United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 21, 2012 Decided July 17, 2012

No. 10-1079

AMERICAN PETROLEUM INSTITUTE AND UTILITY AIR REGULATORY GROUP,
PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

NATURAL RESOURCES DEFENSE COUNCIL,
INTERVENOR

Consolidated with 10-1080

On Petitions for Review of Final Action
of the Environmental Protection Agency

Allison D. Wood argued the cause for petitioner American Petroleum Institute. *William Pedersen* argued the cause for petitioner Interstate Natural Gas Association of America. With them on the briefs was *Lucinda Minton Langworthy*. *Joan Dreskin, Timm L. Abendroth, Daniel J. Regan Jr.*, and *Janice K. Raburn* entered appearances.

Norman L. Rave Jr., U.S. Department of Justice, argued the cause for respondent. On the brief was *Angeline Purdy*, Attorney. *Michael Augustini*, Attorney, entered an appearance.

Abigail M. Dillen, *Colin O'Brien*, *John Walke*, and *Adrian Martinez* were on the brief for intervenor Natural Resources Defense Council in support of respondent.

Before: ROGERS, *Circuit Judge*, and EDWARDS and GINSBURG, *Senior Circuit Judges*.

Opinion for the Court filed by *Senior Circuit Judge* GINSBURG.

GINSBURG, *Senior Circuit Judge*: In 2010, the EPA promulgated a final rule adopting a new, one-hour primary national ambient air quality standard (NAAQS) for nitrogen dioxide. The American Petroleum Institute, the Utility Air Regulatory Group, and the Interstate Natural Gas Association of America (collectively the API) petition for review of that rule, claiming the EPA, in adopting the NAAQS, was arbitrary and capricious and violated the Clean Air Act. The API also challenges a statement in the preamble to the final rule regarding the EPA's intended implementation of the NAAQS. We deny the petitions insofar as they challenge the EPA's adoption of the NAAQS, but because the EPA's statement in the preamble was not final, we lack jurisdiction to consider those portions of the petitions.

I. Background

The Clean Air Act requires the EPA to establish a primary and a secondary NAAQS for any pollutant "reasonably ... anticipated to endanger public health or

welfare." 42 U.S.C. § 7408(a)(1)(A). The EPA must set the primary NAAQS at a level "requisite to protect the public health" with "an adequate margin of safety." 42 U.S.C. § 7409(b)(1).

In 1971, in order to control the emission of harmful nitrogen oxides,[*] the EPA established a primary NAAQS for nitrogen dioxide (NO_2) of 53 parts per billion (ppb) for the annual average in any given area. *See* National Primary and Secondary Ambient Air Quality Standards, 36 Fed. Reg. 8186, 8187 (April 30, 1971). Then as now the NAAQS focused specifically upon NO_2 as an indicator for the broader category of nitrogen oxides; because those gases are typically emitted together and in similar proportions, detection of one usually indicates the presence of the others. Combustion processes, especially those occurring in automobile and truck engines and electricity-generating plants, account for most of the production of these compounds. Nitrogen oxides have a variety of documented adverse effects upon human health, including increased airway hyperresponsiveness (contraction of the bronchioles) in asthmatics and increased respiratory illness in children.

The EPA began a review of the NAAQS for NO_2 in 2005 and revised the primary NAAQS in 2010. In the time since its prior review, accumulated epidemiological and clinical evidence suggested adverse health effects occurred at lower concentrations of NO_2, and for exposures of a much shorter duration, than scientists previously had suspected. For that reason, the EPA began to consider whether, because the

[*] The EPA defines this class broadly to include "all forms of oxidized nitrogen (*N*) compounds." ENVIRONMENTAL PROTECTION AGENCY, INTEGRATED SCIENCE ASSESSMENT FOR OXIDES OF NITROGEN – HEALTH CRITERIA 2:1 (2008).

existing NAAQS focused upon the annual average concentration in an area, an additional NAAQS was necessary to protect against the adverse effects of short-term spikes in exposure to NO_2. In 2005, the EPA made a general call for information, 70 Fed. Reg. 73,236 (Dec. 9, 2005), and in 2007, after notice and comment, it published the methodology it would use to review the NAAQS for NO_2, *see* EPA, INTEGRATED REVIEW PLAN FOR THE PRIMARY NATIONAL AMBIENT AIR QUALITY STANDARD FOR NITROGEN DIOXIDE (Aug. 2007). The Review Plan described the EPA's plans to synthesize the results of existing epidemiological and clinical research regarding the health effects of exposure to NO_2, develop forecasts of improved air quality under a hypothetical new NAAQS set at various levels then under consideration, submit such analyses for external review, and after public notice and comment adopt a new NAAQS. *Id.* at 2–3.

In 2008, pursuant to the Review Plan, the EPA released its Integrated Science Assessment, in which it undertook "to critically evaluate and assess the latest scientific information published since [the review it conducted in 1993]." ENVIRONMENTAL PROTECTION AGENCY, INTEGRATED SCIENCE ASSESSMENT FOR OXIDES OF NITROGEN – HEALTH CRITERIA xxvii (2008) (hereinafter ISA). The ISA discussed epidemiological evidence that showed "positive associations of short-term ambient NO_2 concentrations below the current NAAQS level with increased numbers of [emergency room] visits and hospital admissions for respiratory causes." *Id.* at 5:11. Many studies observed such effects in areas with average daily concentrations of NO_2 between 3 and 50 ppb. *Id.* The EPA also presented its updated version of a meta-analysis[*] of clinical studies on the health effects of NO_2 that

[*] A meta-analysis synthesizes the results of multiple studies by performing statistical analyses of the results of those studies.

had been done by L.J. Folinsbee in 1992 and that it had reviewed in its earlier assessment of the NAAQS. *Id.* at 3:14–16. The agency made three changes to the 1992 meta-analysis: It removed one underlying study involving specific airway responses to ragweed, added a new study involving non-specific airway responses, and measured the effects at short-term concentration levels as low as 100 ppb. *Id.* at 3:16. The results of the updated meta-analysis showed a statistically significant 66 percent of resting asthmatics experienced an increase in hyperresponsiveness in the presence of NO_2 concentrations of 100 ppb. *Id.* The results did not, however, reveal a dose-response relationship – one in which the measured health effect, here the proportion of asthmatics experiencing hyperresponsiveness, increases due to an increased concentration or dose of some agent, here NO_2 – which would have provided a stronger indication that short-term exposure to NO_2 causes hyperresponsiveness in asthmatics. Indeed, at levels of 200-300 ppb and over 300 ppb still about 60 percent of asthmatics experienced hyperresponsiveness. *Id.* Considering the various clinical and epidemiological studies together, however, the EPA concluded the evidence was "sufficient to infer a causal relationship" between short-term exposure to NO_2 at levels as low as 100 ppb and various types of respiratory morbidity; it also concluded the data were "suggestive but not sufficient to infer a causal relationship" between short-term exposures and mortality. *Id.* at 5:5.

The EPA also assessed risks from NO_2 exposure under three different assumptions about future air quality: (1) future air quality remains at its current level (the "as is" assumption) (2) future air quality just meets the existing NAAQS of 53 ppb (the "just meets" assumption), and (3) future air quality just meets several different potential hourly NAAQS, to wit, 50, 100, 150, and 200 ppb (the "new NAAQS" assumption).

See EPA, RISK AND EXPOSURE ASSESSMENT TO SUPPORT THE REVIEW OF THE NO_2 PRIMARY NATIONAL AMBIENT AIR QUALITY STANDARD 59, 120 (Nov. 2008) (hereinafter REA). The EPA explained that, although it had few actual data showing any areas experienced short-term exposures above the levels of the NAAQS under consideration in the third scenario, REA at 89–95, its simulation procedure showed that at the current level of air quality, people near roads are now and would be in the future exposed numerous times in a year to concentrations above 100 ppb (the short-term exposure level at which the ISA concluded adverse health effects were likely to occur), REA at 97–99. The number of such exposures would rise dramatically under an alternate scenario in which each area was forecasted to just meet the existing annual standard. *Id.* at 144. The agency's projections indicated a one-hour standard (defined by the 3-year average of the 98th percentile of hourly values) of 100 ppb measured area-wide would improve upon the "just meets" but not upon the "as is" scenario; a one-hour standard of 50 ppb would improve upon the "as is" scenario. *Id.*

The EPA submitted both the ISA and the REA to the Clean Air Scientific Advisory Committee (CASAC) for review, as required by the Clean Air Act, 42 U.S.C. 7409(d)(2)(A). The CASAC agreed with the EPA's assessment that the current annual NAAQS was not adequate to protect human health, and it suggested the agency adopt a one-hour standard for NO_2 of no greater than 100 ppb.

In 2009 the EPA proposed to set a new hourly NAAQS with allowable maximum concentration levels between 80 and 100 ppb. 74 Fed. Reg. 34,404 (July 15, 2009). The petitioners each submitted comments criticizing the EPA for proposing a revision to the NAAQS based upon an unpublished study, *i.e.*, the updated meta-analysis, and for

discounting a published and peer-reviewed study that did not conclude exposures to NO_2 at 100 ppb caused a measureable adverse health effect. They also expressed skepticism about the EPA's interpretation of the epidemiological evidence, questioned the assumptions built into the forecasts in the REA, and pointed out the proposed rule provided no guidance as to how a permit applicant for a new or modified source of NO_2 pollution should demonstrate compliance with the new NAAQS.

In its Final Rule, the EPA adopted a new one-hour primary NAAQS, requiring in effect that "the three-year average of the annual 98th percentile of the daily maximum 1-hour average concentration [be] less than or equal to 100 ppb." Primary National Ambient Air Quality Standards for Nitrogen Dioxide, 75 Fed. Reg. 6474, 6531 (Feb. 9, 2010) (codified at 40 C.F.R. § 50.11(f)). The EPA concluded this standard was needed "to provide protection for asthmatics and other at-risk populations against an array of adverse respiratory health effects related to short-term NO_2 exposure." *Id.* at 6502.

II. Analysis

The API petitioned for review of the Final Rule under 42 U.S.C. § 7607(b), which gives this court exclusive jurisdiction to hear a challenge to a NAAQS. We review the EPA's setting of a NAAQS to determine whether it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 7607(d)(9)(A); *see also* 5 U.S.C. § 706(2)(A). According to the API, the EPA was arbitrary and capricious in how it dealt with the record evidence and the NAAQS it adopted is unlawful because more stringent than "requisite to protect the public health" with "an adequate margin of safety," 42 U.S.C. § 7409(b)(1).

In addition, the API argues the EPA's implementation of the NAAQS was arbitrary and capricious because, when the EPA stated a permit applicant for a new or modified source of pollution must demonstrate compliance with the new NAAQS, the agency – or so the API asserts – did not consider whether it would be able to resolve applications within the statutorily required time period or what effect such a requirement might have upon economic growth.

A. The EPA's Adoption of the One Hour NAAQS

The API claims the process by which the EPA adopted the new NAAQS was flawed and the standard must therefore be vacated. More specifically, it faults the EPA for (1) relying upon an unpublished, non-peer-reviewed meta-analysis of clinical studies, (2) discounting a published meta-analysis that called into question the EPA's conclusions, (3) treating the same epidemiological study differently in reviews of the NAAQS for NO_2 and for ozone, and (4) projecting the benefits to air quality from the new NAAQS based upon faulty assumptions.

1. Peer Review of the Meta-Analysis

The API first contends the EPA, by relying upon an internal meta-analysis that was not published, "did not follow its own requirements ... that it rely only on peer-reviewed and published studies in reviewing NAAQS." Pet. Br. at 26. Perhaps the API should have had its brief peer-reviewed. In quoting the EPA's Review Plan, *see* Pet. Br. at 28, the API omits the first and most relevant word of the following sentence: "Generally, only information that has undergone scientific peer review and that has been published (or accepted for publication) in the open literature will be considered," Review Plan at 11; *see also* ISA Annexes at 1:1.

Of course, "generally" here indicates the practice in question will not invariably be followed, *see Kurke v. Oscar Gruss and Son, Inc.*, 454 F.3d 350, 355–56 (D.C. Cir. 2006) ("as ... the word 'generally' suggests, there are exceptions to the rule"); *Bernhardt v. City & Suburban Ry. Co.*, 263 F. 1009, 1015 (D.C. Cir. 1920) ("the word 'generally' ... indicates that there may be [exceptions to the stated rule]"). A bad start for the petitioners.

The API also points to guidelines the EPA promulgated pursuant to the Information Quality Act (IQA), Pub. L. 106-554, § 515(b)(2)(A) (requiring each federal agency to issue guidelines "for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by the agency"), which it contends also require peer review. *See* EPA, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY (Oct. 2002). By their terms, however, the Guidelines provide only "non-binding policy and procedural guidance." *Id.* at 4. Such a statement would not override a specific commitment made elsewhere in the document, *see Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022–23 (D.C. Cir. 2000), but the petitioners point to none. In keeping with the Review Plan and the ISA, the Guidelines also state that "major scientifically and technically based work products ... related to Agency decisions should be peer-reviewed." Guidelines at 11. The use of the phrase "should be" rather than "shall" suggests but does not necessarily mean the Guidelines are not binding. *Compare Doe v. Hampton*, 566 F.2d 265, 281 (D.C. Cir. 1977) ("that the provision in question employs the directory 'should be' rather than the mandatory 'shall' or 'must' ... should not be automatically determinative of the issue"), *with Jolly v. Listerman*, 672 F.2d 935, 945 (D.C. Cir. 1982) ("use of the

word 'should' ... detracts significantly from any claim that this guideline is more than merely precatory"), *and Military Toxics Project v. EPA*, 146 F.3d 948, 958 (D.C. Cir. 1998) (accepting as permissible EPA's interpretation of "word 'should' ... as calling for an exercise of judgment and hence conferring discretion upon the Administrator"). More important, the Guidelines themselves expressly commit "the decision whether to employ peer review" to the discretion of agency management. Guidelines at 11. Finally, the Guidelines note the EPA's Peer Review Handbook "provides detailed guidance for implementing" the agency's peer review policy, *id.*, and the Handbook in turn states specifically the relevant decision-makers "need[] to make a judgment" whether peer review is appropriate in a specific case because "[t]here is no easy single yes/no test," EPA, PEER REVIEW HANDBOOK § 2.2.3 (2000). No doubt the EPA believes peer review is important and it intended to impress that value upon its staff, but the agency did not bind itself to a judicially enforceable norm.

We need not decide the extent, if any, to which an agency must account for any departure from a non-binding guideline, *compare Sitka Sound Seafoods, Inc. v. NLRB*, 206 F.3d 1175, 1182 (D.C. Cir. 2000) (because manual was non-binding, question was whether, apart from requirements of manual, agency acted reasonably), *with Edison Elec. Inst. v. EPA*, 391 F.3d 1267, 1269 & n.3 (D.C. Cir. 2004) (agency must account for departure from non-binding plan), because the EPA, contrary to the API's claim, did not depart from its non-binding peer review policy. The EPA merely updated the Folinsbee meta-analysis, which was originally peer-reviewed and published; the only data it added to the meta-analysis were the results of a study that was itself peer-reviewed and published; and the CASAC peer-reviewed the results of the updated meta-analysis. *See* Peer Review Handbook § 2.4.3(d)

(listing the CASAC among acceptable sources of external peer review); c*f. City of Portland, Or. v. EPA*, 507 F.3d 706, 716 (D.C. Cir. 2007) (holding "advice from [EPA's] Science Advisory Board [a group of outside scientists, similar to the CASAC, organized by the EPA to review its scientific analyses] ... [was an] acceptable form of peer review"). The EPA also relied upon epidemiological studies, as well as individual clinical studies underlying the meta-analysis that had been published and peer-reviewed. The EPA's staff conducting the review of the proposed NAAQS judged the CASAC's review of the meta-analysis was sufficient, and the API has presented no reason for us to disturb that judgment.

2. Treatment of the Goodman Study

Next, the API argues the EPA inappropriately discounted the results of a published meta-analysis by Dr. Julie E. Goodman et al., *Meta-Analysis of Nitrogen Dioxide Exposure and Airway Hyper-Responsiveness in Asthmatics*, 39 CRIT. REV. TOXICOLOGY 719 (2009). According to the API, the study suggests, contrary to the EPA's findings, there is no causal relationship between an increase in ambient concentrations of NO_2 and an increase in health effects, such as airway hyperresponsiveness in asthmatics. The EPA defends its treatment of the study as follows: The agency did not receive the study until after it had conducted the analyses described in the ISA and the REA and submitted them to the CASAC for review; it nevertheless considered the study but found its methodology wanting and therefore not a reason for reopening its review process.

An agency's action is arbitrary and capricious if it "entirely failed to consider an important aspect of the problem [or] offered an explanation for its decision that runs counter to the evidence before the agency." *North Carolina v. EPA*, 531

F.3d 896, 906 (D.C. Cir. 2008) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The API has not shown the EPA's treatment of the Goodman study fell below these standards.

First, the results of the Goodman study did not "run[] counter to the evidence before the agency," *North Carolina*, 531 F.3d at 906. Contrary to the API's description, the study did not establish there was "no dose-response relationship"; it simply failed to reject the null hypothesis to that effect. That is, the authors could not tell whether there is no such relationship or their test merely lacked sufficient power to detect the relationship. *See* David H. Kaye & David A. Freedman, *Reference Guide on Statistics*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 211, 253–54 (Fed. Judicial Ctr. 3d ed. 2011), *available at* http://www.fjc.gov/public/pdf.nsf/lookup/SciMan3D01.pdf/$file/SciMan3D01.pdf. The Goodman study, moreover, did not test for the possibility of a non-linear dose-response relationship.[*] *See* Goodman at 733.

[*] *See* Daniel L. Rubinfeld, *Reference Guide on Multiple Regression*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 303, 316 (explaining "[f]ailure to account for nonlinearities [in the estimated equation] can lead to either overstatement or understatement of the effect of a change in the value of an explanatory variable on the dependent variable"). The underlying data in the EPA's meta-analysis indeed suggest that roughly the same proportion of asthmatics, 58 to 66 percent, experience airway hyperresponsiveness whether exposed to levels of 100 ppb, 200 ppb, or even 300 or more ppb. *See* ISA at 3:14–16. These results are consistent with a non-linear dose-response relationship that increases sharply at a low concentration of ambient NO_2 and then flattens out as the dose nears a concentration of 100 ppb.

Second, because the EPA gave the specific reasons for which it disagreed with Goodman's methodology, it did not "fail[] to consider" the study, nor did it fail to "offer[] an explanation" for not relying upon that study. *North Carolina*, 531 F.3d at 906. The EPA explained that it had decided not to focus upon detecting a dose-response relationship in its meta-analysis because differences in the assumptions made and in the methodologies used in the underlying studies would likely make it impossible to derive a reliable estimate. *See* Final Rule, 75 Fed. Reg. at 6487, 6498. The EPA did acknowledge the limitations inherent in its own study, noting "uncertainty with regard to the magnitude and [to] the clinical-significance of NO_2-induced increases in airway responsiveness," *id.* at 6488, but it explained the Clean Air Act requires the agency to promulgate a primary NAAQS to protect the public health even where, as here, the risks from the pollutant could not be quantified or "precisely identified as to nature or degree," *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002) (internal quotation marks and citation omitted). The EPA was therefore justified in revising the NAAQS considering the evidence of a statistically significant relationship between relevant health conditions and NO_2 exposure at various concentrations, even if the agency did not know the precise dose-response relationship between NO_2 and airway responsiveness, among other health effects.

The API mistakenly places much weight upon our recent decision in *Business Roundtable v. SEC*, 647 F.3d 1144 (D.C. Cir. 2011). As the foregoing discussion makes clear, the EPA's analysis of the proposed NAAQS was materially better than the analysis for which we faulted the SEC in that case. There the agency had ignored "numerous studies submitted by commenters that reached the opposite result" and relied instead upon "two relatively unpersuasive studies." 647 F.3d

at 1150–51. Putting aside the analytical incoherence of the SEC's rationale, which would have been fatal by itself, the evidentiary problem in *Business Roundtable* was not limited to the agency's insufficient treatment of any one study, though there was that, *see id.* at 1151; it was the agency's larger failure to deal with the weight of the evidence against it. The EPA's analysis at issue here was in no way comparable to the botched job on display in *Business Roundtable*. The EPA, in addition to performing a meta-analysis of 19 underlying clinical studies of the effects NO_2 exposure has upon health, relied upon numerous epidemiological studies, which evidenced a relationship between an increase in local ambient NO_2 concentrations and an increase in local emergency room visits, *see* Final Rule, 75 Fed. Reg. at 6488–89. The API has pointed to nothing arbitrary or capricious either in the agency's handling of the Goodman study in particular, or in its treatment of this other record evidence supporting the EPA's conclusion.

3. Treatment of the Schildcrout Study

The API also argues the EPA acted inconsistently, and therefore arbitrarily and capriciously, by relying upon an epidemiological study by Jonathan S. Schildcrout et al., *Ambient Air Pollution and Asthma Exacerbations in Children: An Eight City Analysis*, 164 AM. J. EPIDEMIOLOGY 505–17 (2006), in its review of the NAAQS for NO_2 although the agency allegedly had decided in 2006 not to rely upon the same study when it was reviewing the NAAQS for ozone. According to the EPA, the study came too late in its 2006 review process for ozone but the agency did consider it in a later assessment of recent studies relevant to the NAAQS for ozone. *See* Final Rule, 75 Fed. Reg. at 6486. The agency's explanation is rational, and the API makes no attempt to rebut it; enough said about this issue.

4. Alternate Scenarios

The API next contends the EPA used faulty assumptions in projecting the degree to which air quality would be improved under the new NAAQS and therefore exceeded its authority under the Clean Air Act by adopting a NAAQS more stringent than is "requisite to protect the public health" with "an adequate margin of safety," 42 U.S.C. § 7409(b)(1). In particular, the API points to the EPA's comparison of air quality under various potential new NAAQS against several different projections of air quality without a new NAAQS, including one scenario in which it assumed all areas just meet the current air quality standards. The API underscores that the EPA acknowledged, contrary to this "just meets" assumption, current air quality is significantly better than what the existing annual NAAQS for NO_2 requires, and the EPA has even projected that if it took no action air quality would continue to improve in this respect. Therefore, the API reasons, the EPA should have measured the likely benefits of the new NAAQS relative to a projection of air quality more accurate than its "just meets" scenario, which change it claims would have shown the one-hour NAAQS was not necessary "to protect the public health" with "an adequate margin of safety."

The EPA says the API misunderstands the agency's analysis. In predicting a benefit to air quality from adopting the new NAAQS for NO_2, it did not rely solely upon the assumption that air quality would just meet existing NAAQS if a new NAAQS was not in place; it also measured the improvement in air quality under the "as is" assumption, in which the agency assumed air quality would remain at current levels.

The API is correct to the extent that, as the word "requisite" in § 109(b)(1) of the Clean Air Act indicates, the EPA is to set a NAAQS that is "not lower or higher than is necessary ... to protect the public health," *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 475–76 (2001) (interpreting 42 U.S.C. § 7409(b)(1)). The same statutory provision, however, unhorses the API's argument because it enjoins the EPA to set the standard with "an adequate margin of safety," which means the agency is to "err on the side of caution." *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 533 (D.C. Cir. 2009) (internal quotation marks and citation omitted). In other words the Act contemplates the agency "should set standards providing 'a reasonable degree of protection ... against hazards which research has not yet identified.'" *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010) (quoting *Natural Res. Def. Council v. EPA*, 824 F.2d 1146, 1152 (D.C. Cir. 1987) (en banc)). The uncertainty inherent in predicting the future is particularly vexing when one is making a projection of air quality, the actual future of which depends upon regulatory policy, technological change, economic performance, and political outcomes, among other variables. Although air quality had improved and was expected to keep improving, it was certainly possible this trend would be reversed. Therefore, it was not unreasonable for the EPA to measure expected benefits from the new NAAQS in part upon the assumption that, if the new NAAQS were not adopted, then each area would in the future just meet the existing standard.

Moreover, the EPA maintains its comparison in the REA of expected benefits under a new 100 ppb hourly NAAQS (the "new NAAQS" scenario) against the more realistic "as is" scenario does not, as the API contends, show the new NAAQS would provide no benefit. As the agency explains, the API disregards a critical difference between the

hypothetical 100 ppb standard in the REA and the 100 ppb standard the EPA eventually adopted: The "new NAAQS" scenario in the REA assumed the standard would be set at an area-wide average, *i.e.*, the average value recorded by the monitors in an area equaled the level set by the NAAQS, so that some monitors would record concentrations of NO_2 above and some below that standard. The new NAAQS the EPA actually adopted, however, applies to peak rather than to average concentrations, *i.e.*, it requires that all monitors in an area be below the 100 ppb level. Accordingly, the assumption in the REA that an area meets a hypothetical new NAAQS of 100 ppb does not fully capture the expected improvement in air quality from the hourly 100 ppb peak concentration standard the agency ultimately adopted.

Because a peak hourly concentration of 100 ppb is roughly equivalent to an area-wide hourly average concentration of between 50 and 75 ppb, *see* Final Rule, 75 Fed. Reg. at 6494, the EPA concluded the standard it adopted corresponds more closely to the "new NAAQS" scenario in the REA with a standard of 50 ppb than the scenario using the 100 ppb assumption upon which the API focuses its criticism. In the REA the agency had projected a new NAAQS of 50 ppb area-wide would provide a substantial improvement over current air quality. *See* REA at 120.

Considering its duty to err on the side of caution, we conclude the EPA did not act unreasonably by comparing the benefits of the one-hour standard against not only a scenario based upon existing air quality but also upon an alternate scenario in which areas just meet the annual NAAQS set in 1971. For that reason, and because the record adequately supports the EPA's conclusion that material negative health effects result from ambient air concentrations as low as the 100 ppb level, we cannot conclude the agency was arbitrary

and capricious or violated the Act in adopting that level as the new one-hour NAAQS for NO_2.[*]

B. Statement Regarding Permitting

Finally, the API claims the EPA was arbitrary and capricious when it allegedly decided to require applicants for new or modified sources of pollution under § 165(a) of the Clean Air Act, 42 U.S.C. § 7475(a) (prohibiting construction of a "major emitting facility" without a permit), to demonstrate their compliance with the new NAAQS despite the lack of an adequate technique to model compliance. According to the API, the EPA should have considered the effect of that decision upon the agency's ability to resolve each application within one year of its filing, as required by § 165(c) of the Act, 42 U.S.C. § 7475(c) ("Any completed permit application ... for a major emitting facility ... shall be granted or denied not later than one year after the date of filing"), and upon its alleged duty under § 160(3) of the Act to consider the effect of its permitting decisions upon economic growth, *see* 42 U.S.C. § 7470(3) ("purposes of this part [include] ... insur[ing] that economic growth will occur in a manner consistent with the preservation of existing clean air resources"). The API argues that until such time as methods for modeling compliance with the new one-hour NAAQS are developed and have been approved by the agency, the EPA should allow applicants to demonstrate compliance with the

[*] We note the API does not take issue with the EPA's simulation of air quality at and near roadways as routinely exceeding the new 100 ppb standard. Indeed, counsel for the API confirmed at oral argument that, so long as we accept the agency's findings on the health effects of NO_2 at concentrations as low as 100 ppb and we reject the API's criticism of the agency's forecasts, it has raised no challenge to the EPA's setting of the new NAAQS at 100 ppb. So be it.

pre-existing annual NAAQS, as they previously had to do. The EPA maintains the Final Rule does not constitute a final decision concerning the permitting of new or modified sources under the new NAAQS, and is therefore not subject to judicial review, *see Portland Cement Ass'n v. EPA*, 665 F.3d 177, 193 (D.C. Cir. 2011) ("The Clean Air Act gives [the court] jurisdiction to review only 'final' agency actions" (citing 42 U.S.C. § 7607(b))).

The only reason the API has for suggesting the EPA has taken any final action regarding the permitting of a new or modified source is the statement in the preamble to the Final Rule that "major new and modified sources applying for [permits under § 165 of the Act] will initially be required to demonstrate that their proposed emissions increases of NO_x will not cause or contribute to a violation of ... the [new] 1-hour NO_2 NAAQS." 75 Fed. Reg. at 6525. Although "there is [no] categorical bar to judicial review of a preamble," *Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1222 (D.C. Cir. 1996) (citation omitted), it "is not the norm," *Natural Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009). The operative question when faced with such a challenge is "whether the [preambular statement] has independent legal effect, which in turn is a function of the agency's intention to bind either itself or regulated parties." *Kennecott*, 88 F.3d at 1223.

Any action of an agency, including a statement in a preamble, is "final" only if it (1) "mark[s] the consummation of the agency's decisionmaking process" and (2) is "one by which rights or obligations have been determined, or from which legal consequences will flow[.]" *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (internal quotation marks and citations omitted). The preambular statement challenged here has neither effect, as indicated both on its face and, more clearly,

by the context in which it was made. To be sure, one could reasonably read as mandatory the isolated statement that permit applicants "will initially be required" to meet the new NAAQS. At the same time, the statement could reasonably be read to mean the EPA intends in the future to establish such a requirement, in which case the statement falls short of being the consummation of the agency's decisionmaking process. The Supreme Court similarly has said "a statement in [an agency's land management] plan that [it] 'will' [rather than "shall"] take this, that, or the other action ... is not [a binding commitment] ... absent clear indication" to the contrary, *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 69 (2004), which suggests the statement that applicants "will initially be required" is predictive of the agency's future actions, not one from which "legal consequences w[ould] flow."

Read in context, the lack of finality in the statement is more obvious:

> The EPA acknowledges that a decision to promulgate a new short-term NO_2 NAAQS will clearly have implications for the air permitting process. The full extent of how a new short-term NO_2 NAAQS will affect the [new source review] process will need to be carefully evaluated. First, major new and modified sources applying for [new source review or prevention of significant deterioration] permits will initially be required to demonstrate that their proposed emissions increases of NO_X will not cause or contribute to a violation of ... the annual or 1-hour NO_2 NAAQS ....

Final Rule, 75 Fed. Reg. at 6525. By acknowledging it had not yet, but "w[ould] need to[,] ... carefully evaluate[]" the effect of the new NAAQS on the permitting process, the EPA

made clear it was not making a final decision. The subject statement does not express a final agency action, and so we lack jurisdiction under the Clean Air Act, 42 U.S.C. § 7607(b), to consider the API's challenge to it.

III. Conclusion

Because the API has not shown the EPA's adoption of the one-hour NAAQS for NO_2 was either arbitrary and capricious or in violation of the Clean Air Act, we shall deny the petitions in that respect. The portions of the petitions challenging the EPA's non-final statement regarding permitting in the preamble to the Final Rule we shall dismiss for lack of jurisdiction.

So ordered.