjects in all exposure groups") "would impair use of the data to develop dose response relationships." 65 Fed. Reg. at 76,721. In particular, EPA concluded that "there just are not enough subjects at lower dose levels to show the risk, giving the illusion of a threshold." *Id.* at 76,722.

Petitioners also assert the radium-224 exposure study results, from which EPA inferred that radium-226 and -228 can cause cancer of body parts other than the bone or head, are misleading because isotope -224 has different emissions from

-228 and a far shorter half-life than either -226 or -228. Petitioners point out that EPA itself observed in the NODA that such different characteristics can affect human health differently. EPA made the observation, however, in explaining why -224 had been and might again be considered less risky in *degree* than the other two isotopes, not because of any *qualitative* difference in effect. *See* 65 Fed. Reg. at 21,585–86. Petitioners further contend that there were no data showing that any radium isotope, even radium-224, caused cancer in the esophagus, stomach, colon, lung, skin, ovary, or kidney. Petitioners' Br. at 43. In the Final Rule, however, EPA expressly states that "patients treated with radium-224 were found to have significant increases in breast cancer, *soft tissue sarcomas*, liver cancer, thyroid cancer, cancers of urinary organs, and leukemia." 65 Fed. Reg. at 76,722 (emphasis added). "Soft tissue sarcomas," EPA points out, "can include any tissue in the body except cortical and trabecular bone." Respondent's Br. at 72 n.34 (citing FGR-13 at GL-9). In sum, EPA was justified in relying on the radium-224 studies for its conclusion that, "[g]iven our understanding of radium metabolism and the effects of alpha irradiation, it is expected that ingestion of any of the radium isotopes will increase the risks for various types of cancer other than bone." 65 Fed. Reg. at 76,722.

As additional justification for its model choice, EPA noted that the LNT model derives support "from the linear dose-response relationships observed for most types of cancers in the intermediate- to high-dose range for atomic bomb survivors, and from results of molecular and cellular studies." 65 Fed. Reg. at 76,721. The latter studies, EPA explained, "have shown that a single radiation track traversing a cell nucleus can cause unrepaired or misrepaired DNA lesions and chromosomal aberrations" and "that DNA lesions and chromosomal aberrations can lead to cancer." *Id.* From these data, EPA inferred, logically enough, "that the probability of DNA damage and carcinogenesis is linearly proportional to the dose." *Id.* EPA further noted that its use of the LNT model for radionuclides "is entirely consistent with all past and current observations and recommendations" of a

number of national and international science organizations[20] and that "the U.S. Department of Energy, the U.S. Nuclear Regulatory Commission, and other Federal and State agencies with regulatory authority over radioactive materials also apply the LNT model as the basis for setting regulations and guidelines for radiation protection." *Id.*; *see also* FGR-13 at v ("[S]everal recent expert panels ([United Nations Scientific Committee on the Effects of Atomic Radiation 1993, 1994; National Radiation Protection Board 1993; and the National Council on Radiation Protection and Measurements 1997]) have concluded that the LNT model is sufficiently consistent with current information on carcinogenic effects of radiation that its use is scientifically justifiable for purposes of estimating risks from low doses of radiation. As a practical matter, the LNT approach is universally used for assessing the risk from environmental exposure to radionuclides as well as other carcinogens.")[21]

Finally, petitioners contend EPA did not demonstrate that the FGR-13 model represents the "best available, peer-reviewed science," as required by § 1412(b)(3)(A) ("In carry-

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[20] The agency identified in particular the International Commission on Radiological Protection, the National Council on Radiation Protection and Measurements, the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation, the United Nations Scientific Committee on the Effect of Atomic Radiation, and the National Radiation Protection Board. 65 Fed. Reg. at 76,721.

[21] EPA also stated:

> [T]o address [the] limitations and the uncertainties associated with this model and improve its radiation risk assessments, EPA is actively supporting national and international studies of radiation dosimetry and dose reconstruction, radionuclide biokinetics, quantitative techniques for uncertainty analyses, and long-term follow-up epidemiological studies of populations exposed chronically to low-dose radiation. The Agency also continues to review its policies and positions as new reports and data are published so that the best science is applied.

65 Fed. Reg. at 76,721.

ing out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices. . . .”). As set out above, however, EPA adequately explained, based on scientific data, why it prefers the FGR-13 model and the epidemiological data it used over the dial painter studies and the approaches based thereon that petitioners endorse. Further, as EPA notes, the SAB, whose imprimatur petitioners particularly esteem, reviewed and approved the FGR-13 methodology as it was employed in a 1994 EPA document “Estimating Radiogenic Cancer Risks,” and also reviewed and commented on the interim version reported in 1998, *see* FGR-13 at vi.[22] The substantial scientific support on which EPA relies for selecting the FGR-13 model (and in particular its LNT approach) distinguishes this case from *Chlorine Chemistry Council v. EPA,* 206 F.3d 1286 (D.C. Cir. 2000), in which the court found EPA’s use of a *default* assumption of linearity and zero MCLG violated the SDWA because it “openly overrode the ‘best available’ scientific evidence, which suggested that chloroform is a threshold carcinogen”—a concession EPA had made at oral argument in that case. *See* 206 F.3d at 1290, 1291.

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[22] Petitioners also contend in their reply brief that EPA violated § 1412(b)(3)(B) by failing to specify “an upper bound, lower bound, and central risk estimate” or to identify “the range of alternative risk estimates produced by other methods that use the dial painter studies,” Petitioners’ Reply Br. at 37, and ignored the congressional directive “to inform the public of ‘alternative risk estimates that put the regulation in broader public health context,’ ” *id.* (quoting S. Rep. No. 104-169, at 29). Because this argument was raised in the opening brief only summarily, without explanation or reasoning, *see* Petitioners’ Br. at 33–34, 49, and first raised comprehensibly only in the reply brief, it is waived. *See Tribune Co. v. FCC,* 133 F.3d 61, 69 n.8 (D.C. Cir. 1998) (noting “our requirement that a parties’ [sic] arguments be sufficiently developed lest waived”); *Steel Joist Inst. v. OSHA*, 287 F.3d 1165, 1166 (D.C. Cir. 2002) (argument presented for first time in reply brief held waived) (citing *Benkelman Telephone Co. v. FCC,* 220 F.3d 601, 607 n.10 (D.C. Cir. 2000)).

VI. THE MERITS OF THE URANIUM MCLs

Petitioners also challenge EPA's determination of both the MCLG at 0 μg/L and the MCL at 30 μg/L for uranium on the merits of the science used by EPA. They make three challenges to the MCLG and assert that EPA's reliance on an improper MCLG tainted its MCL determination, as did EPA's reliance on kidney toxicity data. Regarding the MCLG, petitioners contend that (1) "the best available peer-reviewed science," 42 U.S.C. § 300g-1(b)(3)(A)(i), does not support a 0 μg/L MCLG because the LNT model used by EPA is not supported by the science; (2) under EPA's classification system for carcinogens, a 0 μg/L MCLG is inappropriate; and (3) EPA ignored a report by the Agency for Toxic Substances and Disease Registry ("ATSDR") on the toxicity of uranium. Finally, petitioners also argue that EPA's cost-benefit decision, which determined the final level for the MCL, was substantively flawed.

In setting the uranium standard, EPA first set the MCLG for uranium based on the risks of carcinogenicity. 65 Fed. Reg. at 76,712. EPA reasoned that because natural uranium is a radionuclide, and all radionuclides emit ionizing radiation that can cause cancer, there was no threshold level of safety for uranium. *Id.* EPA then concluded that the lowest feasible level for controlling the risks of cancer from natural uranium in drinking water was 20 μg/L. *Id.* Next, EPA addressed the effects of uranium on the human kidney, deciding that the best available science showed that uranium did have toxic effects on the human kidney, and that the level of uranium in drinking water that could be expected to protect human health was 20 μg/L. *Id.* at 76,713. EPA added that 30 μg/L would be expected to protect against the effects of kidney toxicity, *id.* at 76,713–14, but that any higher level might result in serious adverse effects on human kidneys, *id.* at 76,714. Finally, EPA relied on its cost-benefit analysis to conclude that at 30 μg/L essentially the same health benefits could be achieved at much lower cost compared to the 20 μg/L level. *Id.* EPA therefore set the uranium MCL at 30 μg/L.

EPA relied on the LNT model in setting the MCLG for uranium at zero. 65 Fed. Reg. at 76,712. According to petitioners, "there is no evidence in the record to support linearity and no evidence which detracts from the weight of the scientific evidence that supports the application of a non-linear model." Petitioners' Br. at 52. There was evidence in the record, primarily provided by RSH, that radionuclides in general only cause harm above a certain threshold level. There were also specific critiques of the linearity model as applied to uranium. However, the bomb studies in the record provide ample support for the linearity model, *see* 65 Fed. Reg. at 76,721, and there is also evidence in the record that uranium may be a carcinogen without a threshold level of safety. EPA noted that there is clear evidence that uranium (as with all radionuclides in general) emits ionizing radiation, that ionizing radiation causes genetic defects, and that genetic defects may lead to cancer. *See* 65 Fed. Reg. at 21,587, 21,600; 65 Fed. Reg. at 76,721. Although this evidence is based on enriched uranium, that does not exclude the possibility that natural uranium may have the same impact. EPA noted that the impacts of natural uranium may be difficult to detect because of the small doses of radiation involved and the comparatively small changes in cancer risk that would result; moreover, the pathway for causation would be the same for both enriched and natural uranium.

The resolution of this contradictory data lies well within EPA's expertise. *Chlorine Chemistry Council*, on which petitioners rely, is not to the contrary. In that case, the court concluded that EPA's reliance on the LNT model was inappropriate because EPA *itself* concluded that the chemical in question (chloroform) only caused harm above a threshold level. 206 F.3d at 1288. EPA failed to change the MCLG from zero because it wanted to wait for an additional report from SAB. *Id.* The court held that EPA's decision was arbitrary and capricious inasmuch as EPA had already concluded that the best science showed that there was a threshold effect, and EPA could always justify delay by stating that it wanted to wait for additional evidence to come in. *Id.* at 1290–91. In the instant case, by contrast, EPA maintains

that the best available evidence still shows that uranium is a non-threshold carcinogen. Given the contradictory evidence in the record, there is no basis for the court to override EPA's decision for this is not a situation where "there is simply no rational relationship between the model chosen and the situation to which it is applied." *Am. Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1004 (D.C. Cir. 1997) (quotation omitted).

Petitioners' next contention is that EPA did not follow its own procedures for classifying carcinogens when it set the MCLG for uranium at zero. According to petitioners, EPA classifies substances as having an MCL of zero when the substance falls into one of three groups:

> Group A, human carcinogens based on strong evidence of carcinogenicity from drinking water ingestion or sufficient evidence from epidemiological studies; Group B-1, probable human carcinogen based on at least limited evidence of carcinogenicity based on epidemiological studies in humans; Group B-2, probable human carcinogen based on sufficient evidence in animals and inadequate evidence or no data from epidemiological studies in humans.

Petitioners' Br. at 53. EPA does not contest petitioners' characterization of its classification process, but denies that it misapplied it in this case.

Apparently EPA classifies all radionuclides as Group A carcinogens based on the fact that they emit ionizing radiation that can cause cancer. 65 Fed. Reg. at 76,721. Again, this is a reasonable conclusion by EPA based on the evidence in the record. EPA is not relying on data from natural uranium, any effect of which EPA has concluded might be very difficult to detect through epidemiological or laboratory studies, but instead is relying on an extrapolation from other radionuclides and the laboratory and epidemiological data associated with those compounds. *See* 65 Fed. Reg. at 76,-721; *see also* 56 Fed. Reg. at 33,071–72. Although studies to date may not have detected any impacts of natural uranium on cancer rates when it is ingested in drinking water in humans, EPA could reasonably conclude that based on the

known carcinogenic potential of similar substances, natural uranium should also be considered a Group A carcinogen.

Petitioners make much of statements by EPA in its proposed rule in 1991 on a uranium MCLG, where EPA noted that "[s]tudies using natural uranium do not provide direct evidence of carcinogenic potential" in animals and that "[e]xisting human epidemiology data are inadequate to assess the carcinogenicity of uranium ingested in drinking water." 56 Fed. Reg. at 33,076. However, EPA continued to explain in those statements that there were limitations to the studies that had found no effect, that other radionuclides were known to be harmful, that the pathways by which those radionuclides caused harm would be the same as for natural uranium, and that therefore the agency would continue to classify natural uranium as a Group A carcinogen. *Id.*

Petitioners also maintain that EPA improperly relied on data that uranium causes cancer by inhalation in concluding that it should be a Group A carcinogen, and state that this "is a fatal flaw." Petitioners' Br. at 55. It is true that EPA has generally declined to rely on inhalation data when making decisions about the carcinogenic properties of a substance when ingested. *See Int'l Fabricare Inst.*, 972 F.2d at 395. However, the statements made in the 1991 proposed rule do not indicate that EPA significantly relied upon the inhalation data. 56 Fed. Reg. at 33,076.

Petitioners further maintain that EPA should be forced to treat radionuclides in the same manner that it treated asbestos, where EPA concluded that despite asbestos' status as a Group A or B chemical, it would not automatically be treated as a non-threshold carcinogen because the agency believed that the "additional evidence indicates that the overall evidence of carcinogenicity via ingestion is limited or inadequate." National Primary Drinking Water Regulations; Final Rule, 56 Fed. Reg. 3,526, 3,534 (Jan. 30, 1991). However, as EPA points out, asbestos is a completely different chemical from natural uranium. Given the evidence for similar radionuclides, EPA could reasonably conclude that the minimal direct evidence for natural uranium's carcinogenicity should

be treated differently from the slightly more substantial direct evidence for asbestos.

Finally, petitioners contend that EPA ignored a report by the ATSDR on the risks of natural uranium. The ATSDR report concluded that:

> No evidence linking oral exposure to uranium to human cancer has been found. Although natural, depleted, or enriched uranium and uranium compounds have not been evaluated in rodent cancer bioassays by any route by the [National Toxicology Program], there is potential for the carcinogenicity of uranium, since it emits primarily alpha radiation. Nevertheless, no evidence has been found to associate human exposure to uranium compounds and carcinogenicity. The National Academy of Sciences has determined that bone sarcoma is the most likely cancer from oral exposure to uranium; however, their report noted that this cancer has not been observed in exposed humans and concluded that exposure to natural uranium may have no measurable effect.
>
> Similarly, the results of several oral studies with uranium in several species were negative for evidence of cancer induction.

ATSDR, U.S. Dep't of Health and Human Servs., *Toxicological Profile for Uranium* 137–38 (1999) (citations omitted). In replying to commenters who relied on the ATSDR report, EPA stated that "ATSDR's statement does not preclude human carcinogenesis." Comment-Response Document (response to comment 9.A.4). This appears to be a correct reading of the ATSDR report, and, again, EPA is generally entitled to rely on evidence from other radionuclides and the potential for cancer from natural uranium's emission of ionizing radiation in the face of the uncertainty inherent in any scientific study's failure to identify a significant effect. Nor does EPA's failure to mention the ATSDR in its NODA or its technical documents that accompanied the NODA mean, as petitioners maintain, that EPA did not rely on the "best available science." The ATSDR report is not primary research based on ATSDR's own studies; instead, it is a

summary and review of the literature that has been published, the same type of undertaking that EPA's NODA and technical documents performed. We fail to see how EPA's failure to mention the ATSDR report in these documents is fatal to its analysis. Further, EPA's response to the comments mentioning the ATSDR report is adequate.

Petitioners in a footnote of their reply brief also state, "While EPA argues that FGR-13 represents EPA's 'most sophisticated science,' EPA did not utilize FGR-13 to develop the uranium standard. EPA neither disputes nor discusses this point in its brief." Petitioners' Reply Br. at 33 n.150 (citation omitted). Petitioners do not state what legal flaw results from EPA's failure to use FGR-13, although the implication is that EPA did not meet the "best available science" standard of the SDWA. However, petitioners' only references to this argument in their opening brief were two sentences that also referred to EPA's failure to discuss FGR-13 in setting the uranium MCL, without explaining the legal implication of that failure. This is the type of "asserted but unanalyzed" contention that the court will not address. *See SEC v. Banner Fund Int'l*, 211 F.3d 602, 613 (D.C. Cir. 2000) (quoting *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983)).

Because EPA's MCLG is proper, petitioners' challenge to the MCL based on the MCLG fails. To the extent petitioners also challenge EPA's reliance on kidney toxicity data, data which it relied upon in setting the MCL at 30 μg/L, the thrust of petitioners' challenge is that EPA relied on studies that "showed risks so small that EPA could not determine whether exposure resulted in an adverse impact," that EPA admitted that human studies were uncertain as to the actual impacts on kidneys from uranium consumption, and that EPA's conclusions were primarily based on data from experiments on rats using uranyl nitrate, a compound of uranium, rather than natural uranium itself. Petitioners' Br. at 61. However, in the face of uncertain laboratory and epidemiological data, it was reasonable for EPA to take the risk-averse

approach of relying on the animal laboratory data to develop a lower standard.

Regarding petitioners' challenge to EPA's decision to set the final MCL at 30 μg/L based on its cost-benefit analysis, the court's review is limited to determining whether EPA's analysis and final cost-benefit decision is arbitrary and capricious. 42 U.S.C. § 300g-1(b)(6)(D). Petitioners contend that EPA "should have compared the cost per cancer case avoided":

> When EPA selected from the acceptable uranium levels, EPA should have compared the cost per cancer case avoided for each proposed uranium MCL. EPA did not do that. Had the agency done so, it would have found that the incremental cost savings associated with raising the standard from 30 μg/L to 40 μg/L ($64.1 million) was even higher than the incremental cost savings that prompted EPA to raise the standard from 20 μg/L to 30 μg/L ($45.2 million) while still achieving an acceptable cancer risk. Thus if EPA applied the same analysis to the cost differences between 30 μg/L and 40 μg/L, as it did to the costs between 20 μg/L to 30 μg/L, it would have concluded that an increase to 40 μg/L was appropriate.

Petitioners' Br. at 32. The figures that petitioners cite in their brief are the aggregate amounts of money saved by relaxing the standards; at no point did petitioners discuss the increase in the number of cancer deaths or cases that would occur if the standards were relaxed. By definition, however, that increase must be considered in order to compare "the cost per cancer case avoided," as petitioners request. In other words, petitioners' contention is internally inconsistent. Furthermore, a review of EPA's cost-benefit analysis shows that the cost per cancer case avoided is lower between 30 and 40 μg/L compared to between 20 and 30 μg/L, contrary to petitioners' assertions. Most importantly, EPA concluded that kidney risks increased substantially above 30 μg/L, sharply increasing the benefits foregone by raising the stan-

dard above that point. 65 Fed. Reg. at 76,713-14. EPA's decision therefore was not arbitrary and capricious.

VII. THE MERITS OF THE BETA/PHOTON MCLs

As noted above, the 1996 amendments to the SDWA state that:

> In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

42 U.S.C. § 300g-1(b)(3)(A). Petitioners contend that, because EPA did not use today's "best available science" when it promulgated beta/photon MCLs in 1976, it violated § 1412(b)(3)(A)'s "best available science" requirement (as well as the APA) by retaining those pre-existing MCLs in 2000. What EPA should have done in 2000, petitioners insist, is apply the latest risk assessment model—set out in FGR-13—to establish uniform risk at a level EPA deemed appropriate.

EPA does not dispute that it utilized now-outdated methods to predict mortality and morbidity rates for beta/photon emitters in promulgating the 1976 MCLs. The methodology EPA used in 1976 did not differentiate among various beta/photon emitters and their effects on particular organs within the body. *See* 65 Fed. Reg. at 21,602–03. The agency further admits that a newer "effective dose equivalent" methodology, which accounts for a particular organ's sensitivity to radiation, is now available, and that FGR-13 incorporates the newer methodology. *See id.*; Respondent's Br. at 83. Indeed, both parties agree that, for purposes of this challenge to the beta/photon MCLs, FGR-13 represents the "best available science." *See* Petitioners' Reply Br. at 45; Respondent's Br. at 83.

EPA nonetheless insists that it complied with the SDWA's "best available science" requirement, because it used FGR-13

for the analysis that led to its 2000 decision to retain the 1976 MCLs. That analysis disclosed that the 1976 MCLs continue in virtually all cases to confine health risks within the acceptable range of between 1 x 10^{-4} and 1 x 10^{-6} (1 in 10,000 to 1 in 1,000,000) lifetime excess risk of cancer. 65 Fed. Reg. at 21,583, 21,605–14 tbl. II-3. Moreover, EPA also used FGR-13 to evaluate the new beta/photon MCLs that the agency proposed in 1991. EPA decided to retain the 1976 levels in favor of the 1991 proposals because FGR-13 showed that the latter were in almost all cases outside the acceptable range and less protective of human health than the 1976 levels. *Id.* We see nothing unreasonable about EPA's assertion that this approach was consistent with the "best available science," and nothing arbitrary about its decision to retain the 1976 MCLs under these circumstances.

Petitioners do not seriously dispute that EPA used the "best available science" to *analyze* the health risks posed by the 1976 and proposed 1991 MCLs.[23] Instead, they argue that the "best available science" should have led the agency to promulgate beta/photon MCLs that provide a uniform level of protection. Although in 1976 EPA thought that the more than 160 beta/photon MCLs it was setting would yield a consistent risk level of 5.6 x 10^{-5} for each beta/photon emitter, EPA's current analysis discloses that each MCL actually yields a different risk level. *See id.* at 21,582 fig.1; *id.* at 21,605–14 tbl. II-3. Because it is possible to use FGR-13 to establish MCLs with uniform protection levels, petitioners contend that it contradicts the "best available science" not to do so.

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[23] Petitioners did assert in their opening brief that EPA's application of FGR-13 risk coefficients to MCLs derived under different methodologies yielded "an analysis that combined and compared multiple, incompatible generations of science, which necessarily yielded inconsistent and incomparable results." Petitioners' Br. at 75. But EPA reasonably responded that all of the relevant methodologies result in dose limits expressed in pCi/L, which unit is compatible with FGR-13's risk coefficients. Respondent's Br. at 85–86. Petitioners did not return to this issue in their reply brief.

But just because science makes a result possible, does not mean that it would contradict the "best available science" not to achieve it. Indeed, as petitioners conceded at oral argument, there is nothing in the record—neither scientific studies nor anything else—to suggest that the "best available science" itself requires uniformity in risk protection. Nor is there anything in the SDWA that requires that the level of risk protection provided for each contaminant be the same. Accordingly, whether to insist upon uniformity is a policy judgment that the SDWA leaves to EPA's discretion.[24]

In this case, EPA concluded that uniformity was not a goal it should strive to achieve for the beta/photon MCLs. The agency noted that to produce uniformity, it would have to undertake an extensive new rulemaking process. 65 Fed. Reg. at 21,581. And it reasonably concluded that such an effort was unnecessary because, while the actual level of risk posed by the 1976 MCLs varies, in virtually all cases it is within the range regarded as acceptable both in 1976 and today, and below the level of risk expected in 1976. *See id.* at 21,582 fig.1; *id.* at 21,605–14 tbl. II-3. Of the more than 160 existing MCLs, all but ten yield risks below the agency's upper limit of 1×10^{-4}. Respondent's Br. at 83; Tape of Oral Argument, Nov. 20, 2002; *see also* 65 Fed. Reg. at 21,605–14 tbl. II-3. Of those ten, only one (cesium) is likely to be found at decommissioning sites, and none is likely to be found in drinking water. *See* 65 Fed. Reg. at 21,583; Tape of Oral Argument, Nov. 20, 2002.

Uniformity, of course, is not the only thing petitioners are after. Their ultimate aim is to raise at least some of the MCLs, and, accordingly, they argue that the existing MCLs are "artificially low and unnecessarily conservative." Petitioners' Br. at 64. Perhaps for this reason, petitioners sug-

[24] The SDWA plainly contemplates that not all agency decisions under the Act will be science-based. *See* 42 U.S.C. § 300g-1(b)(3)(A) ("In carrying out this section, and, *to the degree that an Agency action is based on science*, the Administrator shall use—(i) the best available, peer-reviewed science . . . ." (emphasis added)).

gest that EPA had no reasonable basis for distinguishing between the 1976 MCLs and the substantially higher MCLs proposed in 1991. But as noted above, EPA did have a rational basis for preferring the 1976 MCLs over those proposed in 1991: the 1991 proposed levels were in almost all cases less protective of human health than the 1976 levels and outside the range of acceptable cancer risk. 65 Fed. Reg. at 21,583; *see id.* at 21,582 fig.1; *id.* at 21,605–14 tbl. II-3.

Moreover, although there is nothing in the record to suggest that the "best available science" requires uniformity, even if it did the anti-backsliding provision of § 1412(b)(9) would still prevent the agency from raising the MCLs above those set in 1976. That provision imposes a limitation on any revision "promulgated in accordance with this section," 42 U.S.C. § 300g-1(b)(9), and the "best available science" provision is a part of the same referenced section, *see id.* § 300g-1(b)(3)(A). Section (b)(9)'s limitation is as follows: "[E]ach revision shall maintain, or provide for greater, protection of the health of persons." *Id.* § 300g-1(b)(9). Once again, petitioners contend that § (b)(9) does not preclude an increase in an MCL when current science shows that the MCL can be increased without reducing the level of protection the agency initially *thought it was providing*. *See supra* Part III.B. And, once again, we accept as reasonable EPA's reading of the section as barring any revision to an existing MCL that does not maintain the level of protection the current MCL *actually provide*s. *See id.* Hence, EPA could not achieve the uniformity for which petitioners argue without *lowering* most of the 1976 beta/photon MCLs until they yield the risk level actually provided by the most protective of those MCLs—a result petitioners do not seek and that would defeat their aim in bringing this petition.

In sum, we conclude that EPA neither failed in its obligation to use the "best available science" nor acted arbitrarily or capriciously in retaining the 1976 beta/photon MCLs.

VIII. FAILURE TO RESPOND TO COMMENTS

Finally, petitioners contend EPA did not adequately respond to comments submitted in opposition to using the LNT

model. Section 553 of the APA requires that an agency "shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation" and, "[a]fter consideration of the relevant matter presented, . . . shall incorporate in the rules adopted a concise general statement of their basis and purpose." 5 U.S.C. § 553(c). The agency "need not address every comment, but it must respond in a reasoned manner to those that raise significant problems." *Reytblatt v. Nuclear Regulatory Comm'n,* 105 F.3d 715, 722 (D.C. Cir. 1997) (citing *Action on Smoking & Health v. CAB,* 699 F.2d 1209, 1216 (D.C. Cir. 1983)). Nevertheless, " '[t]he failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors.' " *Texas Mun. Power Agency v. EPA,* 89 F.3d 858, 876 (D.C. Cir. 1996) (quoting *Thompson v. Clark,* 741 F.2d 401, 409 (D.C. Cir. 1984); alteration in original). The record here does not demonstrate that EPA failed to consider the relevant factors.

Petitioners object to EPA's "general and generic" response to comments, citing specific studies that they contend reflect the "best available science" and show the LNT model is inappropriate. In its first response to a comment challenging the LNT model and zero MCLG (frequently cross-referenced in responses to later comments), EPA summarized its reasons for choosing the LNT model and stated it had "reviewed the documents submitted by the commenter that purport to provide new scientific evidence to counter the Agency's position that there is 'no threshold' for carcinogens such as the radionuclides," that "much of the information in these documents was familiar to the Agency and accordingly had already been considered" and that "the submissions cite anecdotal or case report data, provide comment on other documents or positions or policy decisions, or selected observations" and "do not provide the kind of data that EPA discusses in the remainder of this response." Comment-Response Document 3-5 (response to comment 3.A.1). This response demonstrates that the agency considered and rejected petitioners' arguments (and cited support) for adopting the quad-

ratic model over the LNT model—an issue the agency had already thoroughly addressed in the rulemaking proceeding. This is all that the APA requires.[25] *See Am. Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1005 (D.C. Cir. 1997) (finding comment response sufficient if it "demonstrates that the agency at least considered whether it should adopt [an alternative] model"); *Thompson*, 741 F.2d at 409-10 (concluding that "nothing had been presented which required some explanation beyond that already contained within the rulemaking record to assure [the court] that 'all relevant factors ha[d] been considered' ") (quoting *Home Box Office v. FCC,* 567 F.2d 9, 36 (D.C. Cir. 1977)).[26] Accordingly, we reject petitioners' challenge to the adequacy of EPA's responses to their comments.

IX. CONCLUSION

For these reasons, the petition for review filed by RSH is dismissed for lack of standing, and the remaining petitions for review are denied.

So ordered.

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[25] Petitioners' counsel made it clear at oral argument that their objections to the comment responses are procedural ones, addressed only to the sufficiency of the responses, and are not intended as substantive challenges to the merits.

[26] The response also recited that "[d]etailed responses to the issues raised and the arguments presented in those submissions [would] follow[ ]," and, in many cases, EPA did provide more specific critiques of particular studies. *See, e.g.*, Comment-Response Document 3-14 (response to comment 3.B.5), 3-30 (comment 3.B.16), 3-28 (comment 3.B.23), 3-29 (comment 3.B.26-27).