Complex Case

ORAL ARGUMENT SCHEDULED FOR NOVEMBER 20, 2002

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 01-1028 and consolidated cases

CITY OF WAUKESHA; NUCLEAR ENERGY INSTITUTE, INC.; NATIONAL MINING ASSOCIATION; AND RADIATION, SCIENCE & HEALTH, INC.

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

VILLAGE OF SUSSEX WATER COMMISSION, et al.,

Intervenors.

Petition for Review of Regulations of the United States Environmental Protection Agency

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GLOSSARY OF ACRONYMS AND ABBREVIATIONS

AEA	Atomic Energy Act
APA	Administrative Procedure Act
ATSDR	Agency for Toxic Substances and Disease Registry
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CRD-NODA	Comment Response Document - Notice of Data Availability
EDE	Effective Dose Equivalent
EPA	Environmental Protection Agency
FGR	Federal Guidance Report
HRRCA	Health, Risk, Reduction and Cost Analysis
ICRP	International Commission on Radiological Protection
LNT	Linear Non-Threshold
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
NEI	Nuclear Energy Institute, Inc.
NMA	National Mining Association
NODA	Notice of Data Availability
NPDWR	National Primary Drinking Water Regulations
RfD	Reference Dose
RSH	Radiation, Science & Health, Inc.
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act

SUMMARY OF ARGUMENT

EPA's Response invites the Court to allow the agency to rewrite the Safe Drinking Water Act ("SDWA") and to ignore requirements of that statute and the Administrative Procedure Act ("APA").

EPA would ignore SDWA requirements to publish and use a health risk reduction and cost analysis ("Analysis" or "HRRCA") for the proposed uranium MCL and for each alternative MCL being considered and to publish a cost-benefit determination ("Determination") in time for public comment. The SDWA and the APA required EPA to publish, seek comment on, and use an Analysis for each alternative uranium MCL under consideration, and to publish and seek comment on the Determination.

For the proposed radium and beta/photon MCLs, EPA would rewrite the SDWA to require the Analysis and Determination for only "new" MCLs. Even then, EPA ignores that some of those MCLs are new. Because the statute requires EPA to publish the Analysis "when proposing any" MCL, EPA should have published Analyses for those proposed MCLs. Even if it were relevant, the exemption cited by EPA exempts "established" MCLs only from "standards" – not from the procedures for the Analyses and Determinations required when MCLs are proposed. And the exemption omits any reference to the provision requiring the Analysis. Even if the statute's mandate to maintain health protection were relevant, it applies only when MCLs are established and does not preclude raising an MCL based on current science.

For each of these MCLs, EPA would ignore SDWA requirements to analyze all risks and costs of compliance. The SDWA's mandate is to consider all risks and costs of complying with MCLs, including CERCLA compliance costs, risks from disposal of concentrated waste, and the "deferred costs" EPA played a part in causing.

Petitioners do not ask this Court to exchange judicial robes for laboratory coats and to substitute its judgment for EPA's.

For beta/photon MCLs, Petitioners ask only that EPA abide by the statute and employ what EPA recognizes as the best available science. Having claimed that its recent guidance, FGR-13, is the best science, EPA violated the SDWA's best science mandate by establishing beta/photon MCLs based on obsolete science.

For the remaining MCLs, Petitioners ask that EPA be required to demonstrate on the record that it considered all the relevant factors, used the best science, and provided appropriate responses to significant comments questioning EPA's scientific analysis. EPA ignores the APA and SDWA with inadequate explanations and conclusory responses. Relying on ominous statements of what is "most obvious to the popular mind" and on apocalyptic references,[1] EPA asks the Court to decide whether the agency's science is the best science.

Petitioners have standing. If they prevail on their claims, as standing law presumes, the Court can redress their grievances. NEI and RSH have asserted sufficient interest and injury to bring their grievances to this Court.

The Court should decline EPA's invitations and not reward its rush to finish this rulemaking before the end of 2000. The Court should vacate the Rule and remand with instructions to comply with the APA and the SDWA provisions that Congress wrote.

[1] Respondent's Brief ("Resp.") at 3.

ARGUMENT

I. PETITIONERS HAVE STANDING.

A. EPA's Redressability Attack Is A Merits Argument, Not A Standing Challenge.

EPA's assertion that Waukesha and NEI lack standing because their claims are not redressable assumes that EPA prevails in this litigation. However, the law of standing presumes Petitioners will win and asks only whether the Court can grant relief.[2] It can. If Petitioners are correct that, when proposing to retain existing MCLs, EPA must publish an Analysis of the health risk benefits of the proposed MCLs and its Determination of whether those benefits are cost- justified, the Court can order EPA to do so. If Petitioners are right that EPA did not adequately respond to comments, that can be ordered. If Petitioners are right that EPA did not demonstrate that it satisfied the SDWA's best science mandate, the Court can order EPA to do so. Because a remand may result in changed MCLs,[3] Petitioners have standing.

B. NEI Has Standing.[4]

EPA concedes NEI's prudential standing, challenging only NEI's constitutional standing, which requires an actual or threatened injury, traceable to the challenged action, and likely to be redressed by a favorable court decision.[5] NEI has these.

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[2] *See In Re Thornburgh*, 869 F.2d 1503, 1510-11 (D.C. Cir. 1989).

[3] Contrary to EPA's view, section 1412(b)(9) allows MCL concentration limits to be raised from earlier levels if health protection is maintained. *See* Section VI.D. Because the Court must presume that Petitioners will prevail, for standing purposes, section 1412(b)(9) cannot bar Petitioners' claims.

[4] Because *Sierra Club v. EPA*, 292 F.3d 895 (D.C. Cir. 2002), was decided after Petitioners' initial brief, NEI may supplement its standing arguments here.

[5] *See, e.g., id.* at 898.

1. *International Fabricare Institute* Controls.

EPA's concession that the Nuclear Energy Institute ("NEI") has prudential standing under *International Fabricare Institute v. EPA*, 972 F.2d 384 (D.C. Cir. 1992) ("*IFI*")[6] effectively also concedes constitutional standing. In *IFI*, the Court did not distinguish between constitutional and prudential standing, finding that IFI had both because it faced a "genuine threat of CERCLA liability for the cleanup" and drinking water standards would affect cleanup costs.[7] This case is identical to *IFI* -- NEI members face a genuine threat of CERCLA liability when decommissioning their facilities, and that liability will be affected by the standards EPA adopts. NEI thus has constitutional standing.

2. NEI Members Are Injured.

NEI's members include nuclear power plant licensees that must finance the cleanups associated with decommissioning those facilities. EPA has expressed its intention to impose CERCLA requirements, including the SDWA MCLs, at decommissioned sites.[8] EPA's imposition of MCLs at decommissioned sites affects NEI members' liability.[9] Additionally, NEI members have an interest in the predictability and consistency of these standards.[10] Thus, the MCLs pose a concrete threat of injury to NEI members.[11]

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[6] Resp. at 27 n.15.

[7] *IFI*, 972 F.2d at 390.

[8] *See* Petitioners' Brief ("Pet.") at 24 n.112; *see also* GAO, Radiation Standards: Scientific Basis Inclusive and EPA and NRC Disagreement Continues (June 2000) at 20-23 ("GAO Report"); Declaration of Ralph Andersen (Oct. 2, 2002) ¶¶ 3-4 ("Andersen Decl.") (Attachment A).

[9] Andersen Decl. ¶¶ 6-10. *See also* GAO Report at 21, 25-26 (dual regulation increases compliance costs; more restrictive protection levels are more expensive).

[10] Andersen Decl. ¶ 5.

[11] Although these costs have not yet been incurred, they are a sufficient threat to constitute injury. *See, e.g., Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1289-90 (D.C. Cir. 2000) (organization had

(Continued …)

3. NEI Members' Injuries Are Redressable.[12]

Redressability requires that a plaintiff "benefit in a tangible way from the court's intervention."[13] A ruling that EPA must use best available science to set MCLs and that EPA consider the risks and costs associated with MCLs in CERCLA contexts would advance NEI's interest in consistent, predictable, cleanup standards. NEI members undertaking such cleanup would no longer be burdened by unnecessary costs associated with the use of obsolete beta/photon standards.[14]

C. RSH Has Standing.

EPA argues that Radiation, Science and Health, Inc. ("RSH") failed to establish associational standing. RSH, however, properly alleged that its members would be injured based on the likelihood of increased drinking water costs resulting from this regulation, which EPA recognizes is a cognizable injury.[15] In addition, as reflected in its comments, RSH's organizational purpose includes ensuring that current scientific data and theories are applied to radiation protection policy so that these regulations do not result in unnecessary costs to the public, including its members.[16] RSH, therefore, has sufficiently alleged standing.[17]

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standing even though standard had not yet been applied); *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 51 (D.C. Cir. 1999) (impending threat of injury constitutes injury-in-fact).

[12] *See* Section VI.D.

[13] *Warth v. Seldin*, 422 U.S. 490, 491 (1975).

[14] Andersen Decl. ¶¶ 6-10.

[15] *See* Resp. at 25 n.13 (Bruce Zivney properly alleges injury based on his status as a ratepayer); *see also Environmental Def. Fund, Inc. v. Hardin*, 428 F.2d 1093, 1096-97 (D.C. Cir. 1970) ("Consumers of regulated products and services have standing to protect the public interest in the proper administration of a regulatory system enacted for their benefits."); *Environmental Action v. FERC*, 996 F.2d 401, 406-07 (D.C. Cir. 1993) (injury where agency's action affected electric rates paid by association members).

[16] *See, e.g.*, EPA Comment-Response Document for the Radionuclides Notice of Data Availability (April 2000), at 3-24 (Nov. 2000) (Comment 3.B.19) (DI II-B-16) ("CRD-NODA")

(Continued …)

II. EPA MISCONSTRUES THE SDWA HEALTH RISK REDUCTION AND COST ANALYSIS REQUIREMENTS.

A. EPA Must Complete A Health Risk Reduction And Cost Analysis And Cost-Benefit Determination At The Time Of Proposal For Each MCL Under Consideration.

The plain language of sections 1412(b)(3)(C) and 1412(b)(4)(C) requires EPA to: (1) conduct a health risk reduction and cost analysis ("Analysis" or "HRCCA") for "any" MCL and for "each alternative" MCL under consideration; (2) "use" the "analysis" to make a "determination" whether the benefits of a proposed MCL justify its costs; (3) "publish" the "analysis" and cost-benefit "determination" at the time EPA "is proposing" and "proposes" an MCL; (4) "seek public comment on" that information; and (5) then "use" the analysis, determination, and any public comments to establish MCLs.[18] That language shows that the purpose of these requirements is not only to inform EPA's decision but also to inform the water-consuming and cost-paying public of that information and provide an opportunity for them to express their views.

Rather than publishing the Analyses and Determination "when proposing" MCLs, EPA argues it may do so after closing the comment period and identifying the final MCL, and then only if EPA adopts a "new" MCL. EPA ignores the words Congress used, and would rewrite the

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(Comments Submitted by RSH ("RSH Comments") (DI I-I-1-29) (JA 957); RSH, Low Level Radiation Health Effects: Compiling the Data (1998) ("Compiling the Data") (attached to RSH Comments) § 1.8 (JA 730-731). To meet this requirement, this Court has applied an "undemanding" test, requiring only "mere pertinence between litigation subject and organizational purpose." *Humane Soc'y of the United States v. Hodel*, 840 F.2d 45, 58 (D.C. Cir. 1988) (citations omitted).

[17] EPA argues, erroneously, that RSH may assert alone some or all of the challenges to the use of the LNT model. Resp. at 28 n.16. Waukesha and NMA join in those challenges. Because EPA has acknowledged NMA's standing and Waukesha's injury, Resp. at 25 n.13, these issues are properly before the Court regardless of RSH's standing.

[18] 42 U.S.C. §§ 300g-1(b)(3)(C), (b)(4)(C).

statute by adding the word "new" after the word "any" in section 1412(b)(3)(C).[19] EPA also ignores the purposes of these requirements and the fact that public comments might lead EPA to reach a different conclusion regarding the final MCL or whether to replace an existing MCL with a new one. EPA cannot complain about the burden of these requirements because Congress authorized an appropriation of $35,000,000 a year for fiscal years 1996 through 2003 to EPA to carry them out.[20]

EPA ignored the plain language of the SDWA and failed to comply with these requirements. EPA did not publish any Analyses or Determination for any proposed beta/photon MCL. For uranium, EPA belatedly published an Analysis after deciding upon the final MCL of 30μg/L and published no Determination. In so doing, EPA denied Petitioners an opportunity to comment. For radium, EPA failed to perform Analyses for each of the alternative MCLs under consideration and only conducted a partial Analysis for the final radium standard.

B. EPA Did Not Follow The HRRCA Requirements For The Uranium MCL And Violated The APA.

EPA admits that the section 1412(b)(3) requirements apply to the uranium standard,[21] yet EPA failed to "publish," "seek public comment on," or "use" a HRRCA for the 30μg/L standard. Nor did EPA publish and seek comments on the required Determination.

EPA's justification for these failures is that it completed a HRRCA for the other standards discussed for uranium in the NODA and that it need not "publish, seek public comment on and use" a HRRCA for each standard being considered. EPA ignores the

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[19] *See Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1092-93 (D.C. Cir. 1996) (rejecting EPA's similar attempt to add the word "new" to section 209(e)(2) of the Clean Air Act).

[20] *See* 42 U.S.C. § 300g-l(b)(3)(C)(IV).

[21] Resp. at 12.

unambiguous statutory language and reads the phrase "*each* alternative MCL considered pursuant to paragraph . . . (6)(A)" out of section 1412(b)(3)(C), violating principles of statutory construction.[22] The legislative history also conflicts with EPA's position:

> The Administrator is to conduct a cost benefit analysis for *each* national primary drinking water regulation containing a ... MCL … *before* it is proposed. The analysis will also include consideration of alternative MCLs.... The study is to include a *determination* of the costs and benefits associated with *each alternative MCL ... relative to the other standards under consideration.... The Administrator is to publish and seek comment on the study*....[23]

Without an Analysis to support the proposed standard and each alternative being considered, there can be no Determination regarding the costs and benefits of each alternative, relative to the others under consideration, upon which there can be meaningful public comment and final action. EPA's position is entirely inconsistent with its interpretation of this same provision in the arsenic rule. There, EPA stated that "when proposing an MCL, EPA must *publish, and seek public comment on,* the [HRRCA] of *each* alternative [MCL] considered. *As required by the statute*, EPA issued a HRRCA for arsenic [in the] arsenic proposal," which included an analysis of each of the standards under consideration, including the ultimate arsenic MCL.[24] EPA's contrary interpretation in this Rule deserves no deference.[25]

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[22] *Wisconsin Elec. Power Co. v. Dep't of Energy*, 778 F.2d 1, 10 (D.C. Cir. 1985) (rejecting agency attempt to "blue pencil out" two words of statutory provision).

[23] S. Rep. No. 104-169 at 27 (1995) (JA 1763) (emphasis added).

[24] 66 Fed. Reg. 6976, 6994 (Jan. 22, 2001) (JA 1793) (emphasis added).

[25] *See Center for Sci. in the Pub. Int. v. Dep't of Treasury*, 797 F.2d 995, 999 (D.C. Cir. 1980).

EPA's *post-hoc* justifications relying on APA-related doctrines are insufficient to justify its action.[26] The SDWA establishes specific procedures that must be satisfied. "[W]hen Congress requires specific procedures, agencies may not ignore them or fashion substitutes."[27] Section 1412(b)(3)(C) "goes far beyond the usual requirements of public notice and opportunity for comment set forth in the [APA], and represents the Congressional answer to" the concerns of Congress, industry, the operators of community water systems, and the public.[28] The general APA procedures only afford an opportunity for public comment on "the terms or substance of the proposed rule or ... the subjects and issues involved."[29] Under the SDWA, EPA must publish and seek comment on the HRRCA and Determination for each alternative MCL considered, "use" the Analysis, and follow the remaining requirements in section 1412(b)(3). These specific statutory requirements are necessary to meet the goals of the statute and "must be given their due

[26] EPA relies on theories developed from the APA's notice and comment provision. The "logical outgrowth" test governs how significantly proposals on which public comment have been received may be altered without allowing additional public comment. *See, e.g., National Constructors Ass'n v. Marshal*, 581 F.2d 960, 971 (D.C. Cir. 1978).

[27] *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 4 F. Supp. 2d 435, 448 (M.D.N.C. 1998) ("*Flue-Cured Tobacco*"); *National Constructors*, 581 F.2d at 969-71 (remanding standards for failure to comply with statutorily required procedure and rejecting argument that logical outgrowth doctrine excused the failure); *United Steelworkers of Am. v. Marshall*, 647 F.2d 1189, 1208 (D.C. Cir. 1980) ("*Marshall*") (OSHA must follow specific rulemaking procedures imposed by its authorizing act, not merely requirements of APA); *see also* 1 Kenneth Culp Davis & Richard J. Pierce, Jr., *Administrative Law Treatise* § 7.7, pp. 339-46 (3d ed. 1994) ("Davis") (Congress sometimes requires procedures that supplement the APA's general procedures).

[28] *Flue-Cured Tobacco*, 4 F. Supp. 2d at 448 (discussing additional procedural requirement under Radon Research Act).

[29] 5 U.S.C. § 553(b)(3).

weight."[30] This case is like *Flue-Cured Tobacco* and *Marshall* in that the uranium rule was promulgated in violation of governing statutory procedures.[31]

Even if the Court determines that a "logical outgrowth" test applies, for EPA to prevail the Court must find that Petitioners should have anticipated that the 30µg/L standard would be the final MCL.[32] Because the statutory language states that *each* alternative MCL under consideration shall be the subject of a published Analysis which is subject to public comment, Petitioners never could have anticipated the promulgation of the 30µg/L standard.[33]

EPA's *post-hoc*, conclusory statement that the "purposes of notice and comment have been served" ignores its failure to consider the ultimate MCL in the NODA. Instead, EPA picked the 30µg/L standard and then did an Analysis to justify that choice.[34] This is evident from the Economic Analysis, completed one month before publication of the final rule and well after the close of the NODA comment period, where, for the first time, EPA announced that "EPA now plans to set a uranium MCL of 30µg/L," by "interpolating" data for the 30µg/L level from

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[30] *Zeigler Coal Co. v. Kleppe*, 536 F.2d 398, 403 (D.C. Cir. 1976).

[31] The SDWA is not alone in requiring more than basic APA procedures. *See, e.g.*, Toxic Substances Control Act of 1976, 15 U.S.C. § 2601; Clean Air Act Amendments of 1977, 42 U.S.C. § 7401; Occupational Safety and Health Act of 1970, 29 U.S.C. § 651; and, the Consumer Product Safety Act of 1972, 15 U.S.C. § 2051; *see also* Davis at 340-41.

[32] *See Small Refiner Lead Phase Down Task Force v. EPA*, 705 F.2d 506, 548-49 (D.C. Cir. 1983) (test for logical outgrowth "is whether reasonable commenter should have anticipated that such a requirement would be promulgated.").

[33] *See Shell Oil Co. v. EPA*, 950 F.2d 741, 752 (D.C. Cir. 1991) ("[A]n unexpressed intention cannot convert a final rule into a 'logical outgrowth' that the public should have anticipated. Interested parties cannot be expected to divine the EPA's unspoken thoughts."). Under section 1412(b)(6), EPA chose a final MCL for arsenic from among the levels considered in the proposed rule and addressed in the HRRCA. Here, the 30ug/L level was not among the levels addressed in the NODA or accompanying HRRCA.

[34] Pet. at 30-31.

data on the levels considered in the NODA.[35] The timing of the Analysis for 30μg/L demonstrates that EPA did not properly "use" the Analysis as required by section 1412(b)(3)(C). Moreover, because EPA published the HRRCA for 30μg/L after the close of the NODA comment period, Petitioners were prevented from commenting on the methodologies and analyses in the HRRCA, including what EPA now describes as its "interpolation" of data. They were also precluded from commenting on the merits of a 30μg/L standard as compared to the other standards considered.

Nor did EPA *publish* the Analysis-supported Determination required "[a]t the time the Administrator *proposes* a national drinking water regulation."[36] EPA's *post-hoc* justifications notwithstanding,[37] the agency failed to "publish" the required Determination "at the time" of the proposal.

Accordingly, the agency violated subsections (b)(3)(C) and (b)(4)(C) by failing to publish, seek comment on, and use an Analysis for each alternative MCL and by failing to publish and seek comment on the Determination.[38]

Finally, EPA fails to refute Petitioners' claim that EPA's basis for adjusting the MCL to a higher than feasible level was irrational.[39] Applying EPA's stated basis, the MCL should have

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[35] Economic Analysis at 6-10 (Pet. at 10 n.50) (JA 1240).

[36] 42 U.S.C. § 300g-1(b)(4)(C) (emphasis added).

[37] Resp. at 44.

[38] Even under its mistaken APA analysis, EPA loses. *See Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973) (APA requires agency to make available in time for comments any scientific studies or data it relies upon to support a rule). *See also Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (APA requires agency "to identify and make available technical studies and data employed in reaching the decision to propose particular rules"); *American Med. Ass'n v. Reno,* 57 F.3d 1129, 1133 (D.C. Cir. 1995) ("An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.").

been set at 40μg/L, or higher, because the incremental cost savings associated with raising the standard from 30μg/L to 40μg/L (while maintaining an acceptable cancer risk) are even greater than the incremental cost savings that allegedly prompted EPA to raise the standard from 20μg/L to 30μg/L.[40] EPA's conclusory response that it "did not *believe* that MCL options higher than 30μg/L [would] afford a sufficient measure of protection against kidney toxicity"[41] is unsupportable given EPA's acknowledgement that the "likelihood of any significant effect in population at 30μg/L is very small" and that the "number of kidney toxicity cases the rule will avoid could not be estimated using current risk models."[42] Nowhere in the record does EPA explain why 40μg/L, or higher, poses a greater risk than 30μg/L or one that is too substantial for a final MCL. EPA's failure to explain its rationale and its lack of record support violates the SDWA and the APA.[43]

C. EPA Must Publish Analyses And Determinations For Radium And Beta/Photon MCLs At The Time Of Proposal, When The Agency Was Considering Whether To Change Them.

1. Section 1412(a)(1) Did Not Exempt EPA From Publishing The Analyses And Determination.

The second sentence of section 1412(a)(1) merely protects interim MCLs deemed final by Congress in 1986 from challenge under the section 1412(b)(4) "standards" for MCLs and MCLGs until EPA completes the rulemaking required under section 1412(b)(2). That provision

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[39] Pet. at 31-32.

[40] *Id.*

[41] Resp. at 45 (emphasis added).

[42] 65 Fed. Reg. 76708, 76714 (Dec. 7, 2000) (JA 881).

[43] *See Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996).

directs EPA to promulgate MCLGs for the first time and establish MCLs for these contaminants.[44]

The subsection (a)(1) exemption only protects *established* (not proposed) regulations.[45] The subsection (b)(3)(C) Analyses and subsection (b)(4)(C) Determination must be published at the proposal stage, before a final MCL is established. EPA cannot know at the proposal stage whether its final rule will establish the same MCL, and keep the protection of subsection (a)(1), or establish a different MCL outside the purported protection of subsection (a)(1).

Even if applicable at proposal, subsection (a)(1) applies by its terms only to the "standards" in subsection (b)(4). Those standards are the substantive criteria for MCLGs and MCLs set forth in subsections (b)(4)(A) and (b)(4)(B). They do not include the procedural Determination set forth in subsection (b)(4)(C). That provision imposes no substantive requirement on MCLs, but merely directs EPA to publish its conclusion on whether a proposed MCL's benefits justify its costs. EPA advocates deference to its view that the Determination is a standard, but nothing in the SDWA or the ordinary meaning of "standard"[46] suggests that the term may be read to include procedural requirements calling for a conclusion at the proposal stage. The statutory history confirms this. When Congress enacted section 1412(a)(1) in 1986, it also created section 1412(b)(4), which then contained only the language currently in subsections (b)(4)(A) and (b)(4)(B) setting forth the substantive standards for MCLs and

[44] 42 U.S.C. § 300g-1(b)(2).

[45] *See* 42 U.S.C. § 300g-1(a)(1).

[46] A standard is a substantive criteria against which a rule may be measured.

MCLGs.[47] When enacting subsection (a)(1) in 1986, Congress could not have intended to exempt EPA from the procedural, proposal-stage Analyses and Determination requirements added in 1996.

Even if the subsection (b)(4)(C) Determination were a standard, EPA must still publish the Analyses required by subsection (b)(3)(C). The plain language of subsection (a)(1) applies only to subsection (b)(4). It does not mention subsection (b)(3). There is no basis for EPA's notion that Congress also meant to exempt subsection (b)(3)(C) but mistakenly omitted that provision.[48] While cross-references indicate that the Analysis and Determination are related, the placement of the two activities in separate subsections demonstrates that Congress distinguished between them. It does not follow that the two subsections are so "inextricably linked"[49] that Congress exempted both by only specifying one.

2. The 2000 Beta/Photon And Radium MCLs Are "Different" From 1976 Interim MCLs And Not Subject To Section 1412(a)(1).

For purposes of analyzing risks and costs, the 2000 beta/photon MCL is "different" and EPA must conduct the Analysis and Determination. EPA's 1976 beta/photon rule assumed certain risk and protectiveness information that EPA concedes has been superseded.[50] Thus, EPA's "repromulgation" of the beta/photon MCL effectively issues a different standard than the one issued in 1976.

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[47] *Compare* Safe Drinking Water Amendments of 1985, Pub. L. No. 99-339, 100 Stat. 642 § 101(b)(4) (1986) *with* 42 U.S.C. §§ 300g-1(b)(4)(A)-(B).

[48] *See Sierra Club v. EPA*, 719 F.2d 436, 453 (D.C. Cir. 1983) (when a statute lists specific exceptions, others cannot be implied by EPA).

[49] Resp. at 29.

[50] *See* Section VI.

The final radium MCL is also different. The interim radium MCL was 5 pCi/L for radium-226 and radium-228 combined. It only required monitoring for radium-228 if radium-226 exceeded 3 pCi/L. The final radium MCL is also 5 pCi/L combined, but it requires separate radium-228 monitoring regardless of the concentration of radium-226.[51] EPA calls this only a monitoring amendment that did not change the 5 pCi/L combined "'maximum permissible level'" of radium in water.[52] But the interim radium MCL set no maximum permissible level for radium-228 unless radium-226 exceeded 3 pCi/L.[53] Now, however, there is a limit on radium-228. Hundreds of communities must take steps beyond monitoring to assure that radium-228, as well as radium-226 and radium-228 combined, will not exceed 5 pCi/L.[54]

3. Section 1412(b)(9) Does Not Remove EPA's Obligation To Perform The HRRCA For Radium And Beta/Photon MCLs.

Even if section 1412(b)(9) were to preclude EPA from raising an MCL solely on cost-benefit considerations, it does not prohibit EPA from revising an MCL upward when scientific advances show a contaminant poses less risk than previously believed.[55] Besides providing cost information, a HRRCA evaluates "health risk reduction" benefits and informs EPA's final decision on whether an MCL will "maintain, or provide for greater, protection."[56] Until EPA publishes the Analyses and Determination and considers public comments, it cannot make a

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[51] Pet. at 22-23.

[52] Resp. at 34 (quoting 42 U.S.C. § 300f(3)).

[53] *E.g.*, PHRRCA at ES-2 (Pet. at 10 n.50) (JA 221) (lack of separate radium-228 monitoring was an MCL "loophole").

[54] *E.g.*, Economic Analysis, Chp. 4. (JA 1992-1220); *cf. Portland Cement Ass'n*, 486 F.2d at 400-01 (monitoring change effectively amended environmental standard); *Donner Hanna Coke Corp. v. Costle*, 464 F. Supp. 1295, 1304 (W.D.N.Y. 1979) (same).

[55] *See* Section VI.D.

reasoned decision as to whether an MCL may, or may not, be revised upward. Section 1412(b)(9) is dispositive only at the "promulgation" stage and does not override the HRRCA requirements at the "proposal" stage.[57] Even if section (b)(9) precluded EPA from raising an MCL, the Analyses and Determinations would not be futile because of their intrinsic value as public information on the final MCL.

4. Although EPA First Proposed Revising Them In 1991, Beta/Photon And Radium MCLs Are Subject To The 1996 SDWA Amendments.

EPA did not withdraw its 1991 proposal and was still "proposing" the radium and beta/photon MCLs when Congress enacted sections 1412(b)(3)(C) and 1412(b)(4)(C). If Congress had intended to shield the pending radionuclides proposals from these requirements, it would have enacted a provision like section 1412(b)(6)(C),[58] which shielded the then-pending disinfectant byproducts rule from a portion of the HRRCA process. Congress also considered, but did not adopt, a 1994 bill that would have exempted the radionuclides rule from those requirements.[59]

Also, EPA published the NODA which functioned as a proposal. In it, EPA proposed radium and beta/photon MCLs that were not proposed in 1991 and sought public comment on them.[60] By preparing a partial HRRCA for the radium MCL of 5 pCi/L with separate monitoring

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[56] 42 U.S.C. § 300g-1(b)(9).

[57] *Compare* 42 U.S.C. §§ 300g-1(b)(3), (b)(4) *with* 42 U.S.C. § 300g-1(b)(9).

[58] 42 U.S.C. § 300g-1(b)(6)(C); H.R. Conf. Rep. No. 104-741, at 86-87 (1996).

[59] Safe Drinking Water Act Amendments of 1994, H.R. 3392, 103d Cong., § 4(B)-(C) (1994); *I.N.S. v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) ("Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language").

[60] *E.g.*, 65 Fed. Reg. at 21576, 21577-78, 21580, 21583-85 (Apr. 21, 2000) (JA 2-4, 6, 9-11); *see also* 5 U.S.C. §§ 553(b)-(c); 42 U.S.C. § 300g-1(d).

that was not proposed in 1991, EPA concedes that the NODA functions as a proposal subject to these requirements. The beta/photon and other radium MCLs proposed in the NODA should have been treated in the same manner.

5. Under Ratification Doctrine, The Beta/Photon And Radium MCLs Are Reviewable Under The 1996 SDWA Amendments.

When, as here, an agency reevaluates an existing rule, invites public comment, and purports to repromulgate the same rule, that rule is subject to challenge as though it were new.[61] Were it otherwise, notice and comment would be a "meaningless gesture."[62] By repromulgating the radium and beta/photon MCLs in 2000, EPA reopened them to judicial scrutiny which includes an examination of whether the repromulgated regulations comply with the 1996 Amendments. Regulations "must be consistent with the statute under which they are promulgated."[63]

D. EPA's HRRCAs Must Consider CERCLA Benefits and Costs.

Denying that it must analyze MCL benefits and costs arising in other contexts,[64] EPA cites section 1412(b)(3)(C)(i)(III). That provision, however, excludes only "costs" arising from compliance with "regulations."[65] EPA cannot refute that it failed to analyze *benefits*, nor that the CERCLA *statute* mandates MCL application. EPA argues that CERCLA costs are excluded because regulations also implement MCL requirements. Yet without the statutory mandate, no

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[61] *See, e.g., Public Citizen v. NRC*, 901 F.2d 147, 150 (D.C. Cir. 1990).

[62] *Montana v. Clark*, 749 F.2d 740, 744 (D.C. Cir. 1984).

[63] *United States v. Larionoff*, 431 U.S. 864, 873 (1977).

[64] EPA must consider the costs and benefits of applying MCLs under CERCLA, at decommissioned nuclear facilities, pursuant to state law and in other contexts. Pet. at 24-26.

[65] Pet. at 24-25.

regulations would exist. EPA's claim that distinguishing between statutes and regulations is "meaningless,"[66] contravenes basic tenets of statutory construction. "Regulations" does not mean "statutes," even if the agency layers the former over the latter.

Nor can EPA avoid the legislative history.[67] EPA claims that it directs EPA *not* to consider costs and benefits that have been considered elsewhere.[68] By carving out only those circumstances where a risk-cost analysis has already been done, however, this exception highlights that EPA ordinarily must conduct that analysis.[69]

E. EPA Did Not Analyze Increased Risks Of Radium And Uranium Treatment Wastes.

Congress required EPA to analyze risks that result from compliance with proposed MCLs[70] to avoid regulations that do "more harm than good."[71] EPA claims that its 1994 "Disposal Guidelines" and its response to comments on those Guidelines[72] analyzed the increased risks from the concentrated radioactive wastes from compliance with the radium and uranium MCLs.[73]

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[66] Resp. at 36.

[67] *See* Pet. at 25.

[68] EPA has made clear that the beta/photon MCL will only be applied under CERCLA. *See* Pet. at 24-25 n.115, 71 n.372.

[69] EPA also argues that its commitments to perform a HRRCA should not be held against it. Unexplained reversals of position like this, however, destroy deference. *See Center for Sci.*, 797 F.2d at 999.

[70] *See* 42 U.S.C. § 300g-1(b)(3)(C)(VI).

[71] David W. Schnare, Environmental Rationality and Judicial Review: When Benefits Justify Costs under the Safe Drinking Water Act Amendments of 1996, 5 Hastings W.-Nw.J. Envtl. L. & Pol'y 65, 90 (1998).

[72] Resp. at 41-42.

[73] Pet. at 28-29.

EPA's *post-hoc* rationalization is wrong. Those documents do not analyze the "degree and nature"[74] of risks resulting from treatment of those wastes. Nor do they analyze risks to the public from the unregulated disposal of those wastes.[75] Because EPA violated Congress's requirement to analyze these risks, no one knows whether the radium and uranium MCLs will do more harm than good.[76]

F. EPA Must Consider All Costs Of Complying With The Radium MCL.

To excuse its failure to analyze all the costs of compliance with the final radium MCL, as Congress required,[77] EPA argues that it is "ludicrous" and "absurd" to suggest that the agency should consider the compliance costs to hundreds of regulated entities that have not paid to comply with the radium 5 pCi/L MCL.[78] EPA opines that "[s]urely Congress did not intend" such deferred costs to play a role in the analysis of costs and health benefits of an MCL.[79]

Absent from EPA's argument, however, are the words of Congress. EPA must consider the "costs that are likely to occur as a result of compliance" with the MCL.[80] So-called deferred compliance costs are not excluded.

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[74] 42 U.S.C. § 300g-1(b)(3)(C)(VII).

[75] CRD-NODA at 20-9, 20-19 (JA 1081, 1091).

[76] EPA claims that the final radium MCL will prevent less than one-half a cancer per year, 65 Fed. Reg. at 76735 (JA 902), but no one knows if that good outweighs the harm from the risks caused by compliance with the MCL because EPA did not analyze those risks.

[77] 42 U.S.C. § 300g-1(b)(3)(C)(III); *cf.* 42 U.S.C. § 300g-1(b)(3)(C)(IV).

[78] Resp. at 40; *see also* EPA, Actual Cost for Compliance with the Safe Drinking Water Act Standard for Radium 226 and 228 – Final Report, at 4, 28-30 (July 1998) (I-F-08) (JA 484, 508-510) ("limited" and "incomplete" study showed that deferred compliance costs exceed $160 million in Illinois and Wisconsin alone).

[79] Resp. at 40.

[80] 42 U.S.C. § 300g-1(b)(3)(C)(III).

Also absent from EPA's argument is an acknowledgement of its complicity in causing regulated entities to defer those costs. From 1983 to 1988 EPA notified the public that it might change these MCLs, and from 1988 to 2000 EPA was proposing to increase them.[81] Congress was aware of regulated entities' struggles with compliance when it imposed the requirement that all compliance costs be considered.[82] If "deferred" compliance costs were to be excluded, Congress would have said so.

EPA's imperious view of its prior enforcement advice[83] and its obligation under the statute is contradicted by the words of the statute. When EPA proposes an MCL, the agency must consider all costs of complying with it.

III. EPA VIOLATED THE APA WHEN IT FAILED TO RESPOND ADEQUATELY TO COMMENTS REFUTING THE LNT MODEL.

EPA's responses to comments challenging its reliance on the linear, non-threshold model ("LNT") fail the APA's requirements.[84] Petitioners presented volumes of data on the effects of low-dose exposures to radionuclides, which contradict EPA's claim that, "in the absence of other data," EPA may rely on default assumptions and apply the LNT.[85] Petitioners also provided numerous, peer-reviewed studies finding no adverse, and often beneficial, effects at low-dose

[81] *See* 48 Fed. Reg. 45502 (Oct. 5, 1983); 51 Fed. Reg. 34836 (Sept. 30, 1986); Pet. at 28 (discussing 1988 statements); 56 Fed. Reg. 3526 (Jan. 30, 1991); 65 Fed. Reg. 21576 (Apr. 21, 2000); *see also* Comments of the Illinois Department of Nuclear Safety on the NODA at 2 (June 28, 2000) (I-I2-10) (JA 873).

[82] Pub. L. No. 104-182, § 3(9) (1996).

[83] *See* Pet. at 28.

[84] The LNT is a model based on two key assumptions – that high-dose exposures can be extrapolated to low-dose exposures and that there is no safe threshold. Pet. at 5, 78.

[85] Resp. at 46.

exposures, refuting those assumptions. Because these comments raised significant issues on EPA's model, EPA was required to provide a reasoned response.[86]

EPA does not dispute that the issues raised were significant, only that its responses were inadequate. EPA's responses, however, consisted of conclusory statements, restating EPA's assumptions and asserting that EPA found no "persuasive evidence."[87] These responses lack any analytical defense of EPA's assumptions and provide no explanation of why the evidence is not persuasive.[88] They are insufficient under the APA.

A. Generic Responses To Detailed Comments Are Not Sufficient To Meet The APA's Requirements.

EPA asserts that Petitioners' dispute with EPA's general and generic statements "focuses on only two comments."[89] This is incorrect. EPA only provides meaningful responses to two comments. Petitioners provided numerous detailed comments citing many studies distinct from those in the two comments to which EPA responded. EPA acknowledges that it referred to these general and generic responses to address all of the issues raised and studies provided in "numerous other comments."[90] According to EPA, these few general statements are all the APA requires. EPA is wrong.

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[86] *See Action on Smoking & Health v. Civil Aeronautics Bd.*, 699 F.2d 1209, 1216 (D.C. Cir. 1983).

[87] *IFI*, 972 F.2d at 392 (conclusory statements do not provide a "satisfactory explanation").

[88] *See, e.g., Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 923 (D.C. Cir. 1998) (a full analytical defense and examination of key assumptions are part of EPA's "burden of promulgating and explaining a non-arbitrary, noncapricious rule").

[89] Resp. at 49-50.

[90] *Id.* at 54.

EPA's responses must be "pointed" to the issues raised in the Petitioners' comments.[91] For example, Petitioners submitted peer-reviewed studies, such as studies of radiology workers, nuclear workers, and medical patients, which supported the use of a non-linear model and showed no adverse effects for low-dose exposures.[92] Rather than consider these studies and address these issues, EPA simply refers to Response to Comment 3.A.1, which asserts that the information cited "was familiar," "had been considered in the past," and was "limited to anecdotal or case report data, comments on other documents, positions or policy positions, or selected observations, and thus not of equal weight" to atomic bomb survivor data or molecular and cellular studies.[93] These general responses do not address the specific issues raised in Petitioners' detailed comments.

EPA's responses here stand in stark contrast to those found sufficient in *IFI*, relied on by EPA. In *IFI*, EPA's response to comments, citing specific, epidemiological studies, was sufficient under the APA because EPA discussed the specific reports' deficiencies and provided a detailed explanation of EPA's studies and analysis.[94] Here, however, EPA's general and

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[91] *Id.* at 48. *See, e.g., Central & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000), *cert. denied*, 532 U.S. 1065 (2001) (scope and degree of detail APA requires depends on comments).

[92] *See, e.g.*, CRD-NODA at 3-20/21, 3-27, 3-36/47 (Comments 3.B.13, .15, .24, .34-.35, .37-.38, .41, .45) (JA 953-954, 960, 969-980). EPA also cross-references Response to Comment 3.B.23, which addresses "ecological" studies not epidemiological studies of occupational exposures and medical patients. *Id.*

[93] *Id.* EPA also refers to its responses to Comments 3.B.3 and 3.B.5, which address two specific studies cited by Waukesha on radium dial painters and Waukesha residents. *Id.* These studies are unrelated to the additional studies Petitioners cited in support of separate and distinct issues.

[94] 972 F.2d at 392-95. In *IFI*, EPA's statement that it would use its zero-goal policy when data did not show a safe threshold was found sufficient to respond to comments that did not present any data and were mere assertions that EPA got it wrong. *Id.* at 391. Here, however, Petitioners presented a vast amount of data and numerous, peer-reviewed studies that contradicted EPA's assumptions. EPA was required to "undertake a more detailed re-justification of its prior position." *Id.*

generic statements provide no explanation of why it believes the studies submitted were deficient, and no discussion of EPA's studies or analysis. These general responses do not address the issues raised by Petitioners and are insufficient under the APA.[95]

B. EPA Does Not Provide A "Reasoned" Response To Comments Refuting The LNT's Underlying Assumptions.

EPA provides no explanation or analysis as to why it continues to rely on the LNT despite contradictory evidence. This failure is striking in light of the SDWA's requirement to apply the best available science.[96] At most, EPA responds with unsupported statements that: (a) atomic bomb survivor data support EPA's default assumption of linearity; (b) molecular and cellular studies support EPA's assumption that there is no threshold; and (c) EPA's approach is consistent with "recommendations" from "advisory" boards.[97] EPA's conclusory statements are insufficient.[98]

EPA's conclusory statement that atomic bomb survivor data supports the use of the LNT does not adequately respond to Petitioners' comments.[99] Petitioners commented that the instantaneous, high-dose exposure from the blast and confounding factors, such as war-time

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[95] *Central & S.W. Servs., Inc.*, 220 F.3d at 692 (rejecting EPA's use of a "comprehensive response" rather than addressing particular issue raised).

[96] *See Independent U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847, 852 (D.C. Cir. 1987).

[97] *E.g.*, CRD-NODA at 3-16/20, 3-24/27, 3-34/47, 3-53/55 (Comments 3.B.8, .12-.13, .20, .24, .32-.35, .37-.45, .56-.57, referring to Comment 3.A.1) (JA 949-953, 957-960, 967-980, 986-988).

[98] *See, e.g., American Mining Cong. v. EPA*, 907 F.2d 1179, 1189 (D.C. Cir. 1997) (conclusory statements that wastes had potential for leaching insufficient to address petitioners' challenges concerning particular studies).

[99] Resp. at 55-57. *See, e.g.*, CRD-NODA at 3-18/20, 3-24/27, 3-34/47, 3-53/55 (Comments 3.B.12-.13, .20, .24, .32-.35, .37-.45, .56-.57, referring to Comment 3.A.1) (JA 951-953, 957-960, 967-980, 986-988).

conditions, made such data irrelevant to long-term, chronic exposures to radionuclides.[100] Petitioners also cited numerous peer-reviewed studies, including a study cited by the Committee on the Biological Effects of Ionizing Radiation ("BEIR"), that found the atomic bomb survivor data do not support use of the LNT and show no adverse effects at low doses.[101] Without addressing these criticisms, EPA responded that the submissions are "not of equal weight" and do "not provide the kind of data that EPA discusses in the remainder of the response."[102] This is, however, the very data on which EPA relies, *i.e.*, atomic bomb survivor data.[103] EPA does not provide any analytical support for its conclusory statement that atomic bomb survivor data support the LNT and fails to resolve this contradiction.[104]

EPA's conclusory statement that molecular and cellular studies show that a single particle of ionizing radiation can lead to cancer is similarly insufficient.[105] Petitioners' comments

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[100] *See, e.g.,* RSH Comments at 28-29 (JA 660-661).

[101] *See* CRD-NODA at 3-36 (Comment 3.B.33) (JA 969); RSH Comments at 29-30 (JA 661-662).

[102] CRD-NODA at 3-5/6 (Comment 3.A.1) (JA 938-939). Under EPA's guidelines, the default assumption of linearity drops out when *adequate* data show that linearity is inapplicable, and when there is *sufficient* evidence to support non-linearity. *See* 61 Fed. Reg. 17960, 17969 (Apr. 23, 1996). EPA does not explain why the data the Petitioners presented is not "adequate" or "sufficient" under these guidelines, but simply states it found "no persuasive evidence." CRD-NODA at 3-5/6 (Comment 3.A.1) (JA 938-939).

[103] CRD-NODA at 3-6 (Comment 3.A.1) (JA 939). EPA also allegedly relied on data from "large dose" exposures "for medical purposes." Resp. at 47. Petitioners submitted studies of medical patients exposed to low-doses, which found no adverse effects, contradicting EPA's assumptions. CRD-NODA at 3-32 (Comment 3.B.28) (JA 965). EPA did not explain this contradiction or provide support for its statement.

[104] *See, e.g., Columbia Falls*, 139 F.3d at 923. EPA's assertion that the Chernobyl study did not "provide the dose response data needed" is not responsive. Resp. at 56. This study applied the data EPA relies on to estimate the effects of the Chernobyl incident, and found the LNT did not reflect the actual data. Pet. at 83. This study highlighted the uncertainties of using the atomic bomb survivor data. In light of this evidence, the APA requires EPA to explain why it relied on this data.

[105] CRD-NODA at 3-18/20, 3-24/27, 3-34/47, 3-53/55 (Comment 3.B.12-.13, .20, .24, .32-.35, .37-.45, .56-.57, referring to Comment 3.A.1) (JA 951-953, 957-960, 967-980, 986-988).

disputed this assertion, providing studies establishing that biological effects in cell populations are not restricted to the response of individual cells to DNA damage.[106] Studies presented showed each cell's DNA undergoes millions of mutations every day -- more from normal metabolism and heat than from background levels of radiation (at levels higher than in EPA's standards) -- without leading to cancer.[107] EPA never addressed this. Petitioners also provided hundreds of human and animal studies, including ones cited by the advisory boards on which EPA relies, that show no adverse effects, but often beneficial effects, at low-dose exposures.[108] These studies contradict EPA's theory that ionizing radiation damage to a single cell leads to cancer. EPA responds that such evidence was not "persuasive" and "not of equal weight" to the studies upon which EPA relies,[109] but never explains *why* studies of whole organisms are less "persuasive" than studies of individual cells.

EPA also points to its "lengthy response" to the radium dial painters studies.[110] This response stated that these studies "are interesting," but "of limited value" and disputed the "practical threshold" concept.[111] Petitioners cited numerous studies in addition to the radium dial painters.[112] Petitioners also provided recent analysis of this data that corrects the alleged flaws of

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[106] *E.g.*, RSH Comments, Attachment at 8-17 (JA 671-680).

[107] *Id.*

[108] *E.g.*, CRD-NODA at 3-16/17, 3-20/21, 3-32 (Comments 3.B.9, .13, .15) (JA 949-950, 953-954); RSH Comments, Attachment at 1-8 (JA 665-671).

[109] CRD-NODA at 3-16/17, 3-20/21 (Comments 3.B.9, .13, .15) (JA 949-950, 953-954).

[110] Resp. at 54, 58.

[111] CRD-NODA at 3-11/12 (Comment 3.B.3) (JA 944-945)

[112] *See supra* n.92.

these earlier studies.[113] EPA did not address any of these additional studies. Moreover, Petitioners' comments did not raise the *practical* threshold issue, which hypothesizes that if the dose is low enough a person may not live long enough to get cancer. Petitioners raised an *actual* threshold issue, *i.e.*, low-dose exposures do not lead to cancer.[114] EPA's "response" does not address that issue or explain how EPA resolved it.

Finally, EPA's assertion that use of the LNT is consistent with "observations and recommendations" of "advisory" boards is also deficient.[115] This does not explain *EPA's* analysis of the data and why *EPA* continues to rely on default assumptions. In addition, Petitioners cited statements made by these boards that "[f]ew experimental studies, and essentially no human data, can be said to prove or even to provide direct support for the concept," and that the LNT is "conceptually possible, but with a vanishingly small probability" that these effects could result.[116] FGR-13 similarly notes that the LNT may be inapplicable at low-doses, acknowledging data demonstrating the beneficial effects of low-dose exposures.[117] The qualifying statements made by these boards required a response under the APA. EPA's statement baldly relying on these recommendations is not an adequate response.[118] Moreover,

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[113] *E.g.*, CRD-NODA at 3-18/20 (Comment 3.B.12) (JA 951-953); RSH Comments at 15-16 (JA 647-648).

[114] Pet. at 87-88.

[115] Resp. at 51, 53.

[116] RSH Comments at 1 (quoting National Council on Radiation Protection and Measurements) (JA 633); *see also id.* at 17, 19 (BEIR V cited studies of radiologists and medical patients with long-term, low-dose exposures that found no excess cases of cancer) (JA 649, 651). At most, EPA merely stated that it "disagrees." CRD-NODA at 3-40/41 (Comments 3.B.39-.40) (JA 973-974).

[117] RSH Comments at 5-6 (JA 637-638); CRD-NODA at 3-41 (Comment 3.B.40) (JA 974).

[118] *See Walter O. Boswell Mem'l Hosp. v. Heckler*, 628 F. Supp. 1121, 1126 (D.D.C. 1985) ("cautionary statements" from study agency relied on were "in need of response"). Petitioners' comments

(Continued …)

Petitioners provided scientific, peer-reviewed papers that challenged these "recommendations." EPA did not respond.[119] EPA provides no justification for its failure to respond to these criticisms.[120]

EPA's reliance on conclusory statements and bald assertions that volumes of data and peer-reviewed studies are not "persuasive" allows EPA to ignore public comments on what constitutes the best available science. EPA's view of an arbitrary and capricious APA review leaves the public with no recourse to ensure EPA complies with a statutory mandate in promulgating regulations, provided the agency simply responds to comments by stating, "We don't agree."

EPA relies on the LNT assumption as its basis for each radionuclide MCLG, and, thus, MCL. EPA's failure to provide a reasoned analysis to explain its continued use of the LNT and its failure to consider the data presented are grounds to remand the Rule.[121]

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also noted that EPA has recognized the uncertainties in extrapolating from high-dose to low-dose exposures. CRD-NODA at 3-25, 3-35/36 (Comments 3.B.21, .33) (JA 958, 968-969). EPA's response was merely that it "disagrees." *Id.* at 3-25 (JA 958).

[119] *E.g.*, CRD-NODA, at 3-38/39 (Comment 3.B.37) (JA 971-972), RSH Comments at 11 (criticizing International Agency for Research on Cancer reports) (JA 643); Attachment to RSH Comments at 13, 19-20 (criticizing BEIR reports) (JA 676, 682-683). These comments included reanalysis of data cited and new data, which showed no adverse effects at low doses. *E.g.*, RSH Comments at 11-12, 17-20 (JA 643-644, 649-652). EPA provides no response to these comments.

[120] *See, e.g., Walter O. Boswell Mem'l Hosp.*, 628 F. Supp. at 1125 (response insufficient where agency "baldly relies" on a study, without mentioning criticisms of that study).

[121] *IFI*, 972 F.2d at 389 (this Court will "overturn a rulemaking as arbitrary and capricious where the EPA has failed to respond to specific challenges that are sufficiently central to its decision.").

IV. THE URANIUM MCLG AND MCL VIOLATE THE BEST AVAILABLE SCIENCE REQUIREMENT AND THE APA.

A. EPA's Justifications For The MCLG Are Unfounded.

Section 1412(b) of the SDWA requires EPA to "use the best available, peer-reviewed science."[122] The APA requires that EPA consider the relevant data, provide a satisfactory explanation for its action,[123] demonstrate a rational connection between any model and the reality it purportedly represents,[124] and avoid relying on general data or blanket assumptions when the record contains specific contrary information.[125]

Respondent's brief confirms Petitioners' claim that EPA relied solely on its blanket assumption that "all radionuclides are known human carcinogens"[126] and that "any exposure to uranium, like any exposure to any radionuclide, would cause a cancer risk."[127] Yet, EPA points to no record evidence supporting this assumption regarding ingestion of natural uranium. On the contrary, as EPA admits, "studies using natural uranium do not provide direct evidence of carcinogenic potential."[128] Since the record contains specific evidence to the contrary, EPA's generalized, blanket assumption cannot provide a rational basis for a final rule.

Moreover, as Petitioners noted, the ATSDR study unequivocally states: "No studies linking oral exposure to uranium to human cancer have been found," "[n]o studies were located

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[122] 42 U.S.C. § 300g-1(b)(3)(A)(i).

[123] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983).

[124] *See Columbia Falls*, 139 F.3d at 923.

[125] *See Leather Indus. Ass'n of Am. v. EPA*, 40 F.3d 392, 403 (D.C. Cir. 1994).

[126] Resp. at 9.

[127] *Id*. at 14.

[128] 56 Fed. Reg. 33050, 33072 (July 18, 1991) (JA 1390).

that provided evidence that oral exposure of humans to uranium as an alpha-emitting radiation source causes cancer,"[129] and "exposure to natural uranium is *unlikely to be a significant health risk in the population and may well have no measurable effect*."[130] In light of the ATSDR findings and the lack of contradictory evidence in the record, EPA's reliance solely on a "blanket assumption" is irrational and violates the APA and the SDWA.[131]

In addition, EPA did not satisfactorily explain how its reliance on the blanket, default assumption to place naturally occurring uranium in the Group A, Category I, "known human carcinogen" category through ingestion is consistent with its own carcinogen categorization system. EPA's cancer classification system provides that Group A, Category I substances are substances for which "there is strong evidence of carcinogenicity from drinking water ingestion" typically based on sufficient human epidemiological data.[132] EPA admits, "[e]xisting human epidemiological data are inadequate to assess the carcinogenicity of uranium when ingested in drinking water,"[133] and "animal studies of exposure to natural uranium did not provide direct

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[129] *See* Agency for Toxic Substances and Disease Registry, Toxicological Profile for Uranium, Atlanta, GA at 137 (Sept. 1999) ("ATSDR") (JA 1787).

[130] *Id.* at 138 (JA 1788) (emphasis added); Pet. at 58-60.

[131] While EPA is "not obligated to defer to the views of a sister agency," Resp. at 76, the EPA may not ignore the SDWA and the APA. Petitioners have been unable to find even one reference to the ATSDR study in the NODA, the technical documents supporting the NODA, or the Final Rule. The ATSDR study is not even included in the record. EPA's failure to be "comprehensive" by including the study in the record, its failure to adequately consider and address the ATSDR study, its failure to identify any contradictory data and explain any inconsistencies in the scientific data, and its failure to adequately respond to Petitioners' comments regarding the ATSDR study, violates the SDWA and the APA. *See* 42 U.S.C. § 300g-1(b)(3)(B)(v); *IFI*, 972 F.2d at 389 (rational decision-making requires that EPA "give reasoned responses to all significant comments in a rulemaking proceeding"); *Chemical Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994) (agency cannot respond to comments in unsupported and conclusory fashion when presented with specific, detailed scientific evidence contrary to its position).

[132] 56 Fed. Reg. at 33070 (JA 1388); Pet. at 53-58.

[133] 56 Fed. Reg. at 33070 (JA 1388).

evidence of carcinogenic potential."[134] Consequently, EPA improperly relies on animal studies of exposure to enriched uranium and high activity isotopes of uranium, which are quite dissimilar from natural uranium.[135] Additionally, despite its attempts to discount its reliance on inhalation data to show carcinogenic risk from ingesting naturally occurring uranium,[136] EPA's use of these data is inconsistent with its position in *IFI* that "inhalation data should not be relied upon in a risk assessment for oral exposure."[137] EPA fails to explain its reversal of position on this point.

Finally, EPA does not address Petitioners' assertion that classification of uranium as a Group A, Category I carcinogen is inconsistent with past cancer classification decisions in similar circumstances. EPA classifies asbestos as a Group A, known human carcinogen, based on *inhalation* evidence. EPA did not, however, propose "a MCLG for asbestos based upon this classification, since the evidence for the association between *ingested* asbestos and cancer is limited."[138] Instead, EPA proposed a MCLG for asbestos "*considering the chemical for drinking water purposes as if it were in Group C, based on the limited evidence of carcinogenic effects via ingestion.*"[139] In promulgating the final asbestos MCLG, EPA stated that

> EPA does not automatically place contaminants classified as Group A or B carcinogens in Category I. Additional scrutiny

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[134] *Id.*

[135] For example, EPA admits the effects of radionuclides depend on their unique half-lives, forms of decay, and energy levels, among other factors. *See* 65 Fed. Reg. at 76720 (JA 887).

[136] *See* Resp. at 75.

[137] 972 F.2d at 393; *see also Center for Sci.*, 797 F.2d at 999 (when agency reverses position, it must provide reasoned explanation).

[138] 54 Fed. Reg. 22062, 22072 (May 22, 1989) (JA 1464) (emphasis added).

[139] *Id.* (emphasis added).

> occurs to determine what evidence exists of the chemicals' carcinogenicity via *ingestion* considering pharmacokinetics, exposure, and weight of evidence. *If the additional evidence of carcinogenicity via ingestion is limited or inadequate, then the chemical will be placed in the appropriate category* and a MCLG is calculated accordingly.[140]

The evidence for classifying uranium as other than Category I, Group A carcinogen because of inadequate human and animal evidence of carcinogenicity or lack of data, is even stronger than for asbestos. For asbestos, at least EPA had some evidence of ingestion risk from a National Toxicology Program bioassay; there is no such record evidence for natural uranium.

Because EPA concedes that it has no evidence directly linking ingestion of natural uranium to carcinogenic effects, because EPA must "demonstrate a reasonable connection between the facts on the record and its decision" made pursuant to its statutory authority,[141] and because EPA improperly relied on inhalation data to classify naturally occurring uranium as a "known carcinogen," EPA's MCLG should be remanded.

B. EPA's 30μg/L MCL Is Not Based On the Best Available Science And Violates The APA.

For the final uranium MCL, EPA acknowledges that "kidney toxicity ... determined the upper risk limit in EPA's analysis."[142] To determine kidney toxicity, EPA relied solely on "rat data" involving ingestion of various concentrations of uranyl nitrate, which is not naturally (or widely) occurring in the environment, but is formed during the strictly controlled uranium

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[140] 56 Fed. Reg. 3526, 3534 (Jan. 30, 1991) (JA 1468) (emphasis added); *see also IFI*, 972 F.2d at 384 (affirming classification of perc as Category II carcinogen because contamination did not pose high risk from *ingestion* of drinking water).

[141] *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1064 (D.C. Cir. 1995).

[142] Resp. at 15.

conversion process for nuclear fuel or warhead production.[143] Even though specific studies concerning kidney toxicity from ingestion of natural uranium showed risks so small that EPA could not determine whether exposure resulted in an adverse impact, EPA set the MCL based on the toxic effects of uranyl nitrate. Thus, EPA failed to show that it used the best available science in its analysis of toxic effects of drinking low levels of naturally occurring uranium.[144]

Regarding Petitioner's argument that EPA ignored the human data and relied solely on uranyl nitrate rat data when setting the MCL, EPA claims that it "did not ignore these [human] data."[145] EPA's basis for this claim is a single sentence in the final rule stating "EPA has some human data which demonstrates that mild proteinuria has been observed at drinking water levels between 20μg/L and 100μg/L."[146] That statement does not establish that such data were not ignored, especially where, as here, EPA failed to explain how such data affected the choice of the final MCL. Notably, in the sentence immediately preceding the sentence upon which EPA relies, the agency admits that its "best estimate of the LOAL [for uranium] is 60μg/kg/day, *based on rat data*,"[147] and no mention of any other data, including human data, is made. Further, EPA admits that the scientific basis for the standard is speculative: "An MCL of 30 μg/L represents a relatively small increase [over the feasible level of 20 μg/L] ... compared to the over-all

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[143] EPA defends its reliance on "rat data" by arguing that uranyl nitrate was "an adequate surrogate" for the study of natural uranium. Resp. at 78. This argument is incorrect as uranyl nitrate is not naturally occurring and is soluble and highly absorbed into the body of experimental animals following ingestion and, therefore, is significantly more toxic than naturally-occurring forms of uranium. *See* ATSDR at 152 (JA 1789).

[144] 65 Fed. Reg. at 76713 (JA 880).

[145] Resp. at 79.

[146] 65 Fed. Reg. at 76713 (JA 880).

[147] *Id*. (emphasis added).

uncertainty in the RfD and the *uncertainty* in the importance of the *mild* proteinuria observed for uranium exposures from high drinking water levels."[148] EPA identifies no record evidence of any relationship between mild proteinuria and adverse kidney impacts, much less actual kidney damage.[149]

EPA's failure to adequately consider the data (including human data), or to satisfactorily explain how it did so, and its effect on EPA's decision, demonstrate that EPA did not use the best available science,[150] and failed to adhere to the requirements of reasoned decisionmaking when promulgating the MCL.[151]

V. EPA'S RESPONSE DOES NOT SHOW THAT ITS RADIUM-226 AND RADIUM-228 RISK ASSESSMENT COMPLIED WITH THE SDWA AND APA.

EPA did not use studies of dial painters who ingested radium-226 and radium-228 to assess the health risks of drinking low levels of those isotopes. Dial painters who ingested medium to low doses of those radium isotopes contracted no excess cancers of any type and those who ingested high doses contracted cancer in only the bone and the head. Bone cancer incidence fit a quadratic dose-response curve, meaning that cancer incidence decreased

[148] *Id*. at 76714 (JA 881) (emphasis added).

[149] The only reference in the record indicates that "the variability in the normal range for proteinuria in humans is very large." *Id.* at 76713 (JA 880).

[150] While EPA argues that FGR-13 represents EPA's "most sophisticated science," *see, e.g.*, Resp. at 83, EPA did not utilize FGR-13 to develop the uranium standard. EPA neither disputes nor discusses this point in its brief.

[151] *See Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1034 (D.C. Cir. 2001) (EPA's "failure to 'examine the relevant data and articulate a satisfactory explanation for its action' either is arbitrary decision making or at least prevents a court from finding it non-arbitrary").

exponentially and was less frequent at low doses.[152] EPA ignored the dial painter studies because of the relatively small population, estimated doses, other adverse health effects, and mortality rates.[153]

Instead, EPA quantified the risk of drinking low levels of radium-226 and radium-228 using a general model.[154] EPA's FGR-13 model assumes that all ionizing radiation (including radium-226 and radium-228) causes cancer in 13 human organs.[155] The model uses a linear dose-response curve, which assumes cancer incidence increases in direct proportion to dose and thus is more frequent at low doses than shown by a quadratic dose-response curve. FGR-13 assumes there is no low-dose threshold below which radium does not induce cancer.[156] Thus, EPA's model predicts more risk from exposure to radium-226 or radium-228 than shown in the dial painter studies. The studies used in the model involve persons who were exposed to multiple and different forms of radiation -- neutrons and gamma rays from atomic bomb blasts and radium-224 -- rather than only radium-226 and radium-228. Those studied were not exposed through the ingestion pathway but through external exposure and injection into the blood.[157] Although there were more atomic bomb survivors than dial painters, the bomb survivors' doses

[152] 56 Fed. Reg. at 33072-73 (JA 1390-1391); Technical Support Document at III-5 (Pet. at 4 n.14) (JA 177); Radium Criteria Document at VI-5 to VI-11, VIII-18, IX-4 to IX-5 (Pet. at 7 n.32) (JA 1491-1497, 1523, 1549-1550).

[153] 65 Fed. Reg. at 76721 (JA 888).

[154] 65 Fed. Reg. at 76712 (JA 879).

[155] FGR-13 at 4-5, 186 (Pet. at 5 n.17) (JA 80-81, 123).

[156] FGR-13 at v (JA 79).

[157] FGR-13 at 173 (JA 110); CRD-NODA at 3-35 (JA 968); Radium Criteria Document at VI-12 (JA 1498).

were also estimated after-the-fact,[158] and they also experienced other adverse health effects from wartime devastation.[159] The bomb studies do not demonstrate excess cancer at low doses because the people who received low doses were in the control group that did not contract cancer.[160]

Petitioners showed that EPA violated the SDWA and the APA by deriving MCLs for radium-226 and radium-228 without showing a rational connection between the model and health effects of ingesting low levels of those radium isotopes; without reconciling the results of the model with the conflicting dial painter data; and without evaluating other risk assessment methods.[161] EPA asks the Court to defer to the agency's decision that its general model is better science for evaluating those risks than is the specific data from the dial painters who actually ingested those radium isotopes. EPA fails to show the reasonableness of that decision. It simply refutes uncontested premises, parrots inadequate explanations from the Final Rule, and presents *post-hoc* rationalizations.[162]

A. EPA's Response Addresses Matters Not Contested By Petitioners.

EPA points out that its model relies on epidemiological data.[163] Petitioners acknowledge this.[164] Petitioners complain that EPA failed to satisfactorily explain why it did not use the most relevant data on persons who actually ingested radium-226 and radium-228.

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[158] FGR-13 at 173, D-25 (JA 112, 129).

[159] CRD-NODA at 3-35 (JA 968).

[160] *See* CRD-NODA at 3-35 (JA 968).

[161] Pet. at 34-49.

[162] Resp. at 61-73.

[163] Resp. at 64-65.

[164] Pet. at 9, 47

Petitioners also do not dispute that FGR-13 is an advanced model[165] or that the Science Advisory Board ("SAB") did not identify significant problems with it.[166] The issue is whether EPA justified its decision to defy SAB's 1990 recommendation against using such a model to establish radium MCLs when there was data from people who ingested radium-226 and radium-228.[167] EPA does not show that the SAB revisited this question when reviewing FGR-13 alone.

B. EPA's Response Confirms That The Agency's Sole Reliance On FGR-13 To Assess Health Risks Of Drinking Low Levels Of Radium-226 And Radium-228 Violates The SDWA.

Despite specific evidence from dial painters that ingesting only high doses of radium-226 and radium-228 causes cancer in only two organs, EPA's Response confirms that EPA increased the risk of these isotopes by assuming cancer in 13 organs at low doses, based on bomb survivor and radium-224 studies involving different forms of radiation exposure. Thus, EPA failed to use the best available, peer-reviewed science in its analysis of health effects of drinking low levels of radium-226 and radium-228.[168]

EPA violated section 1412(b)(3)(B) by not explaining in a comprehensive and understandable manner how it reconciled the inconsistencies in dial painter data and its model.[169] EPA claims that FGR-13 contains built-in adjustments that make the results of its model consistent with the dial painter data,[170] but that is not evident from the five sentences from the

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[165] *See* Resp. at 62, 64.

[166] *See* Resp. at 71.

[167] *See* 56 Fed. Reg. at 33055 (JA 1373); SAB Report at Cover Letter 2, 15 (Pet. at 37 n.184) (JA 1575, 1595).

[168] *See* 42 U.S.C. § 300g-1(b)(3)(A).

[169] *See* 42 U.S.C. § 300g-1(b)(3)(B)(v).

[170] Resp. at 69-70.

record cited by EPA. Four sentences from two separate documents discussing an "RBE" adjustment for leukemia do not mention dial painters or studies involving exposure to radium.[171] The isolated sentence from the Federal Register on head cancers does not reference FGR-13 or any document showing this calculation.[172] Absent the *post-hoc* claim in EPA's Response, the statements cited are insufficient to tell the public whether and how EPA reconciled the conflict between the effects of ingesting radium-226 and radium-228 shown in the dial painter studies and the effects predicted by EPA's model. EPA's Federal Register notices and Technical Support Document do not say what its counsel now claims -- that adjustments for leukemia and head cancers based on the dial painter studies are embedded in the model.

EPA violated section 1412(b)(3)(B) by not specifying an upper bound, lower bound, and central risk estimate for radium-226 and radium-228.[173] The MCLs for these isotopes are based on a single risk estimate derived from FGR-13. EPA does not identify the range of alternative risk estimates produced by other methods that use the dial painter studies.[174] Congress told EPA to inform the public of "alternative risk estimates that put the regulation in broader public health context."[175] EPA did not do so.

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[171] FGR-13 at 174 (JA 111); Radiogenic Cancer Risks at 28 (JA 1729) (Pet. at 39 n.199). The key dial painter studies by Roland, Mays, and Schlenker are not included in the list of references of the cited reports. Radiogenic Cancer Risks at 32-35 (JA 1730-1733); FGR-13 at R-1 to R-13 (JA 135-147); *see, infra*, n.178.

[172] 65 Fed. Reg. at 76722 (JA 889).

[173] *See* 42 U.S.C. §§ 300g-1(b)(3)(B)(ii)-(iii).

[174] 65 Fed. Reg. at 21603 (JA 29); Technical Support Document at III-30 (JA 202).

[175] S. Rep. No. 104-169 at 29.

C. EPA's Response Confirms That Its Sole Reliance On FGR-13 Also Violates The APA.

EPA violated the APA by failing to consider all the relevant factors and important aspects of the problem of assessing the risks of drinking low doses of radium-226 and radium-228.[176] EPA's Response confirms that EPA automatically relied on one risk assessment method,[177] without demonstrating that the agency fully-evaluated and compared alternative methods[178] showing less risk based on dial painter studies. EPA only performed half the required analysis. EPA considered only the alleged advantages of the model, and its underlying data on bomb survivors and patients injected with radium-224, and the alleged disadvantages of the dial painter studies and risk assessments based on those studies. EPA has not demonstrated that it considered the advantages of the dial painter studies -- humans exposed through ingestion to only radium-226 and radium-228. Nor has EPA demonstrated that it considered the disadvantages of the bomb studies -- external (not ingestion) exposure, confounding neutron and gamma ray exposure, estimated doses, wartime deprivation, and a no-cancer, low-dose control group.[179]

EPA violated the APA requirement to provide a satisfactory explanation for relying solely on the model and disregarding dial painter data.[180] EPA prefers the model because it relies on a larger population even though they were exposed externally to neutrons and gamma rays. But EPA has not explained why the large population in the bomb studies should receive more

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[176] *See State Farm*, 463 U.S. at 43.

[177] Pet. at 62.

[178] These methods are reflected in studies by Roland, Mays, and Schlenker, evaluated by the National Academy of Sciences and the SAB. BEIR IV at 194-205 (Pet. at 37 n.187) (JA 1634-1639); SAB Report at 16 (JA 1596).

[179] Resp. at 67.

[180] *See State Farm*, 463 U.S. at 43.

weight than the ingestion of only radium-226 and radium-228 in the dial painter studies. Likewise, EPA has not explained the reasonableness of using a model that assumes cancer from exposure to low doses of all forms of ionizing radiation, absent data confirming that assumption, and given data showing no cancers from ingesting lower doses of these radium isotopes.

EPA violated the APA by not explaining why it applied blanket health-effects assumptions about radiation despite specific, contradictory evidence on the effects of radium-226 and radium-228.[181] EPA increased the risk of drinking low doses of these isotopes by assuming they cause cancers in 11 organs where cancers were not observed in dial painters. The agency assumed a linear dose-response relationship for bone cancer, but the specific dial painter data fit a quadratic relationship that shows less risk at low doses. EPA assumed cancer occurrence at low doses, but the specific dial painter data showed none.[182]

EPA violated the APA by not establishing a rational connection between its model and the health effects of drinking low doses of radium-226 and radium-228 that the model purports to represent.[183] EPA claims it reasonably assumed those isotopes cause 13 types of cancers because radium-228 decays into the more carcinogenic radium-224.[184] The agency ignores the fact that radium-226 does not.[185] Even if radium-226 and radium-228 did cause the same six types of cancer as radium-224, EPA has not explained why it may reasonably assume cancers in seven other organs where the dial painter and radium-224 studies show none. EPA assumes all forms

[181] *See Leather Indus.*, 40 F.3d at 403.

[182] Pet. at 36-39.

[183] *See Columbia Falls*, 139 F.3d at 923.

[184] Resp. at 72.

[185] 56 Fed. Reg. at 33065 (JA 1383).

of radiation have the same health effects but ignores its admission that the effects of radionuclides depend on their unique half-lives, forms of decay, and energy levels.[186] EPA says the dial painters are an exception to the general rule that the dose-response curve for radiation is linear and attributes this to flaws in the dial painter studies.[187] EPA does not address the alternative possibility that this generalization does not apply to radium-226 and radium-228.

VI. EPA'S BETA/PHOTON MCL VIOLATES THE BEST AVAILABLE SCIENCE REQUIREMENT AND THE APA.

The SDWA requires EPA to act consistent with best available science "in carrying out [the Act's provisions governing drinking water regulations]" and "to the degree that an Agency action is based on science."[188] If EPA did not use what it believes to be best available science to develop the beta/photon MCL, *i.e.*, FGR-13, (i) EPA cannot have used that science in carrying out section 1412, *i.e.*, in promulgating that MCL, and (ii) EPA did not use that science to perform "an Agency action" that "is based on science." Nevertheless, EPA argues that it has satisfied these requirements because it conducted an after-the-fact "review" of an obsolete interim MCL -- which demonstrated that changes in science had rendered that MCL erratic, unprotective and irrational -- and then repromulgated the MCL anyway. Using "best available science" to conduct a review and then ignoring the results of that review in promulgating a rule, however, is inconsistent with the SDWA's best available science requirements and the APA.

[186] 65 Fed. Reg. at 76720 (JA 887).

[187] Resp. at 68.

[188] 42 U.S.C. § 300g-1(b)(3)(A).

Despite EPA's claims, Petitioners have never sought a "less protective" beta/photon MCL.[189] Rather, Petitioners seek to have EPA use its own benchmarks for "best available science" and "acceptable risk" to "promulgate" an MCL in accordance with the SDWA and the APA.[190] Petitioners acknowledge that EPA, as a policy matter, may select an appropriate cancer risk level. Thereafter, however, EPA must employ "best available science" to establish an MCL corresponding to that risk. EPA must comply with both the "health maintenance" and "best available science" requirements of the SDWA. Had EPA done so here, regulatory "concentration limits" for some beta/photon emitters would increase while others would decrease. The MCL, however, would not be less "protective." Rather, it would be consistent with EPA's own "best available science" and risk limits. Because EPA did not follow this approach, it violated the SDWA's "best available science" requirement and acted arbitrarily.

A. EPA's Own "Best Available Science" Condemns The Beta/Photon Rule.

This challenge does not require the Court to exercise scientific expertise or invade the province of the agency. Rather, the challenge to the beta/photon MCL seeks to have EPA apply its own best available science as the SDWA and APA require.

1. EPA Cannot Dispute That The Science Underlying The Beta/Photon Rule Is Not Best Available Science.

EPA cannot dispute that: (i) dramatic advances in radiation science have occurred since 1976; (ii) the "critical organ" methodology underlying the 1976 beta/photon rule is obsolete; and (iii) EPA's "most sophisticated science" -- FGR-13 -- recognizes that obsolescence,

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[189] *Compare* Resp. at 45 *with* Pet. at 74 & n.384 (advocating use of "recent radiation protection science").

[190] *See* 42 U.S.C. §§ 300g-1(b)(2)(A), (b)(3)(A).

incorporating scientific advances,[191] and providing a more accurate risk assessment.[192] EPA's belittling of the differences between FGR-13 and critical organ approaches is disingenuous. EPA's proposed change in 1991 from 4-mrem/year based on individual organ exposure to 4-mrem EDE/year based on whole-body exposure was not merely "a different unit of measure."[193] Rather, as EPA's own guidance recognizes, this change reflected revolutionary advances over previous science and the newer methodology "superseded" earlier methodologies underlying the 1976 limits.[194] Moreover, EPA has consistently embraced those advances.[195]

2. EPA's "Review" Of The 1976 MCL Cannot Justify Its Repromulgation.

EPA did not use FGR-13 to establish its beta/photon MCL. Recognizing this, EPA euphemistically contends that its repromulgation of the 1976 MCL was "informed by the best available science."[196] Indeed, EPA's only "use" of FGR-13 was a purported reassessment and comparison of the risks associated with an "obsolete" proposed 1991 MCL and the "obsolete" 1976 MCL.[197] This process did not yield an MCL based on best available science.

To satisfy the best available science requirement, EPA must use FGR-13 to decide on the MCL ultimately promulgated. EPA would have this Court believe that so long as EPA

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[191] *See, e.g.*, Resp. at 11 n.5, 83-84; FGR-11 at 2-3, 30, 198-208 (JA 1692-1693, 1706, 1707-1717); FGR-12 at 5-6 (JA 1721-1722).

[192] Resp. at 81, 83, 84.

[193] *Id.* at 81.

[194] FGR-11 at v (JA 1690); *see also id.* at 198 (JA 1707) (critical organ approach rejected internationally); Pet. at 63-65; 65 Fed. Reg. at 21601, 21603 (JA 27, 29); NEI Comments at 6-9 (JA 829-832).

[195] Pet. at 66-67. The only EPA regulations still based on this old science pre-date EPA's abandonment of critical organ methodology, or incorporate by reference SDWA limits.

[196] Resp. at 82.

[197] Resp. at 83-84.

understands how erratic and irrational the 1976 MCL is, it may repromulgate that rule under the SDWA. This is not what Congress had in mind when it directed EPA to use best available science in "carrying out section 1412." Simply *knowing* that the repromulgated MCL is outmoded, yields inconsistent risk protection and is inconsistent with EPA's own risk goal, is not good enough. Instead Congress expected EPA "to revise the [national primary drinking] standard to reflect the more recent [scientific] information."[198]

EPA did not revise this standard using current science; it "reviewed" two "old" versions of the rule, purporting to compare their riskiness using a third generation of science, FGR-13. The "results" of this comparison were predetermined, given EPA's policy choices in 1976 and 1991.[199] Moreover, that "review" cannot transmute the 1976 MCL into a rule based on "best available science."

B. EPA's FGR-13 Analysis Shows That Both The 1976 And 1991-Proposed MCLs Are Inadequate.

EPA suggests that the 1976 MCL passes muster under FGR-13. It does not. Rather than supporting repromulgation of the 1976 MCL, EPA's *post-hoc* review demonstrates that the repromulgated MCL is arbitrary, non-protective, and violates the SDWA. When EPA promulgated that rule in 1976, it did so because, under then-current science, that MCL corresponded to a uniform risk level of 5.6×10^{-5} for each beta/photon emitter. EPA's FGR-13

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[198] H.R. Rep. No. 104-632 at 31 (1996) *reprinted in* 1996 U.S.C.C.A.N. 1366, 1394 (discussing best available science in context of health maintenance provision).

[199] For purposes of this comparison, EPA's "application" of FGR-13 was simply to multiply each of the concentration limits associated with the 1991-proposed MCL and each of the concentration limits associated with the 1976 MCL by the *same* FGR-13 constant. The relative relationship between the "risk" of the 1976 limit and that of the 1991 limit for any particular radionuclide remained identical before and after EPA's "application" of FGR-13. It was no surprise that many of the calculated 1991 risk values were higher than their 1976 counterparts: when EPA proposed the 1991 MCL, as a policy matter, it chose a higher risk level (10^{-4}) than it selected in 1976 (5.6×10^{-5}). Thus, EPA's FGR-13 "reevaluation" was guaranteed to yield higher risk values for the 1991 MCL than for the 1976 MCL.

review of the 1976 Rule, however, showed that the MCL yielded radically different risks than EPA believed in 1976.[200] EPA's own analysis belies its claim that "the existing MCLs are sufficiently protective of human health and thus require no revision."[201] Not only do the recalculated 1976 risks diverge wildly from EPA's 1976 "acceptable risk" of 5.6×10^{-5}, but 13 of the radionuclides fall either above or below the bounds of EPA's more recent "acceptable risk range," which spans two orders of magnitude.[202]

When EPA promulgated the 1976 Rule, it did so because at that time it believed that this MCL would protect all individuals equally, irrespective of the radionuclide to which they were exposed. By contrast, in the current rulemaking, EPA admitted that the 1976 Rule no longer did so, but that, had it used FGR-13 to *develop* its beta/photon MCL, that updated MCL would produce consistent risks across different radionuclides and would satisfy the statutory requirement for best available science.[203] Nevertheless, EPA repromulgated the 1976 MCL, alluding to future actions where it purportedly intended to develop scientifically defensible limits.[204]

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[200] Some of those risks are higher than EPA's original target of 5.6×10^{-5}; some are lower. *See* 65 Fed. Reg. at 21605-21614 (JA 31-40). EPA's 1976 MCL and its associated concentration limits are now effectively a set of random values with little meaning because they ignore scientific advances of the intervening four decades.

[201] Resp. at 82. EPA misrepresents its finding in the Final Rule and to this Court, stating that FGR-13 reveals that the 2000 MCL actually falls within the 10^{-6} to 10^{-4} risk range. *See* 65 Fed. Reg. at 21583 (JA 9); Resp. at 23; *cf.* 65 Fed. Reg. at 21581-82 (JA 7-8); Pet. at 75-77, Attachment A.

[202] *See* Resp. at 84; Pet. at Attachment A.

[203] 65 Fed. Reg. at 76716 (JA 883).

[204] At the time, EPA's rulemaking conceded that the agency ran out of time and would review the beta/photon MCL on an accelerated basis. Pet. at 69-71. EPA, however, repeatedly has flip-flopped its position on the timing, and even its completion, of a beta/photon MCL review. *See id*; Attachment B at

(Continued …)

C. EPA Should Have Promulgated A "Third" MCL In Compliance With the SDWA and APA.

Recognizing that it had no rational basis for distinguishing between the 1976 and 1991-proposed MCLs on the "rounding" grounds articulated in the NODA,[205] EPA abandons that claim in its brief.[206] Having abandoned that justification, EPA is left to argue only that the 1976 MCL is preferable to the 1991-proposed MCL because more of the 1991 values fell outside of the risk range than did those of the 1976 MCL.[207] This newly-developed "lesser of two evils" rationale for repromulgating the 1976 MCL is impermissible under both the SDWA and the APA.[208]

It is not sufficient for some radionuclides, or for the average risk across all 168 beta/photon emitters, to fall within EPA's risk range: individuals are not exposed to an average concentration of all radionuclides. Rather, they are exposed to specific sources of one or more individual radionuclides. Application of the best available science would provide consistent protection for all exposed individuals at the appropriate risk level irrespective of which radionuclide they encounter. Although neither the 1976 or the 1991 MCL would provide this consistent protection, EPA was not limited to choosing between those two MCLs. Indeed, it was not permitted to do so. EPA's own "best available science" -- FGR-13 -- obligated EPA to

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1-2. Despite repeated opportunities and decades of missed deadlines, EPA has never updated the beta/photon MCL (as required by the SDWA) since 1976.

[205] 65 Fed. Reg. at 21581 (JA 7); Pet. at 75-77.

[206] EPA ignored, and thereby apparently conceded, that its rulemaking posits a false dichotomy. *See* Pet. at 74.

[207] Resp. at 82, 84-85. *See also, supra.*, n.199. Even the minor changes in radiation science during the 1990's were enough to push many of the 1991 values above the upper boundary of EPA's risk range.

[208] Additionally, courts do not tolerate *post hoc* rationalizations raised for the first time in litigation. *See, e.g., Burlington Truck Lines, Inc. v. United States,* 371 U.S. 156, 168-69 (1962).

promulgate a "third" rule– *i.e.*, a rule consistent with both "best available science" and an acceptable level of risk.

D. Section 1412(b)(9) Does Not Preclude A Numeric Increase In The MCL.

EPA contends that, irrespective of updated science, the health maintenance provision precludes increasing the MCL or its associated concentration limits.[209] Subsection 1412(b)(9), however, does not require maintenance of particular numeric limits; rather, it requires maintenance of "protection of the health of persons."[210] Health protection is a matter of presumed risk (*e.g.*, calculated number of cancers/million individuals), not dose (*e.g.*, 4 mrem/year) or concentration limit (*e.g*., pCi/L). Thus, when current science shows that the "protection of the health of persons" can be maintained or increased under an MCL with a less stringent numeric limit, EPA may adjust the numeric limit upward. The legislative history repeatedly confirms this: "If new science shows that a less stringent standard would provide the same level of health protection, *the MCL may be revised upward*."[211]

Even if subsection (b)(9) were ambiguous, EPA's interpretation is unreasonable and not entitled to deference.[212] One section of a statute may not render another section "inoperable or superfluous, void or insignificant."[213] EPA must harmonize the health maintenance and best

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[209] Resp. at 24, 31-32.

[210] 42 U.S.C. § 300g-1(b)(9).

[211] S. Rep. No. 104-169 at 33 n.4 (1995) (JA 1769) (emphasis added); *see also id.* at 31 (JA 1767) (standards may be raised, "if new science demonstrates that the current level of health protection can be achieved by a less stringent standard"); *see also id.* at 38 (JA 1774) (EPA may issue less stringent standard based on new scientific information); H.R. Rep. No. 104-632 at 31 (1996) ("the level necessary to maintain public health protection may change as new or additional information becomes available.").

[212] *See, e.g., Independent Ins. Agents of Am., Inc. v. Hawke*, 211 F.3d 638, 643 (D.C. Cir. 2000).

[213] *C.F. Communications Corp.*, 128 F.3d 735, 739 (D.C. Cir. 1997).

available science provisions. Instead, pronouncing the two provisions incompatible, EPA simply discarded the best available science requirement. To give both sections meaning, 1412(b)(9) must permit EPA to raise established *numeric* limits so long as it maintains health protection.

Further, an agency may not rely on *post hoc* rationalizations to justify its rulemaking.[214] In the Final Rule, EPA did not allege that Subsection (b)(9) prohibited EPA from increasing an existing MCL,[215] but instead asserts that position only now. This *post-hoc* rationalization should be rejected.

CONCLUSION

For the foregoing reasons, the Rule should be vacated and remanded.

[214] *See Burlington Truck Lines*, 371 U.S. at 167-69.

[215] At most, EPA quoted subsection (b)(9) but was unwilling to take a position as to whether the section constrained EPA's ability to increase an MCL based on best available science. *See* 65 Fed. Reg. at 76712, 76716 & n.9 (JA 879, 883).

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CERTIFICATE OF COMPLIANCE

Pursuant to Circuit Rule 28(d)(1), I hereby certify on this 17th day of October, 2002 that the foregoing "Joint Reply Brief of Petitioners" contains 13,950 words, as counted by a computer word processing system.

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