

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 06-10551

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| FILED U.S. COURT OF APPEALS ELEVENTH CIRCUIT JUNE 6, 2008 THOMAS K. KAHN CLERK |
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EPA No. 40 CFR 146

MIAMI-DADE COUNTY,
a political subdivision of the State of Florida,

Petitioner,

versus

THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
STEPHEN L. JOHNSON, Administrator,
U.S. Environmental Protection Agency,

Respondents,

No. 06-10574

EPA No. 40 CFR 146

CITY OF COOPER CITY, FLORIDA,
a municipal corporation,

Petitioner,

versus

THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
STEPHEN L. JOHNSON, Administrator,
U.S. Environmental Protection Agency,

Respondents,

No. 06-10575

EPA No. 40 CFR 146

CITY OF MIRAMAR, FLORIDA,
a municipal corporation,

Petitioner,

versus

THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
STEPHEN L. JOHNSON, Administrator,
U.S. Environmental Protection Agency,

Respondents,

No. 06-10576

EPA No. 40 CFR 146

CITY OF SUNRISE,
a Municipal Corporation,
E. CENTRAL REGIONAL WASTEWATER TREATMENT FACILITIES
OPERATION BOARD,
an Interlocal Entity Created pursuant to Section 163.01, et. seq., FLA. Stat.,

Petitioners,

versus

THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
STEPHEN L. JOHNSON, Administrator,
U.S. Environmental Protection Agency,

Respondents,

No. 06-10579

EPA No. 40 CFR 146

SIERRA CLUB,

Petitioner,

versus

THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
STEPHEN L. JOHNSON, Administrator,
U.S. Environmental Protection Agency,

Respondents,

No. 06-10583

EPA No. 40 CFR 146

CITY OF MARGATE, FL,

Petitioner,

versus

THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
STEPHEN L. JOHNSON, Administrator,
U.S. Environmental Protection Agency,

Respondents.

Petitions for Review of a Decision of the
Environmental Protection Agency

(June 6, 2008)

Before BIRCH, PRYOR and KRAVITCH, Circuit Judges.

PER CURIAM:

Miami-Dade County (“the County”), City of Miramar, City of Margate, City of Cooper City, City of Sunrise, East Central Regional Wastewater Treatment Facilities Operation Board (collectively “Municipalities”), and the Sierra Club petition for review of the Final Rule promulgated by the EPA amending the current federal underground injection control (“UIC”) requirements for Class I municipal disposal wells in Florida. 40 C.F.R. § 146.15, 146.16. The petitioners argue that the Final Rule conflicts with the plain language of the authorizing statute, that the EPA’s approach to UIC regulation in South Florida is arbitrary and capricious, and

that the EPA gave insufficient notice of certain terms of the Final Rule in violation of the Administrative Procedure Act (“APA”). We DENY the petition.

I. BACKGROUND

A. Statutory History

In 1974, concerned that drinking water across the country contained unsafe levels of a wide variety of contaminants, Congress passed the Safe Drinking Water Act (“SDWA”). Part C of the act addresses the protection of underground sources of drinking water (“USDW”) against contamination by underground injection of effluent.¹ 42 U.S.C. §§ 300h to 300h-8. Under the SDWA, the EPA promulgates regulations setting parameters for state UIC programs. 42 U.S.C. § 300h(b)(1). State requirements must at least meet, but may also exceed EPA requirements for protection. In protecting USDWs, § 1421(d)(2) of the SDWA states that:

[u]nderground injection endangers drinking water sources if such injection may result in the presence in underground water which supplies or can reasonably be expected to supply any public water system of any contaminant, and if the presence of such contaminant may result in such system’s not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons.

¹A USDW is an aquifer, or portion thereof, that either (a)(1) “supplies any public water system; or (2) . . . contains a sufficient quantity of ground water to supply a public water system; and (i) [c]urrently supplies drinking water for human consumption; or (ii) [c]ontains fewer than 10,000 mg/l total dissolved solids; and (b) . . . is not an exempted aquifer.” 40 C.F.R. § 144.3.

Id. § 300h(d)(2).² Additionally, EPA regulations “shall permit or provide for consideration of varying geologic, hydrological, or historical conditions in different States and in different areas within a State.” Id. § 300h(b)(3)(A).

B. Regulatory and Procedural History

The EPA has implemented Part C of the SDWA at 40 C.F.R. Parts 144-46. In its initial UIC regulations, the EPA defined five classes of injection wells. See 40 C.F.R. §§ 144.6, 146.5. The County and Municipalities own and operate municipal disposal wells, which inject treated domestic wastewater from a variety of facilities. These constitute one type of Class I well, and this is the only class of well at issue in this case.³

Regulatory requirements vary by well class. However, no injection well may cause “the movement of fluid containing any contaminant into [USDWs], if the presence of that contaminant may cause a violation of any primary drinking water regulation . . . or may otherwise adversely affect the health of persons.” 40 C.F.R. § 144.12(a). Within this limitation, the EPA has recognized several

²National “primary drinking water regulation[s]” specify the maximum contaminant levels (“MCL”) for any contaminant in water “delivered to any user of a public water system.” 42 U.S.C. § 300f(1), (3).

³Industrial, radioactive, and hazardous waste disposal wells also fall into Class I. Injection wells operated in relation to oil and natural gas production and mineral extraction fall into Classes II and III, respectively. Class IV includes shallow hazardous or radioactive waste disposal wells. Finally, a variety of specific well types not covered by the other four classes make up Class V. 40 C.F.R. §§ 144.6, 146.5.

approaches for preventing the endangerment of USDWs by underground injection. These include bans on certain types of wells and particular practices, waste isolation, and waste treatment.

Currently applied to wells in Classes I, II, and III, the waste isolation approach keeps injected wastewater from coming into contact with USDWs. Under this “no fluid movement” or the “no migration” standard, any evidence “indicat[ing] the [unauthorized] movement of any contaminant into [a USDW]” requires “the Director [to] prescribe such additional requirements . . . as are necessary to prevent such movement.” 40 C.F.R. § 144.12(b). This rule has applied even in the absence of evidence that a USDW has actually been endangered.

Because this no-fluid-movement standard “is operationally meaningful (i.e., it can be measured or otherwise determined) and because it can be achieved through the use of available, good engineering practices,” the EPA has applied it to wells in Classes I, II, and III since 1980. Consolidated Permit Regulations, 45 Fed. Reg. 33,290, 33,330 (May 19, 1980) (to be codified at 40 C.F.R. pt. 122). However, EPA regulations have also long recognized the viability of alternative approaches. For instance, the regulations give the permitting authority discretion to relieve existing or new Class II wells in existing injection fields of casing and

cementing requirements as long as such wells comply with the casing and cementing regulations extant at the time of drilling or when the field was submitted to the state program for approval, and as long as any resulting “movement of fluids into an underground source of drinking water [will not] create a significant risk to the health of persons.” 40 C.F.R. § 146.22(c)(2), (d)(2). Also, under 40 C.F.R. § 144.82, Class V well operators have discretion to employ a wide range of measures to prevent USDW endangerment – at base, they are prohibited only from injection activities that will result in the presence of a contaminant of concern in a USDW. See 40 C.F.R. § 144.82. As a result, many such wells “inject non-hazardous fluids into and above USDWs.” Consolidated Permit Regulations, 45 Fed. Reg. at 33,330. The EPA recognizes that implementing § 1421(d) in this manner is different from employing the no-fluid-movement approach, but views it as no “more stringent or more inclusive.” Water Programs; Consolidated Permit Regulations and Technical Criteria and Standards; State Underground Injection Control Programs, 45 Fed. Reg. 42,472, 42,477 (June 24, 1980) (to be codified at 40 C.F.R. pts. 122 and 146).

- (1) No-Fluid-Movement Standard & Florida Class I Municipal Disposal Wells.

For more than 20 years, Florida municipalities have injected large quantities of treated domestic effluent into deep underground caverns as an alternative to

surface disposal. The Florida Department of Environmental Protection (FDEP) has administered the federally-approved UIC program that regulates Class I underground injection wells in Florida since 1983. When the FDEP first began issuing permits to Class I wells, it was thought that these cavernous formations would adequately confine the wastewater, isolating it from USDWs. Revision to the Federal Underground Injection Control (UIC) Requirements for Class I – Municipal Wells in Florida, 65 Fed. Reg. 42,234, 42,235 (July 7, 2000) (proposed rules to be codified at 40 C.F.R. pt. 146). Since then, however, groundwater monitoring wells have detected unpermitted fluid movement that has, in some cases, reached USDWs. Additional investigation has shown this fluid movement to have resulted from a failure of the porous rock around the Floridan Aquifer adequately to confine the effluent.⁴

⁴The Upper Floridan Aquifer and the Biscayne Aquifer are the main water sources in South Florida. Certified Extracts of Administrative Record, Vol. 2 (CE2) at 1192. The Floridan Aquifer is quite large, underlying parts of Alabama, southeastern Georgia, southern South Carolina, and all of Florida. CE2 at 1202. It is divided into the Upper and Lower Floridan Aquifers, separated by a middle confining unit. CE2 at 1203. In southeastern Florida, the Floridan is overlain by the surficial Biscayne Aquifer composed of relatively thin layers of sands with some interbedded shell and limestone. CE2 at 1197; CE1 at 332. The Biscayne Aquifer, which is fairly thick, provides most of the water for Southeast Florida. CE2 at 1192, 1196. The surficial aquifers underlying Brevard and Pinellas counties (to the north and west) are much thinner, as is their intermediate confining unit. CE2 at 1192, 1193; CE1 at 332.

(2) Alternative Treatment-Based Approach

a. Proposed Rule

Responding to the detection of this fluid movement and having held a meeting with industry representatives, environmental groups, local governments and other stakeholders, the EPA issued a proposed revision of its regulations on 7 July 2000. This revision would have allowed existing Class I wells in specific areas in Florida to continue to inject if the owners or operators of those wells met certain further treatment requirements. More specifically, the EPA proposed two options that were to apply to all existing Class I municipal disposal wells that had caused or might cause movement of contaminants into USDWs. Revision to UIC Requirements, 65 Fed. Reg. 42,234.

Option 1 would have allowed the continued use of wells as long as the facility in question provided advanced wastewater treatment, high-level disinfection, and a non-endangerment demonstration to show that the injectate would not cause a USDW to exceed any national primary drinking water regulations or other health-based standards. Id. at 42,244. This demonstration would have focused on any contaminants that still exceeded the relevant levels after the specified level of advanced wastewater treatment. Id. at 42,239. It would have required a well-owner to “identify any such contaminants” in the injectate and

“demonstrate that they would not cause similar exceedences” in the USDW at issue. Id. The proposal explained that this demonstration requirement could have been satisfied by something as simple as reference to existing “technical literature describing die-off rates for viruses and other pathogens, or how metals bind in soils compared to the results of ground water sampling and analysis pursuant to § 146.13.” Revision to UIC Requirements, 65 Fed. Reg at 42,240.

Option 2 would have required facilities to conduct an in-depth hydrogeological demonstration that the injection operation would not cause fluids that could migrate into a USDW to exceed any national primary drinking water regulation or other health based standard. Id. at 42,239. The Option 2 demonstration, at a minimum, would have required “ground-water modeling, geochemical analysis, and effluent and ground-water monitoring and analysis.” Id. If the demonstration were unsuccessful, the facility in question would be required to provide advanced treatment as necessary to ensure that injectate would not cause any violation. Id. Option 2 also included a sunset provision which would have required high-level disinfection and advanced wastewater treatment at those facilities by 2015 regardless of any hydrogeological demonstration. Id. at 42,240.

The area in which the proposed revision applied included the following counties: Brevard, Broward, Charlotte, Collier, Flagler, Glades, Hendry,

Highlands, Hillsborough, Indian River, Lee, Manatee, Martin, Miami-Dade, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pinellas, St. Johns, St. Lucie, Sarasota, and Volusia. These counties were included because their underlying geology is predominated by carbonate rocks – a geologic condition which generally involves “fractures, faults, and solution cavities that provide preferential pathways for the movement of underground fluids.” CE1 at 76; 65 Fed. Reg at 42,236-37.

In connection with this proposed rule, the EPA requested public comment as to (1) whether it should select Option 1, Option 2, or a combination of the two, id. at 42,240; (2) the most appropriate of four proposed levels of wastewater treatment under Option 1, id. at 42,239; (3) the need to require pretreatment as an additional condition under Option 2 “to address contaminants that might move through a treatment system and enter into a USDW at concentrations of concern,” id. at 42,240; (4) whether owners and operators were able to provide the kind of hydrogeological and other information necessary for a successful demonstration under Option 2, id.; (5) whether there was a need for any additional monitoring requirements for the Final Rule, id. at 42,239; (6) whether the “proposed rule should apply to existing wells only, or . . . also . . . to new wells,” id. at 42,238; (7) with regard to the sunset provision in Option 2, which of the four levels of

advanced wastewater treatment and nutrient removal proposed under Option 1 should be required, *id.* at 42,240; (8) the general need “to require pretreatment [by industrial users] as an additional condition of authorization,” extending the industrial pretreatment standards presently required by the FDEP, *id.* at 42,239; and, finally, (9) comparing the various means of domestic wastewater disposal in Florida, and considering the “effects . . . those methods have on Florida’s fragile environment,” whether this proposal may result in the increased or decreased use of reuse or other disposal practices such as ocean or other surface water disposal, *id.* at 42,240.⁵ The EPA received just under 1200 comments and also held a series of public meetings during the comment period.

b. Risk Assessment

The same year the proposed options were published, Congress directed the EPA to study the relative risks of deep well injection, ocean disposal, surface discharge, and aquifer recharge of treated effluent in South Florida. In April 2003, the EPA published a Relative Risk Assessment (“Risk Assessment”). Therein the EPA confirmed that effluent from some Florida Class I wells had migrated out of the permitted injection zones and, in a few instances, into USDWs. CE1 at 413.

⁵The EPA also solicited comment as to the assumptions used in its economic analysis of the proposed rule, and as to the potential economic or environmental impact of either making no change or choosing one of the proposed options.

The study also concluded that each alternative disposal method posed enough risk to human health and the environment that none was clearly preferable to underground injection. CE1 at 611-12.

The EPA issued a Notice of Data Availability (NODA) as to the Risk Assessment and its underlying data on 5 May 2003 and requested public comment as to the potential impact of the Risk Assessment on the July 2000 proposed options. Underground Injection Control Program – Revision of Underground Injection Control Requirements for Class I Municipal Wells in Florida; Notice of Data Availability, 68 Fed. Reg. 23,666 (May 5, 2003) (proposed rules to be codified at 40 C.F.R. pt. 146). Specifically, the EPA also asked for comments on (1) “an alternative option for defining the appropriate level of wastewater treatment required for continued injection” (the proposed rule had suggested 4 specific levels of biochemical oxygen demand with disinfection, some also involving nutrient removal)⁶; (2) the “practicability and feasibility” of Option 2 as proposed – particularly as it incorporated an in-depth hydrogeological demonstration – including any suggestions for viable alternatives to the sunset provision requiring treatment by 2015; and (3) the possibility of reclassifying certain Class I wells as

⁶The alternative would adopt the Florida standards applicable either (1) to reclaimed water that might come into contact with people or (2) to Class V wells. Either would require filtration for total suspended solids (TSS control) prior to disinfection. Underground Injection Control Program – NODA, 68 Fed. Reg. at 23,672.

Class V wells, thereby requiring them to meet higher wastewater treatment standards instead of changing the standards for all Class I wells. Id. at 23,672-73. The EPA received a little over 200 additional comments in response to the Risk Assessment NODA.

c. Final Rule

The EPA published a Final Rule revising its UIC regulations on 22 November 2005. According to this Rule, which took effect on 22 December 2005, owners and operators of existing Class I municipal wells have a choice: (1) They may continue to operate under the no-fluid-movement standard, assuming their wells have not been deemed likely to cause fluid movement. If their effluent reaches a USDW, they face the consequences under that standard as originally promulgated. Underground Injection Control Program – Revision to the Federal Underground Injection Control Requirements for Class I Municipal Disposal Wells in Florida, 70 Fed. Reg. 70,513, 70,531-32 (Nov. 22, 2005) (to be codified at 40 C.F.R. pt. 146). Or, (2) they may continue their operations, despite evidence of fluid movement, as long as, within five years after 22 December 2005, they meet additional treatment requirements. Id. In publishing this Final Rule, the EPA explained that these new requirements – including “secondary treatment[] and high-level disinfection” – provide USDWs a level of protection equivalent to that

afforded by the no-fluid-movement standard.⁷ CE1 at 81. The Final Rule further requires that owners and operators with significant industrial users implement a pretreatment program that meets certain Florida standards designed to prevent industrial contaminants from endangering the public. Finally, the Final Rule applies to all existing and new Class I wells in the specified area. Underground Injection Control Program – Revision, 70 Fed. Reg. at 70,532. The EPA observed that the Final Rule was essentially a modified version of Option 1 of the July 2000 Proposed Rule and explained that the non-endangerment demonstration requirement had been eliminated because the Final Rule had adopted a treatment standard which would necessarily eliminate any concern about microorganisms remaining after treatment. Id. at 70,524. The EPA further explained that “uncertainties about the geology of certain counties in Florida make demonstrations inadequate to fully characterize or predict movement of pathogens in the subsurface” and for this reason, the “‘demonstration’ option provided in the proposed rule is not an appropriate way of ensuring non-endangerment.” CE1 at 109, 108.

⁷The applicable standards regarding high-level disinfection are taken from Florida Administrative Code Rule 62-600.440(5). Id. at 70,532. Florida’s high-level disinfection standards set parameters for (1) residual chlorine levels after disinfection, (2) resulting fecal coliform levels, and (3) use of total suspended solids controls. Fla. Admin. Code. Ann. 62-600.440(5).

C. Petitions for Review

The Sierra Club, Miami-Dade County and Palm Beach City filed timely Petitions for Review of this Final Rule on 19 January 2006, pursuant to 42 U.S.C. § 300j-7(a)(2). The next day, City of Cooper City, City of Miramar, City of Sunrise, City of Ft. Lauderdale and City of Margate also filed timely Petitions for Review. The Municipalities' petitions were consolidated with the County's in February 2006, and Sierra Club's petition was, in turn, consolidated with the all of those in March 2006.

(1) Sierra Club

Sierra Club argues that the Final Rule is inconsistent with the definition of endangerment set out in the SDWA. More specifically, Sierra Club reasons, the new regulation fails to protect USDWs as the no-fluid-movement standard did. Sierra Club also argues that the EPA's interpretation of the statute as embodied by the Final Rule is arbitrary and capricious and unsupported by the Risk Assessment or public comments. Sierra Club is particularly concerned that secondary treatment and high-level disinfection, while they might take care of biological pathogens, fail to address the potential entry of industrial and other non-biological contaminants into USDWs.

(2) The County and the Municipalities

The County argues, on the other hand, that the Final Rule exceeds the regulatory authority given the EPA by the SDWA. Specifically, the County argues that the Rule impermissibly broadens the definition of “endangerment.” Like Sierra Club, both the County and the Municipalities also argue that the rule is arbitrary and capricious and unsupported by the Risk Assessment and public comments. Both argue that the Final Rule fails to take into account geographically varied geology as mandated by the SDWA. The County is concerned that the Final Rule improperly assumes pathogens will flow into the Biscayne Aquifer and that the proper standard is whether there is an impact on public water systems, not aquifers. The Municipalities particularly complain that the Risk Assessment was methodologically flawed in 4 specific ways.⁸

⁸The Municipalities also complain of a flawed cost/benefit analysis in the risk assessment, specifically, that the EPA improperly neglected to consider the \$308-539 million cost of retrofitting a new injection facility to comply with the Final Rule. However, the Municipalities have failed to point to any such estimated cost in the administrative record. As discussed in the section on notice and comment, their argument that they received no notice as to application of the Final Rule to all new wells is to no avail. Accordingly, they have waived this argument. See Tex Tin Corp. v. EPA, 935 F.2d 1321, 1323 (D.C. Cir. 1991) (per curiam) (“a party must initially present its comments to the agency during the rulemaking in order for the court to consider the issue”); see also Camp v. Pitts, 411 U.S. 138, 142, 93 S. Ct. 1241, 1244 (1973) (reviewing court ought not rely on materials outside the record in applying the arbitrary and capricious standard).

The Sierra Club, on the other hand, complains that it was improper for the EPA even to consider costs in the course of its rulemaking. However, agencies are permitted to consider costs unless the relevant statute expressly prohibits it. Michigan v. EPA, 213 F.3d 663, 678 (D.C. Cir. 2000) (per curiam). Although the SDWA does not require cost consideration, it does not prohibit it either.

(3) Administrative Procedure Act

Two sets of petitioners also argue that the EPA failed to comply with the notice and comment requirements of the APA. The Sierra Club complains that the Final Rule's abandonment of any demonstration provision is not a logical outgrowth of the proposed rule and its notice and comment process. The Municipalities similarly argue that the proposed rule and its comment process left them insufficient notice of the Final Rule's application to all future Class I wells.

II. DISCUSSION

A. Standard of Review

A final action by the EPA is subject to a highly deferential standard of judicial review under the APA. Thereunder we must “hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A); see also Sierra Club, Inc. v. Leavitt, 488 F.3d 904, 911 (11th Cir. 2007).

B. APA Notice Requirement

As an initial matter, we address the complaints by the Sierra Club and the Municipalities that they received insufficient notice of certain components of the Final Rule. The APA requires that agencies publish notice of their proposed

rulemaking and afford the public an opportunity to comment. 5 U.S.C. § 553

(b)-(c).

[The APA's notice] requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.

Env'tl. Integrity Project v. EPA, 425 F.3d 992, 996 (D.C. Cir. 2005) (quoting Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin., 407 F.3d 1250, 1259 (D.C. Cir. 2005)). An agency satisfies this requirement, "and need not conduct a further round of public comment, as long as its Final Rule is a 'logical outgrowth' of the rule it originally proposed." Ne. Md. Waste Disposal Auth. v. EPA, 358 F.3d 936, 951-52 (D.C. Cir. 2004) (per curiam) (quotation and citation omitted); see also Florida Manufactured Housing Ass'n, Inc. v. Cisneros, 53 F.3d 1565, 1576 n.4 (11th Cir. 1995) (recognizing the usual application for the "logical outgrowth" test). "A rule is deemed a logical outgrowth if interested parties 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." Ne. Md. Waste, 358 F.3d at 952 (quotation and citation omitted); see also First Am. Discount Corp. v. Commodity Futures Trading Comm'n, 222 F.3d 1008, 1015 (D.C. Cir. 2000) (Notice must be "sufficient to advise interested parties that

comments directed to the controverted aspect of the Final Rule should have been made.”) (quotation and citation omitted).

“Notice is inadequate if ‘the interested parties could not reasonably have anticipated the final rulemaking from the draft rule.’” Am. Iron & Steel Inst. v. OSHA, 182 F.3d 1261, 1276 (11th Cir. 1999) (quoting Nat’l Mining Ass’n v. Mine Safety & Health Admin., 116 F.3d 520, 531 (D.C. Cir. 1997) (per curiam)). Under this standard, an agency is not restricted to adopting the position it proposed and on which it sought comment. Ass’n of Battery Recyclers v. EPA, 208 F.3d 1047, 1058 (D.C. Cir. 2000). Such a restriction would undermine the “purpose of notice and comment—to allow an agency to reconsider, and sometimes change, its proposal based on the comments of affected persons.” Id.; see also Ne. Md. Waste, 358 F.3d at 951 (If the EPA were precluded from changing its position, it “could learn from the comments on its proposals only at the peril of subjecting itself to rulemaking without end.”) (citation omitted).

“[T]he ultimate outcome of . . . rulemaking might be no rule, or only partial adoption of the proposed comprehensive rule.” Ass’n of Am. R.R.s v. DOT, 38 F.3d 582, 589 (D.C. Cir. 1994) (per curiam); see also Long Island Care at Home, Ltd. v. Coke, __ U.S. __, __, 127 S. Ct. 2339, 2351 (2007) (“[A]fter . . . consideration the [agency] might choose to adopt the proposal or to withdraw it.”);

Am. Iron & Steel Inst. v. EPA, 886 F.2d 390, 400 (D.C. Cir. 1989) (“[o]ne logical outgrowth of a proposal is . . . to refrain from taking the proposed step”); Natural Res. Def. Council, Inc., v. Thomas, 838 F.2d 1224, 1242 (D.C. Cir. 1988) (“[T]he EPA can obviously promulgate a final regulation that differs in some respects from its proposed regulation.”). Finally, although they may not provide the only basis upon which an agency claims to have satisfied the notice requirement, comments may be adduced as evidence of the adequacy of notice. See Nat’l Mining Ass’n v. Mine Safety & Health Admin., 512 F.3d 696, 699 (D.C. Cir. 2008); Horsehead Res. Dev. Co. v. Browner, 16 F.3d 1246, 1268 (D.C. Cir. 1994) (per curiam); see also Ne. Md. Waste, 358 F.3d at 952 (comments filed in support of and in opposition to proposed distinction demonstrated that interested parties understood issues and stakes).

(1) Abandonment of Demonstration Requirement

The Sierra Club challenges the Final Rule’s elimination of any demonstration requirement. First, the EPA initially solicited general comments on its proposed approaches for regulating Class 1 injection wells in South Florida. Then, in its Notice of Data Availability, it specifically requested further comment on whether, given the findings of the Risk Assessment, the type of hydrogeologic demonstrations set out in Option 2 of the proposed rule were practicable and

feasible. Underground Injection Control Program – NODA, 68 Fed. Reg. at 23,673. All interested parties, including Sierra Club, had ample opportunity to comment. The commentary provided ample support for the proposition that the technical challenges and factual uncertainties would generally prevent a convincing in-depth hydrogeological demonstration of wastewater fate and transport as described in originally proposed Option 2. See CE1 at 113, 120, 180-82. Accordingly, elimination of this demonstration requirement in the promulgation of the Final Rule constitutes a logical outgrowth of the proposal and comments. See Ass’n of Battery Recyclers, 208 F.3d at 1058; Horsehead Res. Dev. Co., 16 F.3d at 1268.

However, Sierra Club is also concerned about notice of elimination of the “non-endangerment” demonstration which was part of Option 1 of the July 2000 Proposed Rule. First, it is true that neither the EPA, nor any other party, has pointed to any evidence that the EPA specifically put this element of Option 1 up for comment, as it did with the in-depth demonstration required under proposed Option 2.⁹ It is also true that no party has pointed to any comment specifically addressing the simplified non-endangerment requirement in such a way as to make

⁹Each party had ample opportunity to address this issue in the round of letter briefs following oral argument. Letter briefs were submitted by the EPA, the County, and the Municipalities. For whatever reason, Sierra Club chose not to submit a letter brief.

it clear that commenters considered it independently at issue. Each of these would weigh in favor of our finding the Final Rule not to be a logical outgrowth. See Ne. Md. Waste, 358 F.3d at 952; First Am. Discount Corp., 222 F.3d at 1015; Horsehead Resource Dev. Co., 16 F.3d at 1268. However, the record as a whole weighs otherwise.

First, both environmental groups and municipal entities commented on the inherent unreliability of the hydrogeological demonstration proposed for Option 2, and so on its insufficiency as a tool to protect USDWs. Supp. Appx. 33 (comment of LEAF) (“EPA is proposing to rely on [a] process, involving demonstrations through models and review and decision-making by government, that has been proven fundamentally deficient in ensuring compliance with the SDWA.”), 74 (comment of Florida Chapter, Sierra Club) (“the EPA is repeating reliance on demonstrations that are not field-verified”), 128 (comment of Hillsborough County, Florida) (“It will not always be possible to perform a detailed hydrogeological analysis to demonstrate whether or not a Class I [] municipal well would cause violation of primary standards in the USDW” because of uncertainty about movement of water in subsurface Florida.); CE1 at 254 (comment of LEAF) (“the hydrogeological demonstration proposed in Option 2 is worthless”). But see CE1 at 274 (FWEA Utility Council) (supporting Option 2 demonstration). Second,

advanced wastewater treatment and disinfection have been shown, by the Risk Assessment, effectively to eliminate pathogens (the contaminants of concern according to the Risk Assessment). CE1 at 81, 97. Therefore, it is only logical to conclude, in the face of the significantly higher treatment levels adopted in the Final Rule, that the simplified, technical-literature-based non-endangerment demonstration has essentially become irrelevant. In other words, the Final Rule operates on the principle that the only way to “demonstrate” non-endangerment is to meet the specified higher treatment requirements. For these reasons, we find, as to the elimination of the non-endangerment requirement, that the Final Rule is a logical outgrowth of the proposed rule and its notice and comment period.¹⁰

¹⁰The Sierra Club also argues that the change from a mandatory demonstration of non-endangerment to monitoring at the discretion of the Florida director constitutes a “‘marked shift in emphasis between the proposed regulations and the final rules’” and, as such, “is not a ‘logical outgrowth’ of the proposed rule.” Sierra Club Br. at 48 (quoting Shell Oil Co. v. EPA, 950 F.2d 741, 751 (D.C. Cir. 1991) (per curiam)). More specifically, Sierra Club argues that proposed Options 1 and 2 would have required “a pre-injection demonstration confirming that fluids violating National Primary Drinking Water Standards and other public health standards would not migrate into and contaminate USDWs,” and that elimination of the demonstration requirement represented a “radical shift away from USDW protection” afforded by the proposed rule. Id. at 48-49 (citing Natural Res. Def. Council v. EPA, 279 F.3d 1180, 1188 (9th Cir. 2002)).

As discussed, because of (1) the particular role the non-endangerment demonstration played in proposed Option 1 (which incorporated less stringent treatment requirements), (2) the comments concerning the lack of reliability regarding hydrogeological demonstrations, and (3) the much higher treatment level imposed by the Final Rule, there was not as much a shift in emphasis here as a shift in approach. Instead of requiring each well operator to demonstrate that, by the time any injectate were to reach a USDW, it would not contaminate it, the Final Rule requires treatment which has been shown sufficiently to remove identified contaminants of concern at the point of injection so as to protect USDWs from eventual contamination in all cases. Underground Injection Control Program – Revision, 70 Fed. Reg. 70,523-24. We see no “radical” or “fundamental policy shift” precluding a finding of the Final Rule’s logical

Northeast Maryland Waste, 358 F.3d 936 at 951-52; Ass'n of Am. R.R.s, 38 F.3d at 589; see also Long Island Care at Home, ___ U.S. ___, ___, 127 S. Ct. at 2351; Thomas, 838 F.2d at 1242.

Even if we had found the Final Rule not to have been a logical outgrowth of the proposed rule, Sierra Club would also need to show that it was prejudiced by the lack of opportunity to comment. “[B]efore we may vacate an agency action [for procedural failure] during the notice-and-comment period, we must take ‘due account . . . of the rule of prejudicial error.’” Owner-Operator Indep. Drivers Ass’n, Inc. v. Fed. Motor Carrier Safety Admin., 494 F.3d 188, 202 (D.C. Cir 2007) (quoting 5 U.S.C. § 706). To show prejudicial error, a petitioner “must indicate with reasonable specificity,” the aspect of the rule to which it objects and “how it might have responded if given the opportunity.” Id. At base, the petitioner must demonstrate that “on remand, [it] can mount a credible challenge . . . and [was] thus prejudiced by the absence of an opportunity to do so before the agency.” Id. (quotations and citations omitted).

In this case, although the Sierra Club has specified the aspect of the Final Rule to which it objects, it has failed to address how it would have mounted a “credible challenge” to the elimination of the simplified non-endangerment

outgrowth. See Natural Res. Def. Council, 279 F.3d at 1188.

demonstration. See id. In its briefs, the Sierra Club has argued that, had it known the demonstration requirement was at issue, “it could have submitted specific scientific evidence, including expert testimony on the full range of dangerous contaminants remaining in wastewater following treatment, the inability of the required treatment to remove those contaminants, and the potential health effects from exposure to such contaminants through drinking water.” Sierra Club Br. at 44. It also stated that “[w]ithout the demonstration, Option 1 is but a shell of its former self.” Sierra Club Reply Br. at 15. It offers nothing more specific.

Further, throughout this process, Sierra Club has essentially argued that nothing short of enforcement of the no-fluid-movement standard will satisfy the statutory requirements of the SDWA. Additionally, in its initial brief, Sierra Club conceded that it believed the non-endangerment demonstration of Option 1, as proposed, “would be arbitrary, capricious, an abuse of discretion and contrary to law in violation of 5 U.S.C. § 706(2)(A).” Sierra Club Br. at 41 n.10.

Accordingly, it is not credible for the Sierra Club also to argue that the simplified non-endangerment demonstration proposed in Option 1 would have provided additional value in protecting underground drinking water. Finally, in arguing against the adoption of either of the proposed rules, the Sierra Club has had ample opportunity to make all of its arguments regarding the “range of dangerous

contaminants remaining in wastewater following treatment” and their potential health effects. Id. at 44. The EPA, in turn, has considered and responded based on the data gained through its Risk Assessment and other comments. See Underground Injection Control Program – Revision, 70 Fed. Reg. 70,513. Accordingly, we conclude that, even if there were inadequate notice, the Sierra Club has failed to show the necessary prejudicial error as to insufficient notice of elimination of the non-endangerment demonstration requirement.

(2) Application of Rule to All Existing and Future Wells

The Municipalities argue that the Proposed Rule would have applied only to existing wells that had demonstrated fluid movement while the Final Rule, without providing adequate notice, applies to every new injection well. In the preamble to the Proposed Rule, however, the EPA specifically requested comment “on whether this proposed rule should apply to existing wells only, or if this proposed rule should also apply to new wells.” Revision to UIC Requirements, 65 Fed. Reg. at 42,238. That this was sufficient notice to raise the issue of the scope of the Proposed Rule is borne out by several comments on the scope of the rule. See CE1 at 115 (EPA summary of comments); see also, e.g., CE2 at 1016 (Reef Relief); CE2 at 1087 (Theresa Foley). Thus, not only did the EPA provide adequate notice, but several concerned parties filed comments related to the

proposed scope of the rule, further demonstrating the adequacy of that notice. See Ne. Md. Waste, 358 F.3d at 952; Horsehead Res. Dev. Co., 16 F.3d at 1268.

Because the Final Rule meets all APA notice requirements, we proceed to examine the rule itself.

C. “Endangerment” Under the SDWA

The Sierra Club, the Municipalities, and the County argue, from opposing positions, that the concept of endangerment of USDWs embodied in the Final Rule is inconsistent with that outlined by the SDWA.

(1) Congressional Intent

When issues of statutory construction are raised, a court must first determine whether Congress has “directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter.” Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842, 104 S. Ct. 2778, 2781 (1984). If Congress did not express its intent unambiguously, we defer to the agency’s interpretation if it “is based on a permissible construction of the statute.” Legal Envtl. Assistance Found., Inc. v. EPA, 118 F.3d 1467, 1473 (11th Cir. 1997) (quoting Chevron, 467 U.S. at 843, 104 S. Ct. at 2782). Accordingly, we recognize that “when an agency is charged with administering a statute, part of the authority it receives is the power to give reasonable content to the statute’s textual

ambiguities” – in other words, the authority to fill gaps. Dep’t of Treasury, IRS v. Fed. Labor Relations Auth., 494 U.S. 922, 933, 110 S. Ct. 1623, 1629 (1990); see also Walther v. Bauknecht, 155 Fed. Appx. 463, 466-67 (11th Cir. 2005) (unpublished) (per curiam) (“[Chevron] deference is a tool of statutory construction whereby courts are instructed to defer to the reasonable interpretations of expert agencies charged by Congress to fill any gap left, implicitly or explicitly, in the statutes they administer.”) (citation omitted).

Under the first level of Chevron analysis, we employ the “traditional tools of statutory construction” to determine Congressional intent. See Chevron, 467 U.S. at 843 n.9, 104 S. Ct. at 2781. These tools include examination of the text of the statute, its structure, and its stated purpose. See Nat’l Ass’n of State Util. Consumer Advocates v. FCC, 457 F.3d 1238, 1252 (11th Cir. 2006), cert. denied, Sprint Nextel Corp. v. Nat’l Ass’n of State Util. Consumer Advocates, ___ U.S. ___, 128 S. Ct. 1119 (2008).

The relevant statutory text is as follows:

Underground injection endangers drinking water sources if such injection may result in the presence in underground water which supplies or can reasonably be expected to supply any public water system of any contaminant, and if the presence of such contaminant may result in such system’s not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons.

42 U.S.C. § 300h(d)(2). Despite this lengthy definition of endangerment, § 1421(d)(2) does not directly speak to precisely how the EPA should balance risks in promulgating regulations protecting USDWs. See Chevron, 467 U.S. at 842, 104 S. Ct. at 2781; see also Goldstein v. SEC, 451 F.3d 873, 878 (D.C. Cir. 2006) (a definition only clarifies, however, to the extent of its defining terms). Instead, Congress made the EPA responsible for regulating underground injection that “may result” in the presence of contaminants in underground water, if the presence of such contaminants “may result” in the violation of drinking water regulations or “may otherwise adversely affect” public health. 42 U.S.C. § 300h(d)(2) (emphasis added). Through repeated reference to the possibility that a USDW could be endangered, Congress established no particular metric for evaluating endangerment. Instead, it explicitly left the EPA to give specific meaning to the endangerment standard. See, e.g., 42 U.S.C. § 300h(b)(1) (providing for the EPA’s publication of “minimum requirements for effective [state] programs to prevent underground injection which endangers drinking water sources within the meaning of subsection (d)(2) of this section.”).

This conclusion is consistent with the idea that, in the context of environmental legislation and otherwise, “a determination of endangerment to public health is necessarily a question of policy that is to be based on an

assessment of risks and that should not be bound by either the procedural or the substantive rigor proper for questions of fact.” Ethyl Corp. v. EPA, 541 F.2d 1, 24 (D.C. Cir. 1976) (en banc) (addressing the Clean Air Act). Recognizing, in this context, that it was not necessarily the best equipped to make such an analysis, Congress left determination of the most appropriate standards to the expertise of the agency. Thus, we conclude that the SDWA delegated to the EPA the type of “gapfilling” authority entitled to further analysis under Chevron. See Dep’t of Treasury, 494 U.S. at 933, 110 S. Ct. at 1630.

The County and the Municipalities also argue that the Final Rule’s concept of endangerment nevertheless exceeds the authority granted by the SDWA by protecting more than it is authorized to protect. However, although the language in § 1421(d)(2) does frame the EPA’s regulatory authority, it cannot be read explicitly to restrict that authority to circumstances where risk of contamination to USDWs or public water supplies is all but certain, or even to restrict that authority according to a particular metric.¹¹ The statute’s precautionary purpose is clear and

¹¹In its reply, the County argues that the SDWA does offer metrics in the form of its definition of endangerment. This is not the case. A metric, by definition, is expressed in quantifiable terms. The statute provides only broad parameters for the presence in USDWs of any contaminant the presence of which might result in violation of any national primary drinking water regulation or might otherwise adversely affect public health. Although “national primary drinking water regulations” might be deemed precisely quantifiable, “adverse” effects on public health are not. Therefore, the statute lacks sufficient metrics to support the County’s argument. In either case, the statute’s use of the words “may” and “might” moves even further in the opposite direction of a metric. Additionally, although the County argues that the statute requires

the “actual contamination of drinking water is not a prerequisite either for the establishment of regulations or permit requirements or for the enforcement thereof.” See H.R. Rep No. 93-1185, at 32 (1974), reprinted in 1974 U.S.C.C.A.N. 6454, 6484.

At the other end of the spectrum, the Sierra Club’s argument that the Final Rule is contrary to the authority delegated by the statute – because the statute requires a no-fluid-movement standard – must also fail. As the Sierra Club points out, the legislative history indicates that “endangerment” is to be “liberally construed so as to effectuate the preventative and public health protective purposes of the bill.” Id. However, despite this evidence that the statutory language was intended for liberal construction, no mention is made of a blanket no-fluid-movement standard. Further, Congress has explicitly incorporated no-fluid-movement or “no migration” standards into other similar statutes. See, e.g., Resource, Conservation and Recovery Act (“RCRA”), 42 U.S.C. § 6924(d) (incorporating a “no migration” standard for land disposal of hazardous wastes).

protection of USDWs only if a municipality’s drinking water processing would not remove contaminants prior to distribution of drinking water, the statute requires the EPA to protect the source of the drinking water, not the system of supply. 42 U.S.C. § 300h(b)(1); see also H.R. Rep. No. 93-1185, at 28 (1974), reprinted in 1974 U.S.C.C.A.N. 6454, 6484 (committee’s intent was to protect both actual and potential drinking water sources).

It could have done so here as well, but has apparently chosen not to do so. We therefore proceed to the second level of Chevron analysis.

(2) EPA's Interpretation of the SDWA

An agency's construction of a statute is "deemed reasonable if it is not arbitrary, capricious, or clearly contrary to law." Ala. Power Co. v. FERC, 22 F.3d 270, 272 (11th Cir. 1994). An agency rule is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 103 S. Ct. 2856, 2867 (1983); Ala.-Tombigbee Rivers Coalition v. Kempthorne, 477 F.3d 1250, 1254 (11th Cir. 2007).

"Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect." Ethyl Corp., 541 F.2d at 28. This standard upholds agency actions as long as there is a rational basis for the agency decision. Arango v. U.S. Dep't of

Treasury, 115 F.3d 922, 928 (11th Cir. 1997); Manasota-88, Inc. v. Thomas, 799 F.2d 687, 691 (11th Cir. 1986). “The reviewing court may not substitute its judgment for that of the agency but must, instead, defer to the agency’s technical expertise.” City Of Oxford, Ga. v. F.A.A., 428 F.3d 1346, 1352 (11th Cir. 2005). Indeed, courts must be “extremely deferential” when an agency’s decision rests on the evaluation of complex scientific data within the agency’s technical expertise. New York v. Reilly, 969 F.2d 1147, 1152 (D.C. Cir. 1992). In such a situation, although a reviewing court may not “rubber stamp” an agency decision, it “‘must look at the [agency’s] decision not as the chemist, biologist, or statistician that [it is] qualified neither by training nor experience to be, but as a reviewing court exercising . . . certain minimal standards of rationality.’” Chemical Mfrs. Ass’n v. EPA, 870 F.2d 177, 199-200 (5th Cir. 1989) (quoting Am. Paper Inst. v. EPA, 660 F.2d 954, 963 (4th Cir. 1981) (quoting Ethyl Corp., 541 F.2d at 36-37)).

Further, the EPA is compelled to exercise its judgment in the face of scientific uncertainty unless that uncertainty is so profound that it precludes any reasoned judgment. See Massachusetts v. EPA, ___ U.S. ___, ___, 127 S. Ct. 1438, 1463 (2007) (recognizing this obligation in the context of the uncertainty concerning global climate change). Even “probative preliminary data not yet certifiable as ‘fact’” may provide an appropriate basis for promulgation of

regulations. Ethyl, 541 F.2d at 28. Generally, “it is only when a model bears no rational relationship to the characteristics of the data to which it is applied that we will hold that the use of the model was arbitrary and capricious.” Appalachian Power Co. v. EPA, 135 F.3d 791, 802 (D.C. Cir. 1998) (per curiam).

Just decades – less than an instant in geologic time – after the EPA first promulgated its regulations under the SDWA, it became apparent that the no-fluid-movement standard was not viable after all for many parts of southern Florida. Fluid movement resulting from the operation of certain Class I wells was violating applicable UIC regulations. Since that violation was a function of geology, and therefore not amenable to technological correction, the affected wells were unable to comply with the statute and would have had to cease operating. See Underground Injection Control Program – Revision, 70 Fed. Reg. at 70,523. In some instances, closure of the wells would have disrupted municipalities’ sole method of disposing of millions of gallons of wastewater per day. See CE1 at 402. To address this problem, the EPA created a regulatory alternative to the no-fluid-movement standard: allowing facilities unable fully to isolate wastewater injectate instead to apply advanced wastewater treatment and high-level disinfection prior to

injection.¹² The parties argue from opposing positions that the EPA's new rule is arbitrary, capricious, and unsupported by the record.

¹²The Sierra Club also asserts that the Final Rule is invalid in that it reverses a long-standing policy of prohibiting any migration of injectate into USDWs. If an agency adequately explains the reasons for a reversal of policy, however, "change is not invalidating, since the whole point of Chevron is to leave the discretion provided by the ambiguities of a statute with the implementing agency." Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 981, 125 S. Ct. 2688, 2699-2700 (2005) (quotation and citation omitted). Similarly, interpretive changes are permitted as long as they create no unfair surprise, and unfair surprise is deemed unlikely when notice and comment periods have been incorporated into process. See Long Island Care at Home, __ U.S. at __, 127 S. Ct. at 2349. The reasons given by the EPA, however, as discussed, make clear that this is more a case of broadening options than of reversing policy. Further, agencies "'must consider varying interpretations and the wisdom of [their] policies on a continuing basis' . . . for example, in response to changed factual circumstances." Brand X, 545 U.S. at 981, 125 S. Ct. at 2700 (quoting Chevron, 467 US. at 863-64, 104 S. Ct. at 2792).

Since the promulgation of the no-fluid-movement standard, scientists have gained a greater understanding of the subsurface environment in southern Florida. The no-fluid-movement standard is not feasible for many areas thereof. Accordingly, another approach to non-endangering waste disposal must be found. The Risk Assessment indicates both that none of the other three methods of waste disposal is necessarily preferable to underground injection and that secondary treatment and high-level disinfection will protect USDWs against endangerment as well as an effective waste isolation approach would. CE1 at 81, 97. Further, the EPA has explained that the Final Rule protects USDWs against endangerment through pretreatment of injectate rather than through reliance on the confining properties of underground hydrogeology. Comparing the two methods, the EPA explained that the "alternative treatment requirements are also 'operationally meaningful' in that they address the contaminants of concern in municipal wastewater via proven, long-used technologies that have been shown to remove a high percentage of pathogens of concern." CE1 at 97. Accordingly, although the Final Rule is really a regulatory alternative to longstanding policy and not a reversal of that policy, the EPA has offered adequate explanation for any reversal of policy that might be perceived. See Brand X, 545 U.S. at 981, 125 S. Ct. at 2699-2700. Further, because multiple periods of notice and comment were incorporated into the process, during which all of these issues were discussed at length, even if there had been an interpretive change, there was no unfair surprise to invalidate the Final Rule. See Long Island Care at Home, __ U.S. at __, 127 S. Ct. at 2349.

(a) Rule is Arbitrary and Capricious – Not Strict Enough

(i) Failure to Consider Non-Biological Contaminants

We first address the Sierra Club’s argument that the Final Rule is inconsistent with a reasonable interpretation of the statutory “non-endangerment” provision because it does not address the possible presence of non-biological contaminants in the treated injectate, such as radioactive, pharmaceutical, industrial and other hazardous wastes, particularly those from industrial users. Sierra Club asserts that the EPA’s focus on the “primary risk” associated with pathogenic microorganisms “entirely failed to consider the risks” of these other pollutants, and thus is arbitrary and capricious. Sierra Club Reply at 7, 8.

The EPA’s Risk Assessment models, however, show that representative non-biological contaminants will not migrate into USDWs, which are located above points of injection, in quantities great enough to exceed maximum acceptable contaminant levels (MCLs). See CE1 at 445-47. The Sierra Club argues that this cannot be reconciled with the Risk Assessment’s acknowledgment of a lack of precise data regarding the transport of contaminants underground. However, the Risk Assessment included a risk characterization using a transportation model to predict the potential final concentrations of certain representative non-biological contaminants. That model accounted for various risk mitigation factors, such as

the variety of natural chemical and physical processes to which injectate is subject after injection, including biodegradation, hydrolysis, sorption, volatilization, radioactive decay, transformation, and chemical or biological stabilization, which tend to mitigate the risk of endangerment. See CE1 at 444.¹³ The model also employed conservative assumptions as to rates of travel through the subsurface formations.¹⁴ The study still showed that USDWs above points of injection would not exceed MCLs for chemical contaminants¹⁵ or exceed health-based criteria for ammonia. CE1 at 446, 461. On this basis, the Risk Assessment concluded that pathogens were the only threat that would not be adequately addressed by the lower treatment requirements in place at the time of the study. CE1 at 463, 601, 603. The EPA raised treatment requirements to address this problem. We therefore conclude that the EPA model bears a rational relationship to the characteristics of the data to which it was applied and thus is not arbitrary or capricious. See Appalachian Power Co., 135 F.3d at 802.

Further, the Final Rule does, in fact, specifically address the potential for non-biological contaminants. First, the Final Rule requires that facilities with

¹³Microbial pathogens – particularly fecal coliforms and viruses, on the other hand, may well survive longer in groundwater than in surface water. See CE1 at 456.

¹⁴These assumptions tend to overestimate exposure and risk. See CE1 at 447.

¹⁵In fact, they would be below permissible drinking water levels. CE1 at 461.

significant industrial users implement industrial pretreatment; owners and operators must either pretreat or certify that there are no significant industrial users, consistent with the standards set in Rule 62-610.330 of the Florida Admin. Code. Underground Injection Control Program – Revision, 70 Fed. Reg. at 70,532. Thus, any industrial waste rising above this level would necessarily be pretreated to Florida’s reclaimed water standards.¹⁶

The EPA has also generally explained that the Final Rule does not require all facilities to institute treatment targeting these other specific non-biological contaminants for four basic reasons. First, the Risk Assessment found that the only contaminants that posed a potential threat to USDWs were pathogenic microorganisms. Second, Class I wells are already prohibited from injecting listed or characteristically hazardous waste streams in the first place. Third, each such well is allowed to inject only wastewater that has received the level of treatment specified in its individual permit, as deemed necessary to prevent endangerment. Finally, many other contaminants are already addressed through the EPA’s existing pretreatment regulations, and any future apparent threat could be addressed on an individual basis. On these and the preceding bases, we conclude that the EPA has

¹⁶The record reflects that fourteen of the sixteen facilities that have caused or are likely to cause fluid movement into a USDW already have industrial pretreatment programs in place, and that the remaining two have conducted surveys indicating that they are not handling waste streams from “significant industrial users.” CE1 at 113.

a reasonable basis for the Final Rule's approach to non-biological contaminants. See Motor Vehicle Mfrs. Ass'n, 463 U.S. at 43, 103 S. Ct. at 2856; Kempthorne, 477 F.3d at 1254.

More generally, the Sierra Club asserts that the Final Rule fails to address the existence of several potential threats to human health posed by pathogens, nutrients, and other contaminants, arguing from the position that all such risks should be analyzed and eliminated prior to injection. However, the SDWA mandates only that the EPA protect against endangerment to USDWs, not necessarily against contaminants extant at the point of injection. This distinction allows for the consideration of factors that would mitigate risks between the point of injection and contact with a USDW. In other words, because wastewater is injected below USDWs, it must travel upwards to make contact. As discussed, in making that journey, the injectate is subject to a variety of chemical and physical processes that mitigate risk. Underground Injection Control Program – Revision, 70 Fed. Reg. at 70,532. The EPA's risk assessment modeling employed conservative estimates of the exposure of injectate to these mitigating factors thereby, if anything, overestimating risk. CE1 at 444-48. The EPA's risk characterization indicated that although total suspended solids, color, odor, nutrient contamination, byproducts of disinfection, and industrial discharge contamination

might remain problematic at the point of injection even after the Final Rule's required treatment, by the time the treated injectate was likely to come into contact with a USDW, that risk would have been sufficiently mitigated. CE1 at 445-47. Accordingly, we conclude that the Sierra Club's record-based objections fail to invalidate the Final Rule.

(ii) Impermissible Consideration of Alternative Methods

The Sierra Club would also have us invalidate the Final Rule on the ground that the EPA impermissibly considered the utility of underground injection of waste in comparison with other disposal options. Because Congress specifically directed the EPA to analyze and compare the relative risks of these options in its 2000 Risk Assessment, consideration of that factor was not only permissible, but mandated. CE1 at 352 (“Within available funds, the conferees direct EPA to conduct a relative risk assessment of deep-well injection, ocean disposal, surface discharge, and aquifer recharge of treated effluent in South Florida, in close cooperation with the Florida Department of Environmental Protection and South Florida municipal water utilities.”). Accordingly, there is no basis for invalidating the Final Rule on this ground. See Motor Vehicles Mfrs. Ass’n, 463 U.S. at 43, 103 S. Ct. at 2867.

(b) Rule is Arbitrary and Capricious – Too Restrictive

(i) Geological Variation

The Municipalities and County first complain that the Final Rule fails to take into account differences in Florida geology and hydrology, as required by the SDWA. The record reflects that the subsurface environment in southern Florida is characterized by cavernous formations overlain by permeable carbonate rock, which, in places, prevents attainment of the no-fluid-movement standard. These carbonate formations – including the Floridan Aquifer itself, which underlies most of Florida as well as portions of neighboring states – are characterized by significantly variable porosity and permeability resulting from fracturing and other geologic processes that occur after formation. Revision to UIC Requirements, 65 Fed. Reg. at 42,236. Because these processes continue to take place due to subsurface fluid movement, the extent to which any given portion of the formation is permeable at any given time is not easily predicted. The EPA has restricted application of the Final Rule to counties characterized by this type of underground geology which may not reliably confine and isolate injected wastewater from USDWs. Accordingly, we conclude that the EPA’s consideration of variation within the subsurface geology of south Florida was sufficient.

The County also argues that the EPA improperly failed to consider the presence of the confining Hawthorne Layer, which likely effectively isolates the Biscayne Aquifer from the Floridan Aquifer, when it applied the Final Rule to Miami-Dade County. However, the EPA is charged with protecting the Floridan Aquifer itself because portions of that aquifer are designated a USDW, even though Miami-Dade County does not currently draw from it. See Underground Injection Control Program – Revision, 70 Fed. Reg. 70,516; 40 C.F.R. § 144.3; see also H.R. Rep. No. 93-1185 (1974), reprinted in 1974 U.S.C.C.A.N. at 6484. (“The Committee seeks to protect not only currently-used sources of drinking water, but also potential drinking water sources for the future. This may include water sources which presently exceed minimum intake water quality requirements or maximum contaminant levels or which are not presently accessible for use as a community drinking water supply source.”). Accordingly, we conclude that neither argument has pointed to evidence of insufficient consideration of geologic variation.

(ii) Flawed Methodology

The Municipalities argue that the Final Rule is not supported by the record due to four alleged flaws in the Risk Assessment’s methodology: (1) failure to consider the concentration of contaminants already present in the aquifers, (2)

failure to employ a quantitative probabilistic risk analysis methodology, (3) failure to consider the results of a then-unpublished University of Miami study of well-disposal practices, and (4) faulty assumptions about contaminant plumes. These criticisms are based on a review of the Risk Assessment performed by two scholars, a geologist, and a public utilities manager.

The review, however, fails directly to support these criticisms. As an initial matter, it directly states that the Risk Assessment's general approach and methodology were "generally appropriate for the problem addressed." CE1 at 284. As for the four specific criticisms, first, the Risk Assessment did incorporate the limited data available at the time of the study regarding the quality of groundwater prior to construction and operation of injection wells. CE1 at 412-13. The EPA also analyzed current and historic groundwater monitoring for the representative counties – particularly, for example, observing a period of fecal coliform spikes in the mid-nineties which was finally alleviated by well disinfection. CE1 at 415-20.

Second, although it is true that the EPA did not perform a quantitative probabilistic risk analysis, even the review, as noted, states that the Risk Assessment's methodology was appropriate for the problem it addressed. CE1 at 284. Also, the law does not require selection of the single best methodology in any case, but only a study "based on a consideration of the relevant factors" and in the

construction of which there has been no “clear error of judgment.” Citizens to Preserve Overland Park, Inc. v. Volpe, 401 U.S. 402, 416, 91 S. Ct. 814, 824 (1971), abrogated on other grounds, Califano v. Sanders, 430 U.S. 99, 97 S. Ct. 980 (1977).

The EPA concedes that the nature of the available data left it unable to perform a quantitative probabilistic risk analysis of the type suggested in the review, but argues that it performed the most rigorous analysis possible given the available data. According to the Risk Assessment, microbial pathogens in the aquifer will likely not degrade at as great a rate as they would in surface water. CE1 at 456, 599. The uncertainty as to this rate of degradation was coupled with general uncertainty stemming from the variable carbonate geology. Explaining that it is much easier and more efficient to prevent groundwater contamination than to try to decontaminate it later, the EPA addressed these uncertainties by making conservative assumptions regarding rates of degradation and travel of effluent through the subsurface environment. The use of this methodology is a legitimate discretionary decision on the part of the EPA. See Am. Iron & Steel Inst. v. EPA, 115 F.3d 979, 993 (D.C. Cir. 1997) (per curiam) (“[I]t is within EPA’s discretion to decide that in the wake of uncertainty, it would be better to give the values a conservative bent rather than err on the other side.”); Reilly, 969 F.2d at 1152.

Third, even according to the review, the findings of the Risk Assessment are not inconsistent with those of the Miami study.¹⁷ CE1 at 280, 283. Whether or not this is the case, even though the EPA was obligated to employ the best science, it had no absolute obligation to incorporate the findings of any other particular study because the EPA was conducting an independent risk assessment. See Tex. Office of Pub. Util. Counsel v. FCC, 265 F.3d 313, 328 n.7 (5th Cir. 2001) (“An agency need not respond to every study, and only has to address significant comments.”) (quotations omitted); Hughes River Watershed Conservancy v. Johnson, 165 F.3d 283, 289 (4th Cir. 1999) (agency need not consider every study as long as it addresses specific concerns raised by comments) (citing Roanoke River Basin Ass’n v. Hudson, 940 F.2d 58, 64 (4th Cir. 1991) (stating that an agency is required only to address specific concerns and explain why it found them unpersuasive)).

Fourth, the Municipalities claim that the Risk Assessment makes flawed assumptions as to conductivity rates in different risk scenarios and the rate of dilution of contaminant plumes. Due to uncertainties resulting from limited

¹⁷Although the Municipalities assert that the Miami study contained contrary scientific data, they point to no such instance, and the record cite in their brief corresponds to a page of the review (CE1 at 280) which says that, generally, results of the Risk Assessment should have been compared with those of other studies. It does not characterize the results of any such comparison.

availability of data, the EPA again chose the most conservative, protective approach in modeling its assumptions as to dilution and conductivity rates. This is permissible. See Am. Iron & Steel Inst., 115 F.3d at 993. It applied different conductivity rates in light of both known geologic characteristics of subsurface Florida (such as porous and more confining material, and the existence of fractures and fissures) and the geologic uncertainties about exactly what exists where within the aquifers. We conclude that the technical judgment made by the EPA was reasonable. See West Virginia v. EPA, 362 F.3d 861, 866-67 (D.C. Cir. 2004) (deference is due to an agency’s modeling of complex phenomena, so long as “model assumptions . . . have a ‘rational relationship’ to the real world”). This is another instance of a technical judgment lying fully within the scope of the EPA’s agency discretion. See Reilly, 969 F2d at 1152.

(iii) Justification for High-Level Disinfection

Finally, the County additionally complains that the Final Rule’s imposition of a high-level disinfection requirement, as opposed to some lower level of disinfection, is arbitrary and capricious. However, the high-level disinfection standard is the same one imposed by the State of Florida upon any wastewater that might come into contact with the public before microbial pathogens have a chance sufficiently to degrade. Incomplete information about the movement and fate of

pathogens during the injection process and beyond serves as a rational basis for requiring high-level disinfection prior to injection to prevent endangerment to USDWs. See Am. Iron & Steel Inst., 115 F.3d at 993.

For all of these reasons, we conclude that the Final Rule is a reasonable interpretation of the statute, is sufficiently supported by the administrative record, and is not arbitrary and capricious. Thus, we defer to the judgment of the EPA. See Chevron, 467 U.S. at 843, 104 S. Ct. at 2782; Legal Env'tl. Assistance Found., 118 F.3d at 1473.

III. CONCLUSION

The County, the Municipalities, and the Sierra Club petition for review of the Final Rule promulgated by the EPA amending the current federal underground injection control requirements for Class I municipal disposal wells in Florida. We conclude that the EPA afforded sufficient public notice of both the elimination of the non-endangerment demonstration requirement and the application of the Final Rule to new Class I wells as required by the APA. We further conclude that the petitioners have failed to show that the Final Rule is inconsistent with the statutory authority granted the EPA under the SDWA or that the Final Rule is unsupported by the record, or otherwise arbitrary and capricious. Accordingly, the petition is **DENIED.**