ORAL ARGUMENT NOT YET SCHEDULED

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 10-1079 (consolidated with No. 10-1080)

AMERICAN PETROLEUM INSTITUTE, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

ON CONSOLIDATED PETITIONS FOR REVIEW OF FINAL ACTION BY THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BRIEF FOR RESPONDENT

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DATED: October 28, 2011 (Initial Brief)

RESPONDENTS' CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit R. 28(a)(1), Respondent United States Environmental Protection Agency submits this certificate as to parties, rulings and related cases.

(A) Parties and amici: All parties and intervenors are listed in the Brief for Petitioners. There are no amici.

(B) Rulings under review: This is a set of consolidated petitions for review of the final EPA rule entitled "Primary National Ambient Air Quality Standards for Nitrogen Dioxide," 75 Fed. Reg. 6,474 (Feb. 9, 2010).

(C) Related cases: These consolidated cases have not previously been before this or any other Court. To the best of the undersigned counsel's knowledge, there are no related cases in this or any other Court.

DATED: October 28, 2011

/s/ Angeline Purdy
Counsel for Respondent

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GLOSSARY

Act	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
EPA	United States Environmental Protection Agency
ISA	Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (July 2008)
JA	Joint Appendix
NAAQS	National Ambient Air Quality Standard
NO_2	Nitrogen Dioxide
Pet. Br.	Petitioners' Opening Brief
ppb	parts per billion
ppm	parts per million
PM	Particulate Matter
PSD	Prevention of Significant Deterioration
REA	Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard (November 2008)
Review Plan	Integrated Review Plan for the Primary National Ambient Air Quality Standard for Nitrogen Dioxide (August 2007)

JURISDICTION

The Court has jurisdiction over Petitioners' challenge to the final rule revising the National Ambient Air Quality Standard ("NAAQS") for nitrogen dioxide ("NO_2") pursuant to 42 U.S.C. § 7607(b). EPA did not, however, take final action to apply the revised NAAQS to Prevention of Significant Deterioration ("PSD") permitting decisions or to otherwise implement the revised NAAQS in this Rule; thus, Petitioners' claims that EPA erred in doing so are not within the Court's jurisdiction.

STATUTES AND REGULATIONS

Pertinent statutes and regulations are set forth in the addendum to Petitioners' brief.

STATEMENT OF ISSUES

1. Did EPA reasonably supplement the pre-existing NAAQS for NO_2, which included only an annual average standard, with a one-hour standard designed to protect public health from adverse effects associated with short-term NO_2 exposure?

2. Did EPA reasonably consider an updated analysis that reflects current scientific information regarding the effects of short-term NO_2 exposure?

3. Did EPA reasonably decline to reopen the air quality criteria for the NO_2 NAAQS to assess a study that arrived after the proposal, and that had not undergone a statutorily-mandated review?

4. Did EPA reasonably determine that an hourly standard of 100 ppb was required to protect public health, with an adequate safety margin, from short-term NO_2 exposure?

5. Given that EPA is precluded from considering the cost or feasibility of implementation when establishing or revising a NAAQS, did EPA reasonably decline to consider the economic or logistical consequences of establishing an hourly NO_2 NAAQS?

6. Section 165 of the Clean Air Act provides that, to obtain PSD permits, certain pollution sources must demonstrate that their emissions "will not cause, or contribute to, air pollution in excess of any . . . [NAAQS]." 42 U.S.C. § 7475(a)(3).

a. Did EPA take action in this rule to make the NAAQS applicable in PSD permitting decisions, or merely follow its longstanding reasonable interpretation of this language as automatically rendering a revised NAAQS immediately applicable to such decisions?

b. Was EPA required – or even authorized – to institute a blanket delay of the applicability of the PSD applicability of the revised NAAQS?

7. Did EPA reasonably defer taking action to implement the revised NO_2 NAAQS in this Rule?

STATEMENT OF THE CASE

Section 109 of the Clean Air Act ("CAA" or "Act") requires EPA to establish, and periodically review, NAAQS for certain pollutants. See 42 U.S.C. § 7409(a), (d). "Primary" NAAQS must be established at a level that is "requisite to protect the public health," with "an adequate margin of safety." Id. § 7409(b)(1). Following its review of the primary NAAQS for NO_2, including careful consideration of the significant body of scientific evidence that had developed since the last such review, EPA concluded that an annual standard alone was no longer sufficiently protective of public health. See Primary National Ambient Air Quality Standards for Nitrogen Dioxide: Final Rule, 75 Fed. Reg. 6,474, 6,475, 6,480-90 (Feb. 9, 2010) ("Rule"). EPA therefore revised the primary NO_2 NAAQS by adding a one-hour standard. Id. at 6,475, 6,498-6,502. Petitioners American Petroleum Institute, et al. (collectively "API" or "Petitioners") thereafter timely filed this petition challenging EPA's revision of the NO_2 NAAQS.

STATEMENT OF FACTS

I. STATUTORY BACKGROUND

A. Establishment Of A NAAQS.

The Act is intended to "protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare." 42 U.S.C. § 7401(b)(1). The Act sets up a comprehensive and detailed program for control of air pollution through a system of shared federal and state responsibility. As part of this program, EPA is required to establish NAAQS for certain air pollutants limiting concentrations of those pollutants in the "ambient," or outside, air. Id. §§ 7408(a)(1), 7409(a), (b).

The NAAQS process begins with the development of air quality criteria, which must reflect the latest scientific knowledge regarding "all identifiable effects on public health or welfare" that may result from a pollutant's presence in the ambient air. Id. § 7408(a)(2). Based on the air quality criteria, EPA promulgates NAAQS to protect against a pollutant's effects on public health and welfare. Id. § 7409(a)(1)(A), (b). The basic elements of a NAAQS are (1) the "indicator," which defines the pollutant to be measured; (2) the "level," which defines the allowable concentration of the indicator in the air; (3) the "form," which defines the air quality statistic used to identify the concentration to be compared to the level of the standard (e.g., the highest value in a year); and (4) the "averaging

time," which defines the time period over which the level must be met. 75 Fed. Reg. 6,477 and n.5; see also American Farm Bureau Fed'n v. EPA, 559 F.3d 512, 516 (D.C. Cir. 2009).

"Primary" NAAQS are air quality standards "the attainment and maintenance of which in the judgment of the Administrator, . . . are requisite to protect the public health," with "an adequate margin of safety."[1] 42 U.S.C. § 7409(b)(1). EPA must set NAAQS based solely on public health considerations, without reference to the cost or feasibility of achieving the standards. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 471 (2001); see also American Petroleum Inst. v. Costle, 665 F.2d 1176, 1185 (D.C. Cir. 1981). The "[p]ublic health" that EPA must protect includes not only the health of average individuals, but also that of sensitive people (such asthmatics) who may be particularly vulnerable to air pollution. American Lung Ass'n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998).

To ensure that the NAAQS keep pace with advances in scientific knowledge, Congress required EPA and an independent scientific review committee (the Clean Air Scientific Advisory Committee, or "CASAC") to review

[1] "Secondary" NAAQS are set "to protect the public welfare from . . . adverse effects" associated with a pollutant's presence in the air. 42 U.S.C. § 7409(b)(2). The secondary NO_2 NAAQS is not at issue in this matter; thus, unless noted otherwise, the term "NAAQS" as used herein refers solely to the primary NAAQS.

air quality criteria and NAAQS at least once every five years. 42 U.S.C. § 7409(d). CASAC is directed to recommend revisions, and after considering those recommendations the Administrator is to revise the air quality criteria and the NAAQS "as may be appropriate in accordance with [sections 108 and 109(b)]." Id. § 7409(d)(1). EPA must explain any significant departure from CASAC's recommendations. Id. §§ 7409(d)(2), 7607(d)(3)(C). The final decision on whether a NAAQS should be retained or revised is, however, a public health policy judgment made by the Administrator. See id. § 7409(d); 75 Fed. Reg. 6,483.

B. NAAQS And PSD Permitting Decisions.

Once a NAAQS is established, attaining the standard is primarily the responsibility of the states. See 42 U.S.C. § 7407(a). One program used to attain and maintain the NAAQS is the PSD program.[2] This program establishes preconstruction permitting requirements for certain pollution sources in areas that either are in attainment with the NAAQS or that cannot be classified.[3] See id. §§

[2] The PSD program operates predominantly through EPA-approved state programs. See 42 U.S.C. §§ 7410(a)(2)(C), 7471; 40 C.F.R. § 51.166. EPA also manages a federal PSD program, which it administers in the absence of an approved state program, and which some states administer by delegation. See 42 U.S.C. § 7475; 40 C.F.R. § 52.21(a)(1).

[3] The Act defines "attainment" as meeting the NAAQS for a pollutant for which a NAAQS has been designated, and "nonattainment" as not meeting the NAAQS for (footnote con't)

7410(a)(2)(C), 7475. To obtain a permit, a facility owner or operator must demonstrate (among other things) that "emissions from construction or operation of such facility will not cause, or contribute to, air pollution in excess of any . . . national ambient air quality standard in any air quality control region." Id. § 7475(a)(3); see also 40 C.F.R. §§ 51.166(k)(1)(i), 52.21(k)(1)(i).

II. REVIEW AND REVISION OF THE NO_2 NAAQS

Oxides of nitrogen, including nitric oxide and NO_2, are emitted as a product of combustion. Integrated Science Assessment ("ISA") at 2-2 (JA XX). Nitric oxide rapidly converts to NO_2 when emitted to the ambient air, and NO_2 has been the indicator (i.e., the pollutant measured) for the NAAQS since 1971. At that time, EPA established a NO_2 NAAQS of 53 parts per billion (ppb), annual average. 75 Fed. Reg. 6,476.

Traffic-related exposures can dominate personal exposures to NO_2. 74 Fed. Reg. 34,404, 34,401 (July 15, 2009). Concentrations of NO_2 on or adjacent to roads can be 30% to 100% higher than concentrations measured away from roads. Id. at 34,409. The pre-2010 NO_2 monitoring network primarily measures concentrations representative of a broad geographic area ("area-wide

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such a pollutant. See 42 U.S.C. § 7407(d)(1)(A). Currently, there are no nonattainment areas in the United States for the NO_2 NAAQS. 75 Fed. Reg. 6,476.

concentrations"), rather than peak concentrations such as those expected to occur on or near roads.[4] See 74 Fed. Reg. 34,408; 75 Fed. Reg. 6,479. Compliance with the 53 ppb annual standard is determined by averaging hourly NO_2 concentrations measured at a monitoring site over the course of a calendar year. 40 C.F.R. pt. 50, App. S § 5.1. EPA reviewed both the underlying air quality criteria and the 53 ppb annual standard in 1985 and again in 1996, concluding both times that the annual standard remained requisite to protect public health with an adequate margin of safety. 42 U.S.C. § 7409(b)(1); 75 Fed. Reg. 6,476.

EPA initiated its latest review of the NO_2 NAAQS in December, 2005. 75 Fed. Reg. 6,476. Since 1996, a substantial number of new peer-reviewed studies became available evaluating the effect of short-term NO_2 exposure on public health. Id. at 6,478, 6,480. As discussed in more detail in the following sections, after an extensive review process, based in large part upon this newly-available evidence EPA concluded that the annual standard alone was "not requisite to protect public health with an adequate margin of safety." Id. at 6,490. EPA therefore revised the NO_2 NAAQS, adding a 100 ppb hourly standard designed to protect against short-term exposures. See id. at 6,475, 6,502. EPA did not,

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[4] Because the current monitoring network is not oriented to measuring peak concentrations, EPA substantially revised the requirements for that network in the Rule. 74 Fed. Reg. 34,441. Petitioners do not challenge that aspect of the Rule.

however, take any action in this rulemaking to implement the revised NO_2 NAAQS.

A. Air Quality Criteria And The Health Effects of NO_2.

A NAAQS must be based on air quality criteria that "reflect the latest scientific knowledge" regarding the public health and welfare effects of a pollutant in the ambient air. 42 U.S.C. § 7408(a)(2). EPA began examining the air quality criteria underlying the NO_2 NAAQS by issuing a general call for information. 75 Fed. Reg. 6,476. EPA then made a draft review plan for the NO_2 NAAQS available for public comment. Id. After consultation with CASAC, including a public teleconference, EPA finalized the plan in August, 2007. See Integrated Review Plan for the Primary National Ambient Air Quality Standard for Nitrogen Dioxide ("Review Plan") (excerpts at JA XX-XX).

Consistent with the Review Plan, EPA developed the ISA to provide "a concise synthesis of the most policy-relevant science." Review Plan at 2 (JA XX); see also ISA at xxvii (JA XX) (purpose of ISA "is to critically evaluate and assess the latest scientific information published since the 1993 NOx Air Quality Criteria Document."). CASAC reviewed a first and second draft of the ISA, both times at a public meeting. 75 Fed. Reg. 6,476-77. EPA considered CASAC and public comments in developing the final ISA, which was released in July, 2008. Id. at 6,477.

EPA had previously concluded that exposure to ambient NO_2 has two health effects of particular concern: increased airway hyperresponsiveness in asthmatics following short-term exposures, and increased respiratory illness in children following longer-term exposures. Id. at 6,479; ISA at 5-4 (JA XX). Airway hyperresponsiveness refers to a condition in which the larger airways of the lungs constrict and narrow in response to a variety of stimuli. See ISA at 3-9 (JA XX). In asthmatics, airway hyperresponsiveness following NO_2 or other pollutant exposures may increase respiratory symptoms and worsen asthma control. ISA at 3-10 (JA XX).

At the time of the previous review, epidemiologic evidence concerning the respiratory effects of short-term NO_2 exposure was limited. 75 Fed. Reg. 6,480; ISA at 5-4 (JA XX). A substantial body of evidence has since developed regarding the health effects of short-term NO_2 exposure, including controlled human exposure studies, animal studies, and, particularly, epidemiologic evidence. 75 Fed. Reg. 6,480; ISA at 5-4 (JA XX); see also id. at 5-6. As EPA explained in the proposed Rule:

> The epidemiologic evidence has grown substantially with the addition of field and panel studies, intervention studies, time-series studies of effects such as emergency department visits and hospital admissions, and a substantial number of studies evaluating mortality risk associated with short-term NO_2 exposures. . . . [N]o epidemiologic studies were available in1993 that assessed relationships between NO_2 and outcomes such as hospital admissions, emergency department

> visits, or mortality. In contrast, dozens of epidemiologic studies on such outcomes, conducted at recent and current ambient NO_2 concentrations, are now included in this evaluation.

74 Fed. Reg. 34,425.

The ISA ultimately concluded that "[t]aken together, recent studies provided scientific evidence that NO_2 is associated with a range of respiratory effects and provide evidence **sufficient to infer a likely causal relationship between short-term NO_2 exposure and adverse effects on the respiratory system**." ISA at 5-6 (JA XX) (bold in original); see generally ISA Table 5.3-1 and Sections 5.3, 5.4 (JA XX, XX-XX) (summarizing key findings regarding health effects of NO_2 exposure); 75 Fed. Reg. 6,480-6,481.[5] Epidemiologic evidence in particular showed positive associations between short-term NO_2 concentrations and respiratory symptoms, hospitalization, and emergency room visits, including areas with ambient levels of NO_2 well below the 53 ppb annual standard. ISA at 5-6 (JA XX). CASAC concurred with the primary conclusions reached in the ISA, and in particular with the conclusion that current scientific information is sufficient to

[5] For purposes of this review EPA considered short-term exposures to be those lasting minutes or hours, and long-term exposures to be those lasting weeks or years. See Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard ("REA") at 280 (JA XX); 74 Fed. Reg. 34,425.

infer a likely causal relationship between short-term NO_2 exposure and adverse respiratory effects. See CASAC letter of June 25, 2008 at 4 (JA XX).

In contrast to its conclusions regarding short-term NO_2 exposure, the ISA concluded that newly-available evidence was not sufficient to establish that long-term NO_2 exposure causes health problems beyond those already identified in the 1993 review. See ISA at 5-6, Table 5.3-1 (JA XX). EPA's analysis going forward thus focused on whether the 53 ppb annual average standard protects public health with an adequate safety margin from short-term NO_2 exposure. See 75 Fed. Reg. 6,482, 6,484

B. Risks Associated With Short-Term NO_2 Exposure.

EPA developed a Risk and Exposure Assessment ("REA") containing quantitative assessments of NO_2 exposures and human health risks associated with multiple air quality scenarios. See REA at 3 (JA XX). CASAC reviewed a first draft of the REA at a public meeting in May, 2008. 75 Fed. Reg. 6,477. After EPA considered comments from CASAC and the public, it released a second draft of the REA for public comment. Id. This draft was released in two stages, both of which CASAC also reviewed at public meetings. Id. EPA again considered both public and CASAC comments in developing the final REA, which was released in November, 2008. See id.

The REA uses data gathered from the existing area-wide NO_2 monitoring network, together with the latest modeling and health information, to assess potential short-term NO_2 exposures to people throughout an area and the associated health risks under different air quality scenarios: (1) "as-is" air quality; (2) air quality with NO_2 levels adjusted to simulate just meeting the annual NO_2 NAAQS (the standard under review); and (3) air quality with NO_2 levels adjusted to simulate just meeting potential one-hour standards.[6] Id. at 6,482, 6,488; REA at 3 (JA XX). Exposure estimates take into account the variability in NO_2 concentrations across an area, which can be considerably higher near major roads than away from such roads. 75 Fed. Reg. 6,479; see also ISA at 5-3 (JA XX) (NO_2 concentrations "are highly spatially and temporally variable in urban areas"). As EPA explained, considering potential exposures under alternative air-quality scenarios allowed EPA to evaluate exposures and risks that would be permissible under both the then-current standard and potential alternative standards, thereby informing EPA's judgment regarding whether those standards protect public health with an adequate safety margin 75 Fed. Reg. 6,488.

[6] Although Petitioners argue that EPA should not have considered alternative air quality scenarios at all, see infra at 39-43, Petitioners do not challenge EPA's methodology in doing so..

In the clinical studies, increases in airway hyperresponsiveness were observed in people with asthma following short-term NO_2 exposure at levels as low as 100 ppb (the lowest level studied). ISA at 5-10-5-11 (JA XX-XX); see generally id. Section 5.3.2.1 (JA XX-XX). The REA concluded that, given "as is" air quality, individuals on or near roadways could expect to suffer short-term NO_2 exposures at or above this level multiple times during the year. See REA at 120, Table 7-29, columns 1, 7 (JA XX); see also id. at 89-90, 204-07 (Figures 8-17 to 8-20) (JA XX-XX, XX-XX).[7] If air quality just met the 53 ppb annual standard, the REA estimated that the number of short-term exposures to over 100 ppb, and the number of NO_2-related emergency room visits, would rise significantly. See id. at 120, Table 7-29, columns 2, 8; 271-72 (Table 9-3 and 9-4) (JA XX, XX-XX).

The 100-ppb hourly standard adopted by EPA, which reflects the allowable *peak* NO_2 concentration in an area (including concentrations measured near roads), would be expected to result in *area-wide* concentrations of 50-75 ppb. 75 Fed. Reg. 6,494-95 and n.14. Thus, the hourly standard adopted by EPA cannot be directly compared to the REA's alternative standard of 100 ppb, which is based on area-wide concentrations of 100 ppb. The REA estimated that if concentrations at

[7] For example, Figure 8-19 indicates nearly all people with asthma experienced six or more exposures at or above 100 ppb for the year 2002 in Atlanta. REA at 206 (JA XX).

area-wide monitors met a standard of 50 ppb (0.05 ppm), the number of potential exposures to NO_2 concentrations above 100ppb, and the number of NO_2-related emergency room visits, would drop significantly as compared to current conditions. REA at 120, Table 7-29, columns 3, 9 (JA XX); see also id. at 206, 211 (Figures 8-19 and 8-24) (JA XX-XX); id. at 270-272, (Tables 9-2-9-4) (JA XX-XX).

The REA also considered the available health evidence, including controlled human exposure studies and the substantial body of epidemiologic studies reporting associations between short-term increases in NO_2 concentrations and increased emergency room visits, hospitalizations, and other adverse health effects. The REA noted that "[p]ositive and statistically significant associations were observed in several key U.S. epidemiologic studies associated with 1-h[our] daily maximum levels of NO_2 close to [100 ppb]," in addition to one study where associations were reported at 50 ppb at area-wide monitors. REA at 303 (JA XX); 75 Fed. Reg. 6,501. With regard to the current standard, the REA concluded that "[w]hen taken together, the results of epidemiologic and experimental studies form a plausible and coherent data set that supports a relationship between NO_2 and respiratory endpoints, including symptoms and [emergency room] visits (ISA, section 5.4), at ambient concentrations that are present in areas that meet the current NO_2 NAAQS." REA at 282 (JA XX).

C. Revision Of The NAAQS.

CASAC found the final REA to be "satisfactory in its approach," and concluded that it provided a "needed bridge" from the ISA's analysis of scientific evidence to characterizing risks and exposures under different exposure profiles. See J.M. Samet Letter of 12/16/2008 at 2 (JA XX); 75 Fed. Reg. 6,485. CASAC also stated that it concurred with the REA's conclusion that the existing NO_2 NAAQS was not sufficient to protect human health, and that it should therefore be revised. 12/16/08 Letter at 2 (JA XX). Based on the REA's discussion of the evidence, CASAC agreed that a one-hour standard was necessary and "firmly recommend[ed]" that the level of that standard not exceed 100 ppb. Id.; 75 Fed. Reg. 6,487. After EPA proposed an hourly standard, CASAC reiterated its advice that "the level of the one-hour NO_2 standard should be within the range of 80-100 ppb and not above 100 ppb." J.M. Samet Letter of Sept. 9, 2009 at 2 (JA XX); see also 75 Fed. Reg. 6,501.[8]

After considering the evidence assessed in the ISA, the exposure and risk analyses and policy options presented in the REA, and comments from CASAC and the public, EPA concluded that the annual NO_2 NAAQS needed to be revised

[8] CASAC noted that this range depended on the use of near-road monitors, and that "approximately equivalent" protection would be afforded by a standard in the range of 50-75 ppb if area-wide monitors were used. 9/9/09 Letter at 2 (JA XX).

in order to protect public health. 75 Fed. Reg. 6,488-90. EPA found the growth in epidemiologic evidence since the last review of this NAAQS to be particularly significant, noting that this evidence provided the primary support for the ISA's conclusion that short-term NO_2 exposures are likely to cause adverse respiratory effects. Id. at 6,490. EPA further noted that epidemiologic studies reported associations between short-term NO_2 concentrations and adverse respiratory effects, even in locations with ambient NO_2 concentrations well below the level of the annual NO_2 standard. Id. at 6,489. Given this and other evidence in the ISA, EPA concluded that "the scientific evidence calls into question the adequacy of the current standard to protect public health." Id.

EPA was also "mindful" of the fact that the evidence and analyses in the ISA and the REA "support the public health importance of roadway-associated NO_2 exposures." Id. at 6,493. As EPA noted, millions of people in the United States live, work, or attend school near major roadways, and therefore can be exposed to NO_2 concentrations far higher than those generally measured by the area-wide monitors of the pre-Rule monitoring network. Id. at 6,481-82. Asthmatics and other highly susceptible individuals exposed to roadway levels of NO_2 would be at an even higher risk of suffering health effects from such exposure. Id. at 6,482.

Because the Administrator judged the annual NO_2 NAAQS alone to be insufficient to protect public health with an adequate margin of safety, particularly as regards respiratory effects associated with short-term exposures, EPA supplemented the annual NO_2 NAAQS with a one-hour standard of 100 ppb. 75 Fed. Reg. 6,475. This 100 ppb level reflects the maximum allowable NO_2 concentration anywhere in an area, including on or near roadways. In EPA's judgment, this standard is expected to limit short-term NO_2 exposures to concentrations that have been reported to increase airway hyperresponsiveness in asthmatics. 75 Fed. Reg. 6,494; see generally id. at 6,493-95. In addition, because roadway NO_2 concentrations can be considerably higher than those in surrounding areas, limiting the maximum allowable concentration at any location to 100 ppb is expected to limit area-wide concentrations of NO_2 to approximately 50 to 75 ppb. 75 Fed. Reg. 6,501; see also id. at 6,494 n.14. This is below the area-wide levels in locations where key United States epidemiological studies reported that ambient NO_2 is associated with increases in respiratory-related hospital admissions and emergency room visits. 75 Fed. Reg. 6,501. The 100 pbb standard thus addresses the range of health risks from short-term NO_2 exposures evidenced in the clinical and epidemiologic studies.

STANDARD OF REVIEW

The standard of review is set forth in Section 307(d)(9) of the Act, 42 U.S.C. § 7607(d)(9), under which the Court asks whether the challenged action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Id. This standard of review "is a narrow one," and the Court is not "to substitute its judgment for that of the agency." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The pertinent question is simply "whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43-44 (1983) (citation omitted); see also Lead Indus. Ass'n, Inc. v. EPA, 647 F.2d 1130, 1145 (D.C. Cir. 1980) (arbitrary and capricious standard "is highly deferential, and presumes agency action to be valid.")

Particular deference is given to an agency with regard to technical matters within its area of expertise, and the Court may not "second-guess the Agency's expert decisionmaker." Lead Indus., 647 F.2d at 1146. A court examines EPA'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 [its] narrowly defined duty of holding agencies to certain minimal standards of rationality." Id. (citing Ethyl Corp. v. EPA, 541 F.2d 1, 36-37 (D.C. Cir. 1976)). EPA is,

moreover, entitled to weigh conflicting evidence and act even in the face of some uncertainty. See Ethyl Corp., 541 F.2d at 27-28; see also Lead Indus., 647 F.2d at 1160 ("disagreement among the experts is inevitable when the issues involved are at the 'very frontiers of scientific knowledge,' and such disagreement does not preclude us from finding that the Administrator's decisions are adequately supported by the evidence in the record").

Judicial deference also extends to an agency's interpretation of a statute it administers. Chevron, U.S.A. Inc. v. NRDC, 467 U.S. 837, 842-45 (1984). Under Chevron, if Congress has "directly spoken to the precise question at issue," that intent must be given effect. 467 U.S. at 842-43. However, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. at 843.

SUMMARY OF ARGUMENT

Since EPA's last review of the NO_2 NAAQS, a significant body of scientific information (including most prominently a number of epidemiologic studies) has become available regarding the harmful respiratory effects of short-term NO_2 exposure. The evidence indicates that such exposure is associated with a range of serious adverse health effect in areas with air quality well below the current annual standard. Based on this and other evidence, EPA concluded that the existing

annual average standard alone was not sufficient to protect public health from the harmful effects of NO_2 exposure with an adequate safety margin, and revised the NO_2 NAAQS by adding an hourly 100 ppb standard. Recognizing that NO_2 concentrations can vary widely across an area, the 100 ppb standard must be met with respect to the maximum concentration at any monitored location within a given area. This standard will protect people from the risk of adverse effects identified in clinical and epidemiologic studies.

Petitioners do not take issue with the vast majority of the scientific evidence underlying EPA's revision of the NO_2 NAAQS. They focus, instead, on two specific analyses of airway responsiveness following NO_2 exposures, arguing that EPA should not have considered one particular analysis, and should instead have relied on a different analysis that reaches conclusions that Petitioners prefer. The record demonstrates, however, that EPA's analysis of the published and peer-reviewed material was appropriate, transparent, and consistent with all applicable guidelines, and that EPA appropriately gave the study Petitioners prefer only provisional consideration.

Petitioners' argument that the 100-ppb hourly standard is not "requisite to protect public health" appears to be based on a misunderstanding of some of the data underlying EPA's conclusion that this standard will limit the adverse respiratory effects of short-term NO_2 exposure. Petitioners also ignore the fact that

a NAAQS must include an adequate margin of safety, and that assessing health risks and safety margins is a public health policy judgment as well as a scientific one –a judgment that is, moreover, left to the discretion of the Administrator. The 100 pbb standard is well-supported by the record, and endorsed by CASAC. Petitioners have thus failed to demonstrate that the 100 ppb hourly standard is arbitrary, capricious, or otherwise unlawful.

Finally, Petitioners argue that the revised NO_2 NAAQS should not immediately apply to PSD permitting decisions. To the extent that Petitioners are arguing that the revised NAAQS should be vacated or remanded due to implementation concerns, their argument runs counter to a solid body of precedent establishing that EPA cannot consider the cost or feasibility of implementing a NAAQS when setting that NAAQS. And to the extent that Petitioners are arguing that the revised NAAQS should not be applied to PSD permitting decisions (or at least should not be applied immediately), their argument is equally flawed. EPA has long interpreted the statute such that a new or revised NAAQS is immediately applicable to PSD permitting decisions by operation of law, without any further action by EPA; thus, contrary to Petitioners' assertions, EPA had no need to, and did not, take action to make the revised NAAQS immediately applicable. Petitioners have, moreover, failed to demonstrate that EPA either could or should have considered taking action to delay the PSD applicability of the revised

NAAQS, or that EPA took, or was required to take, any further steps to implement that NAAQS at this time. Petitioners' challenge to the application of the revised NAAQS to the PSD permitting program must therefore be rejected.

ARGUMENT

I. EPA'S CONCLUSION THAT THE 100 PPB STANDARD IS REQUISITE TO PROTECT PUBLIC HEALTH WITH AN ADEQUATE MARGIN OF SAFETY IS SUPPORTED BY A ROBUST ADMINISTRATIVE RECORD.

In 1996, EPA concluded that the annual NO_2 NAAQS adequately protected human health. Fourteen years later, having considered a significant body of scientific information that was not available in 1996, EPA concluded that the annual standard alone was no longer sufficient to meet the requirement that NAAQS be set at a level "requisite to protect the public health," with "an adequate margin of safety." Petitioners characterize this as a "change[] in policy" or "shift in position" that EPA is required to justify. Petitioners' Opening Brief ("Pet. Br.") at 36-37. Petitioners cannot, however, shift the burden of proof to EPA merely by claiming that EPA has changed its position. They must, instead, demonstrate based on the administrative record for this action that EPA's adoption of a one-hour NO_2 NAAQS was arbitrary, capricious, or otherwise unlawful.

Petitioners cannot do so. The fact that EPA reached different conclusions at different times based on different records is not a change in policy – it is, instead,

responsible agency action, and wholly consistent with Congress' requirement that EPA periodically review and revise the air quality criteria and the NAAQS in order to ensure continued protection of human health. See American Farm Bureau, 559 F.3d at 521 (agency did not "commit itself irrevocably" by stating view of certain studies in prior review of NAAQS; "if the relevant facts have changed or the EPA has reasonably made a different policy judgment, then it need only explain itself and we will defer"). As even Petitioners acknowledge, the Act requires EPA to revise a NAAQS not only in order to "prevent[] pollution levels that have been demonstrated to be harmful," but also to prevent "lower pollutant levels that may pose an unacceptable risk of harm." Pet. Br. at 38-39 (citation omitted).

EPA's decision to set a short-term standard to protect against risks associated with short-term exposure to NO_2 is well-supported by the scientific record, as well as being endorsed by CASAC, an independent science review panel. EPA has presented a "rational basis" for its decision, and that decision must be affirmed. Lead Indus., 647 F.2d at 1145. The petition for review should therefore be denied.

A. The Revised NAAQS Is Based On Sound Scientific Information.

The Administrator's conclusion that the annual NO_2 NAAQS needed to be supplemented with an hourly standard was based on an extensive body of peer-reviewed scientific information, all of which underwent intensive Agency,

CASAC, and public scrutiny. See supra at 7-18. Most significantly, whereas in the last review there was scant epidemiologic evidence assessing the effects of short-term NO_2 exposure, by the time of this review dozens of such studies had become available. See 75 Fed. Reg. 6,478; 74 Fed. Reg. 34,425. Petitioners do not attack the vast majority of the scientific evidence that EPA relied on, arguing instead that EPA improperly relied on an updated analysis of clinical studies, and should have relied on a different analysis that Petitioners regard as superior. See Pet. Br. at 26-38. Petitioners have, however, failed to offer anything that could overcome the voluminous scientific evidence in the administrative record, and the deference due EPA's technical expertise and exercise of judgment in weighing that evidence.

1. EPA appropriately updated an analysis of airway responsiveness.

One of the key health effects in EPA's review of the NO_2 NAAQS was increased airway responsiveness following NO_2 exposure. See supra at 10. In EPA's prior review of the NAAQS, EPA considered (among other scientific information) a meta-analysis (the "Folinsbee analysis") aggregating the results of 19 clinical studies of airway responsiveness. See ISA at 3-14-16 and Table 3.1-2 (JA XX-XX). The Folinsbee analysis was peer-reviewed, published, and reviewed by CASAC in connection with the prior review. 75 Fed. Reg. 6,487.

In bringing the Folinsbee analysis forward to this review, EPA made modest updates to that analysis to present data more relevant to the specific issues of concern to EPA in this rulemaking. Petitioners' objections to EPA's treatment of the Folinsbee analysis – which was, ultimately, merely one of many pieces of scientific evidence supporting EPA's conclusions – are wholly without merit.

a. EPA appropriately updated the Folinsbee analysis by incorporating new data relevant to the issues in this rulemaking.

Based on 19 clinical studies, the Folinsbee analysis examined increased airway responsiveness at NO_2 exposure levels as low as 0.1 ppm (100 ppb). See 75 Fed. Reg. 6,487; ISA at 3-15 (JA XX). The results of these studies, together with information about the number of subjects studied and the level of NO_2 exposure, were presented in the ISA as Table 3.1-2. ISA at 3-15 (JA XX). In the prior NAAQS review, Folinsbee aggregated the results of different studies to generate an overall "meta-analysis" of the percentage of subjects experiencing effects at different levels. In this review, EPA again aggregated the numbers of subjects from different studies to assess the percentage of subjects experiencing effects. The data from the Folinsbee analysis were, however, updated by removing the results of a single study that considered airway responsiveness to a specific allergen (ragweed) and adding the results of a peer-reviewed and published study considering non-specific airway responsiveness to histamine. This allowed EPA to

consider data from studies that all addressed the same general health effect, i.e., non-specific airway responsiveness. See 75 Fed. Reg. 6,487; ISA at 3-16 (JA XX). EPA then re-presented a summary of the results of the clinical studies considered in this analysis as Table 3.1-3 of the ISA. See 75 Fed. Reg. 6,487.

As EPA explained, its presentation of the results of the updated Folinsbee analysis did not change the substantive results of that analysis. Id. Four of the studies reviewed in Folinsbee's original analysis evaluated the effects of exposure to NO_2 at concentrations of 0.1 ppm (100 ppb). See ISA at 3-15, Table 3.1-2 (JA XX). The original analysis presented the results of these studies together with one additional study evaluating the effects of exposures to NO_2 at 140 ppb; described them collectively as studies considering exposures less than 200 ppb; and found increased airway responsiveness in 65% of resting asthmatics at that level. 75 Fed. Reg. 6,487. In this review, EPA grouped only the studies that considered NO_2 exposures at 100 ppb, and reported results at that exposure level as a distinct category. See ISA at 3-16, Table 3.1-3 (JA XX). By doing so, EPA was able to focus specifically on the potential for exposures at 100 ppb to increase airway responsiveness. EPA's presentation of the updated data shows that 66% of resting asthmatics are affected by short-term NO_2 exposures of 100 ppb, and 67% by exposures between 100 and 150 ppb – results that are consistent with the data presented in the original Folinsbee analysis. See id.

Contrary to Petitioners' assertions, this updated analysis – while significant – was not the sole basis for revising the NO_2 NAAQS, or for setting the hourly standard at 100 ppb. See Pet Br. at 10, 27, 28. The most important change since the prior review of the NO_2 NAAQS was the availability of epidemiological evidence associating short-term NO_2 concentrations with respiratory effects responsible for hospital admissions, emergency room visits, and mortality, including in areas with NO_2 levels well below the annual standard. See 75 Fed. Reg. 6,478, 6,480. In the earlier review, there were no such studies; the ISA, however, considered dozens of epidemiologic studies conducted at recent and current ambient NO_2 concentrations identifying such outcomes – including a group of studies where hospital admissions and emergency room visits were associated with one-hour area-wide concentrations of 85-94 ppb – as well as other scientific evidence. See 75 Fed. Reg. 6,478, 6,500; 74 Fed. Reg. 34,425. Indeed, one of the very passages cited by Petitioners as purported support for the proposition that EPA relied almost exclusively on the updated Folinsbee analysis identifies epidemiologic studies, controlled human exposure studies, the risk and exposure analyses contained in the REA, and additional evidence presented in the ISA, as

supporting EPA's conclusions. 75 Fed. Reg. at 6,500-01; compare Pet. Br. at 28 (citing 75 Fed. Reg. 6,500).[9]

Nor have Petitioners demonstrated that, by updating and presenting the original data, EPA created what is "essentially a new study." Pet. Br. at 31. This claim is based on a fundamental misunderstanding of what EPA actually did.[10] EPA did not re-weight data from the studies considered by Folinsbee, or otherwise alter the basic analytic framework established in the original meta-analysis. EPA simply removed the data from one study (out of nineteen considered in the original analysis), replaced it with data from a more recent and more relevant study, and presented the results in a way that focused on the exposure levels of most concern in this review. As discussed above, moreover, this data substitution did not produce any substantively different results.

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[9] Petitioners also cite 75 Fed. Reg. 6,494, which discusses EPA's consideration of the scientific and exposure/risk information in general. Pet. Br. at 28. The cited passage refers to key epidemiologic studies, but says nothing one way or the other about EPA's use of or reliance on the updated Folinsbee analysis.

[10] Petitioners suggest that if the original and updated versions of the Folinsbee analysis were "the same study," then that study "produced two different results" in this review and in EPA's prior review of the NO_2 NAAQS. Pet. Br. at 37. EPA never claimed that the two versions of the analysis are "the same study," only that they lead to similar conclusions. As discussed in the text, moreover, the updated Folinsbee analysis was not solely responsible for the "different results" of this review.

b. EPA's update of the Folinsbee analysis was transparent and consistent with all applicable guidelines.

Petitioners argue that EPA's update of the Folinsbee analysis was not peer-reviewed, published, or even fully disclosed. See Pet. Br. at 10-11, 18-19, 26-33. Petitioners have, however, failed to demonstrate any lack of expert review or transparency. Both the original Folinsbee analysis and the additional study incorporated into that analysis were published and peer-reviewed. See 75 Fed. Reg. 6,487. EPA's presentation and interpretation of the Folinsbee data was also subject to external peer review by CASAC, an independent body of scientific experts. Id. Petitioners argue that this review was insufficient, speculating that EPA "may" have inappropriately selected the recent airway responsiveness study used to update the Folinsbee analysis. Pet. Br. at 29-30. Petitioners do not, however, offer any actual criticism of the additional study, or any evidence that it was inappropriate for EPA to consider that study.

Nor have petitioners shown any lack of transparency in EPA's updating of the Folinsbee analysis. The ISA itself clearly identifies the studies and the process that were used in preparing Table 3.1-3. All of the data needed to produce the results in Table 3.1-3 were provided in Table 3.1-2 and in the footnote of Table 3.1-3 itself. ISA at 3-15-16 (JA XX-XX). Petitioners' assertion that information concerning EPA's presentation of the updated Folinsbee analysis was first

presented in the final ISA, Pet. Br. at 31, while correct, is misleading, because the final ISA was by no means the end of the review process. The second draft REA (which underwent public and CASAC review) incorporated analysis from the ISA, including Table 3.1-3 (there shown as Table 4-1). Second Draft REA at 24 (JA XX). EPA's updating of the Folinsbee analysis was also discussed in the proposed Rule. See 74 Fed. Reg. 34,415. EPA thus fully, and transparently, explained its actions.

Petitioners have, moreover, failed to support their claim that EPA's use of the updated Folinsbee analysis violated the Information Quality Act.[11] See Pet. Br. at 31-32. That Act requires the Office of Management and Budget ("OMB") to issue guidelines that ensure and maximize the quality, objectivity, utility, and integrity of information disseminated by federal agencies, and that require federal agencies to issue their own information quality guidelines. 44 U.S.C.A. § 3516 nn. (a), (b). Both OMB and EPA have issued such guidelines (as Petitioners acknowledge, Pet. Br. at 31-32); thus, there has been no violation of the statute itself. Nor have Petitioners shown any deviations from relevant EPA guidelines.

[11] Petitioners appear to regard the Review Plan and the ISA as "regulations" that EPA was required to follow. See Pet. Br. at 26-27. Not only have Petitioners failed to demonstrate this, but for the reasons discussed in the text, Petitioners have failed to demonstrate that EPA's use of the Folinsbee analysis in any way conflicted with the Review Plan and the ISA.

The central purpose of EPA's guidelines is to ensure that information disseminated by EPA is of high quality, through the use of peer review and other processes. See EPA Information Quality Guidelines at 3-4, 11 (JA XX-XX). For the reasons discussed above, EPA's use and updating of the Folinsbee analysis following review by CASAC and the public amply satisfies this standard.

2. EPA reasonably concluded that the Goodman study did not warrant reopening the air quality criteria for this review.

Petitioners argue that instead of using the updated Folinsbee analysis, EPA should have relied on a study that petitioners prefer (the "Goodman study"). See Pet. Br. at 33-36. The record demonstrates, however, that EPA gave this late-arriving study all the consideration it was due under the Act. Petitioners' objection to EPA's treatment of the Goodman study is, at base, a policy disagreement – in other words, Petitioners believe that EPA should have used a different approach to determining which public health effects and risks warrant revision of a NAAQS. The mere fact that Petitioners disagree with EPA's choices, however, does not render those choices arbitrary or capricious.

a. The Goodman study was not available in time to form part of the air quality criteria for this review.

A NAAQS must be based on established "air quality criteria," which are subject to review by CASAC. 42 U.S.C. §§ 7408 (a)(2), 7409(b)(1), (d)(2)(B). As EPA explained, given that NAAQS decisions may have "profound impacts on

public health and welfare," those decisions should be based on "studies that have been rigorously assessed in an integrative manner, not only by EPA, but also by [CASAC], as well as the public review that accompanies this process." 75 Fed. Reg. 6,478.

The Goodman study was completed in 2009, and was not even available until long after the ISA and the REA – which constitute the air quality criteria on which the revised NO_2 NAAQS is based – were complete. See 75 Fed. Reg. 6,487 n. 9. The studies assessed in the ISA and the REA had already undergone rigorous CASAC and public review; the Goodman study had not. Consistent with its longstanding interpretation of Section 109 and its practice in prior NAAQS reviews, EPA therefore treated the Goodman study as a "new study," which EPA provisionally considered in the context of the findings made in the ISA, solely in order to determine whether that study warranted reopening the air quality criteria for this review. 75 Fed. Reg. 6,478, 6,487 n.9.

Based on this provisional review, EPA concluded that neither the Goodman study nor any other "new studies" received since the ISA and REA were finalized materially changed any of EPA's scientific conclusions regarding the health effects of NO_2, and that therefore there was no basis for reopening the air quality criteria for this review. Id. With regard to the Goodman study in particular, EPA noted that the study shows that significant percentages of resting asthmatics exposed to

NO_2 experienced increased airway responsiveness. 75 Fed. Reg. 6,487. As discussed in the next section, these findings are generally consistent with both the original and updated Folinsbee analysis.

Petitioners' claim that EPA did not give the Goodman study "any weight," Pet. Br. at 33, is thus contradicted by the record. EPA gave this late-arriving study all of the weight to which it was entitled as a "new study" by considering it provisionally, and determining that it contained nothing that would warrant reopening the air quality criteria on which the revised NO_2 NAAQS was based. As this Court has recognized, "new information continually comes to light on the subject of many proposed rules," but "[f]inality . . . has a place in administrative rulemaking, just as it does in judicial decisionmaking." Sierra Club v. Costle, 657 F.2d 298, 400 (D.C. Cir. 1981). This is particularly true for NAAQS, which are required by statute to be based on air quality criteria reviewed by CASAC, and which are regularly updated. There will, of course, be future reviews of the NO_2 NAAQS – and EPA has stated that it will fully consider the "new studies" submitted during this review at that time. 75 Fed. Reg. at 6,478. Until then, however, EPA's provisional consideration of the Goodman study in light of the

conclusions reached in the ISA and REA accorded that study all the weight and consideration it was due.[12]

b. The Goodman study does not contradict EPA's conclusion that a 100 ppb standard is requisite to protect public health.

Even if the Goodman study had arrived in time to be incorporated into this review, it would not have changed EPA's conclusions. First, Goodman's results are largely consistent with the original and updated Folinsbee analysis. Figure 2a of the Goodman study reported that at exposures less than 0.2 ppm (200 ppb), 61% of resting asthmatics suffered increased airway responsiveness; for exposures of 0.2 to less than 0.3 ppm (200 ppb to less than 300 ppb), the percentage rises to 66%. 75 Fed. Reg. 6,487. This result is similar to that reached in EPA's updated analysis, which showed increased airway responsiveness in 66% of resting asthmatics at exposures of 0.1 ppm (100 ppb); 67% of resting asthmatics at exposures between .1 and .15 ppm (100 to 150 ppb); and 75 % of resting

[12] Business Roundtable v. SEC, 647 F.3d 1144 (D.C. Cir. 2011), Pet Br. at 33-34, is distinguishable. In that case, the SEC "completely discounted" numerous studies submitted during the comment period that contradicted the agency's position. Business Roundtable, 647 F.3d at 1150-51. As discussed in the text, EPA did not "completely discount" the Goodman study (which was submitted after the development of the air quality criteria for this review), and that study does not contradict EPA's position.

asthmatics at exposures of 0.2 to less than 0.3 ppm (200 ppb to less than 300 ppb). ISA at 3-16, Table 3.1-3 (JA XX); REA at 33-34 and Table 4-5 (JA XX-XX). [13]

More broadly, Dr. Goodman was concerned with examining whether there is a dose-response relationship between NO_2 exposure and airway responsiveness in asthmatics – in other words, with *quantifying* the magnitude of effects occurring at various levels of exposure to NO_2. See Pet. Br. at 34. Petitioners' claim that EPA "dismissed" this approach, Pet. Br. at 35, misses the point. EPA did not claim that there is anything inherently wrong with attempting to establish such a dose-response relationship.[14] Based on its view of the science, EPA took a different

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[13] Petitioners argue that Dr. Goodman "strongly denies" that her study is generally consistent with EPA's conclusions. Pet. Br. at 35. Petitioners rely on an April 2010 memorandum that significantly postdates the Rule, and that is not in the record for judicial review. See 42 U.S.C. § 7607(d)(7)(A). Nor does the memorandum support Petitioners' argument. Nowhere does Dr. Goodman address – let alone deny – EPA's conclusion that her study and EPA's review of the science show that similar percentages of asthmatics experienced increased airway responsiveness to similar NO_2 exposures. See 75 Fed. Reg. 6,487; April 9, 2010, Goodman memo (JA XX-XX).

[14] EPA concluded that due to multiple differences in study protocols, existing data could not be used to establish a dose-response relationship. 75 Fed. Reg. 6,487, 6,498. Petitioners argue that if EPA did not believe that Goodman could use "existing data" to determine whether a dose-response relationship exists, EPA was not entitled to rely on "existing evidence" to conclude that a significant fraction of asthmatics experience some increased airway responsiveness at exposures as low as 100 ppb. Pet. Br. at 35. There is no inconsistency. Due to differences between the studies, EPA judged the data adequate to answer one limited question (the

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approach to assessing public health risks, choosing to consider the fraction of asthmatics experiencing some increase in airway responsiveness without attempting to establish the precise degree of response to a specific dose.

This choice lies squarely within the realm left to EPA's discretion. Petitioners argue that because *Goodman* concluded that there were "no clinically relevant effects" at exposures less than 600 ppb, NO_2 exposures at lower levels have "no measurable effect on public health." Pet. Br. 34. The statute, however, leaves it to *the Administrator* to determine what is required to protect public health – and requires the Administrator to set a standard with an adequate safety margin. EPA determined that airway hyperresponsiveness due to NO_2 exposures of 100 ppb presented a risk of adverse health effects for some individuals, particularly those with serious asthma, and that protection from this risk was warranted. 75 Fed. Reg. 6,501. CASAC agreed with this conclusion. See 12/16/08 Letter at 2 (JA XX). As EPA explained – and as this Court has recognized – determining what is required to protect public health, and how large the margin of safety should be, is a public health policy judgment as well as a scientific one. See 75 Fed. Reg. 6,483; Ethyl Corp., 541 F.2d at 24 (determining whether public health is threatened

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existence and direction of an effect) but inadequate to answer a different, more complex question (the magnitude of the effect and how it changes as the dose varies).

"is necessarily a question of policy that is to be based on an assessment of risks . . ."); Lead Indus., 647 F.2d at 1146 (Congress left formulation of NAAQS to Administrator, and "[t]his task presents complex questions of science, law, and social policy under the Act."). Petitioners' disagreement with EPA's policy choices does not render those choices arbitrary or capricious.

Even assuming, moreover, that Goodman were correct, and that the health effects her meta-analysis found were too small to be considered adverse, see Pet. Br. at 16, the Administrator was still entitled to consider the existence of those effects in determining what is required to protect public health with an adequate safety margin. EPA acknowledged that there is uncertainty over the magnitude and clinical significance of airway hyperresponsiveness, but – particularly in light of the greatly expanded body of epidemiologic studies – concluded that difficulty in fully characterizing this risk does not mean it should be ignored in setting the standard. 75 Fed. Reg. 6,487-88, 6,501. This Court has repeatedly recognized this as a proper approach to setting a NAAQS. See Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 618 (D.C. Cir. 2010) ("EPA should set standards providing 'a reasonable degree of protection . . . against hazards which research has not yet identified'") (citing NRDC v. EPA, 824 F.2d 1146, 1152 (D.C. Cir. 1987) (en banc)); Lead Indus., 647 F.2d at 1154 (Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects

which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement."); American Farm Bureau, 559 F.3d at 533 (Act permits Administrator to "err on the side of caution" in setting NAAQS) (citation omitted).

3. There is no inconsistency in EPA's treatment of the Schildcrout study.

Petitioners argue that EPA acted inconsistently by relying on a study by J.S. Schildcrout in this review, while declining to rely on that study in its 2006 review of the ozone NAAQS. Pet. Br. at 37-38. Petitioners' claim that EPA previously declined to rely on this study due to flaws in its design is based on a comment submitted on the proposed Rule. Pet. Br. at 37; 75 Fed. Reg. 6,486 (quoting comment from National Association of Manufacturers). As EPA explained in response, the Schildcrout study did not appear in the peer-reviewed literature soon enough to be incorporated into the 2006 ozone review. 75 Fed. Reg. 6,486. The study is, however, being considered in EPA's current review of the ozone NAAQS. Petitioners' assertion that EPA found the Schildcrout study to be fundamentally flawed, see Pet. Br. at 38, thus finds no support in the record.

B. EPA Appropriately Considered Multiple Air Quality Scenarios.

The ISA concluded that the body of scientific evidence discussed in detail above was "sufficient to infer a likely causal relationship" between short-term NO_2

exposures and respiratory effects. 75 Fed. Reg. 6,489; supra at 10-11. In the Administrator's judgment, this meant that determining whether the annual-average NO_2 NAAQS protects public health with an adequate safety margin required EPA to consider, at a minimum, whether that standard provides adequate protection against respiratory effects associated with short-term NO_2 exposure. As it had planned to do from the outset of this review, see Review Plan at 2 (JA XX), and as it had done in prior reviews, 75 Fed. Reg. 6,488, EPA considered multiple air quality scenarios in addressing this question. EPA examined potential short-term exposures and health risks associated with (1) recent ambient NO_2 levels; (2) NO_2 levels adjusted to simulate just meeting the annual NO_2 NAAQS (i.e., the standard under review); and (3) NO_2 levels adjusted to simulate just meeting potential alternative standards. See 75 Fed. Reg. 6,482.

Petitioners' claim that EPA should have considered only "as is" air quality, see Pet. Br. at 39-41, ignores what was at issue in this review. The question before EPA was not whether present *air quality* threatens human health; it was, instead, whether the existing *standard* protects public health with an adequate safety margin. See 75 Fed. Reg. 6,488. In examining this question, EPA naturally adjusted air quality so that it could consider potential short-term NO_2 exposures and risks if that standard is just satisfied, as well as potential exposures given existing air quality. Id. As EPA explained, such adjustments "are clearly useful to

inform a decision on the issue before EPA (*i.e.*, the adequacy of public health protection associated with allowable NO_2 air quality under the standard)." Id. By adjusting air quality to simulate exposures and risks given potential revisions to the NAAQS, EPA was similarly able to assess public health risks under possible alternative standards. Id.; see also REA at 284 (JA XX) (air quality adjustment "does not reflect a judgment that levels of NO_2 are likely to increase," but rather that current or alternative standards "could allow for such increases"). Petitioners' casual dismissal of adjusted air quality as a "fictional scenario," Pet. Br. at 40, takes no account of the questions that EPA was considering or its explanation for considering adjusted air quality.

That does not mean, of course, that EPA simply ignored existing air quality. Petitioners' claim that the Administrator "never considered what risks to public health were posed by 'as is' ambient NO_2 levels," Pet. Br. at 40, is made without attribution – which is unsurprising, since that claim is flatly contradicted by the record.[15] As EPA explained epidemiologic studies considered in the ISA reported "positive, and often statistically significant, associations" between real-world

[15] Elsewhere, Petitioners cite 75 Fed. Reg. 6,488/2-3 for the proposition that EPA "rejected consideration of current air quality." Pet. Br. at 20. The cited passage disagrees with comments suggesting "that exposure- and risk-related considerations in the NAAQS review should rely *only* on unadjusted air quality," (emphasis added), but says nothing to suggest that current air quality is irrelevant.

short-term ambient NO_2 concentrations and respiratory symptoms, hospital admissions, and emergency room visits, including in many areas with NO_2 concentrations below the level of the annual NO_2 NAAQS. 75 Fed. Reg. 6,489. EPA discussed this information at length in considering whether the annual NO_2 NAAQS was adequate to protect public health. See 74 Fed. Reg. 34,425-27; 75 Fed. Reg. 6,488-90. The REA also thoroughly considered exposures and risks associated with "as-is" air quality. See, e.g., REA at 85-101, 197-207 (JA XX-XX, XX-XX). The Administrator took all of this information into consideration before concluding that the annual NO_2 NAAQS was inadequate to protect public health from short-term NO_2 exposure with an adequate safety margin, and that an additional 100 ppb hourly standard was necessary. 75 Fed. Reg. 6,488.

Petitioners also do not, and cannot, cite anything that supports their related assertion that EPA determined that the annual NO_2 NAAQS was not protective of public health solely by "comparing the risks associated with [air quality adjusted to just meet the annual NAAQS]" to risks associated with NO_2 exposures under various potential one-hour standards. Pet. Br. at 40; see also id. at 39 (claiming without citation that Administrator "focused entirely" on exposures and risks associated with NO_2 exposures at level of annual NO_2 NAAQS). Petitioners point to a single out-of-context quotation, which states EPA's view (endorsed by CASAC) that estimated risks based on adjusted air quality "can reasonably be

concluded to be important from a public health perspective." Pet. Br. at 41; 75 Fed. Reg. 6,489. That these risks may be important does not, however, mean that EPA's findings in this case were based solely on such risks. In the Administrator's view, the REA's exposure and risk-based analysis, including the analysis of alternative air-quality scenarios, "*reinforce[d]* the scientific evidence in supporting the conclusion that consideration should be given to revising the current standard . . . ." 75 Fed. Reg. 6,489-90 (emphasis added).

C. The Revised NAAQS Is Necessary To Protect Public Health.

Petitioners' assertion that the new hourly standard is unnecessary because EPA has "acknowledge[d]" that risks associated with air quality that just meets the annual NO_2 NAAQS "will never occur," Pet. Br. at 41, is, yet again, entirely unattributed – and no such acknowledgement can be found anywhere in the record.[16] Petitioners appear to be confusing the risks posed by long-term exposure to ambient levels of NO_2 in areas that meet the annual NAAQS with the risks of

[16] Petitioners also make the slightly less sweeping claim that EPA has acknowledged that it is "entirely unlikely" that NO_2 levels will rise to the level of the annual NAAQS. Pet. Br. at 39. To support this claim, Petitioners rely on an EPA air quality report that is not contained in the administrative record, and that therefore is not part of the record for judicial review. See 42 U.S.C. § 7607(d)(7)(A). This overall long-term air quality report is, moreover, irrelevant to determining whether *short-term* NO_2 concentrations of concern are occurring anywhere in the country.

greatest concern to EPA in this review – i.e., those posed by *short-term* exposures to NO_2 levels that exceed 100 ppb. The annual standard is satisfied as long as the average of all hourly concentrations remains below 53 ppb. See supra at 7-8. Short-term NO_2 levels could, however, exceed 100 ppb hundreds of times a year and still allow an area to satisfy the annual standard. 75 Fed. Reg. 6,483; 74 Fed. Reg. 34,434, Table 1. EPA thus adopted a short-term standard in order to control short-term peak concentrations not reached by the annual standard.

Petitioners' claim that the REA demonstrates that current air quality already adequately protects public health, Pet. Br. at 41-42, arises from a similar misconception. In this instance, petitioners confuse concentrations representative of a broad geographic area with peak concentrations within the area. The REA tables that Petitioners cite identify risks given "as is" air quality and potential alternative hourly standards. As discussed supra at 14-15, the analysis of potential alternative standards in the REA is based on hourly NO_2 concentrations measured by the pre-2010 monitoring network, where monitors are generally sited to measure average concentrations across an area, not to measure peak concentrations (e.g., those near a road) within that area. See 74 Fed. Reg. 34,441. The new hourly NO_2 NAAQS, however, measures compliance with the 100 ppb maximum NO_2 concentration *at peak locations within an area*. The 100 ppb standard adopted by EPA thus cannot be directly compared to the 100 ppb alternative

standard discussed in the REA, as they represent very different air quality scenarios. The 100 ppb hourly standard adopted by EPA has to be achieved everywhere in an area, including near roadways, and is expected to result in area-wide concentrations (i.e., those used for alternative standards in the REA) of approximately 50-75 ppb. 75 Fed. Reg. 6,494 n.14.

Given the steep gradient that can exist between near-road and area-wide NO_2 concentrations, and given that the revised NAAQS reflects the maximum NO_2 concentration allowed in an area, the estimated number of emergency room visits shown in Figure 4-1 (JA XX) associated with a 100 ppb standard (shown as 0.1 ppm in Tables 9-2 through 9-4 of the REA (JA XX-XX), measured at an area-wide monitor) does not correspond to the number of such visits that would be estimated to be associated with the revised NAAQS, which is a 100 ppb standard measured at peak concentration.[17] The risk associated with the 100 ppb peak concentration standard actually adopted by EPA would be expected to be considerably lower

[17] Petitioners suggest in passing that calculations regarding the potential health impacts of NO_2 exposures given various alternative standards are based on models that do not control for pollutants other than NO_2. See Pet. Br. at 42 n.18, 43 n.19. As EPA explained in response to comments, this issue was "thoroughly reviewed in the ISA," which concluded that associations between short-term NO_2 exposure and respiratory effects "are generally robust to adjustment for co-pollutants in multipollutant models." 75 Fed. Reg. 6,485. In addition, human and animal experimental studies support the conclusion that short-term NO_2 exposure has an independent effect. Id.

than the figure reported as ".1 ppm," and possibly as low as the risk reported in Figure 4-1 at ".05 ppm" (50 ppb), which is lower than the risk shown in that figure for "as is" air quality. 75 Fed. Reg. 6,494-95; see also 9/9/09 Letter at 2 (JA XX).

Petitioners also misinterpret Table B-48 (JA XX), which again assumes a 100 ppb standard based on ambient NO_2 concentrations measured by area-wide monitors. See Pet. Br. at 43. Given the difference between area-wide and near-road concentrations, it is more appropriate to compare the percentage of exposures under "as is" conditions with the percentage of exposures under an area-wide hourly standard with a level as low as 50 ppb. Table B-48 shows that, at a 50 ppb standard measured at area-wide monitors, an estimated 3% of asthmatics would be exposed to NO_2 concentrations of 300 ppb at least twice a year – a significant drop from the 32% suffering such exposures given existing air quality.[18] See REA at B-114 (JA XX).

[18] Petitioners similarly misinterpret Table 4-8 in Appendix C of the REA. Pet. Br. at 42. The fifth column of that table shows NO_2-related emergency room visits given a standard of .1 ppm (100 ppb) measured at area-wide monitors. Given the potential variances in NO_2 concentrations from location to location within an area, the effects of the 100 ppb peak concentration standard are more likely to be represented by the column that assumes an area-wide concentration as low as .5 ppm (50 ppb). This column in Table 4-8 shows that fewer NO_2-related emergency room visits would likely result, as compared to current conditions.

Petitioners have, in sum, failed to offer anything to undermine the substantial scientific record (which extends well beyond the REA, see supra at 9-12, 16-17) underlying EPA's determination that the annual NO_2 NAAQS did not adequately protect against short-term NO_2 exposures, and that a 100 ppb hourly standard was required in order to fully protect public health.

II. PETITIONERS' CONCERNS REGARDING IMPLEMENTATION OF THE REVISED NO_2 NAAQS ARE NOT PROPERLY BEFORE THE COURT.

Petitioners also raise a number of arguments regarding EPA's allegedly arbitrary failure to consider the economic and practical effects "of declaring the new NAAQS immediately effective." Pet. Br. at 47; see generally id. at 46-55. EPA may not consider anything other than public health or welfare in establishing or revising a NAAQS. See 42 U.S.C. § 7409(b); Whitman, 531 U.S. at 465 (text of Section 109(b)(1) "does not permit the EPA to consider costs in setting the standards"); Lead Indus., 647 F.2d at 1148-49 ("Section 109(b) speaks only of protecting the public health and welfare. . . ."); American Petroleum Inst., 665 F.2d at 1185 ("API's argument that the Administrator erred in not considering attainability and cost justifications for the ozone standards was specifically rejected in the Lead Industries case."). Petitioners' assertion that EPA should have considered economic and logistical impacts before "declaring" the revised NAAQS applicable to PSD permitting decisions appears to be a thinly-veiled attempt to

escape the plain language of the statute and the significant body of precedent precluding EPA from considering the difficulties of *implementing* a NAAQS when *revising* a NAAQS. To the extent that Petitioners are arguing that the revised NAAQS should be vacated or remanded for this reason, their argument must be rejected.

To the extent that Petitioners are arguing that EPA took some distinct action to apply the revised NAAQS to PSD permitting decisions, and that *that* action should be vacated or remanded as arbitrary or capricious, their argument is founded on series of false premises: that EPA took such an action at all, as opposed to the revised NAAQS becoming applicable by operation of law; that EPA has discretion to generally suspend the PSD applicability of a revised NAAQS, and has routinely done so in the past; and that it is impossible to apply the revised NAAQS to PSD permitting decisions. Petitioners have failed to demonstrate that any of these premises is sound, and their implementation arguments must therefore be rejected.

A. The Revised NAAQS Is Applicable To PSD Permitting Decisions By Operation Of Law.

Section 165 of the Act forbids construction of a "major emitting facility" in an attainment area unless "a permit has been issued for such proposed facility . . . setting forth emission limitations . . . which conform to the requirements of this

part." 42 U.S.C. § 7475(a)(1). To obtain such a permit, the owner or operator of a proposed facility must demonstrate that, among other things, "emissions from construction or operation of such facility will not cause, or contribute to, air pollution in excess of *any . . . national ambient air quality standard* in any air quality control region." 42 U.S.C. § 7475(a)(3) (emphasis added).

EPA's longstanding view is that this statutory language means that a new or revised NAAQS immediately applies to PSD permitting decisions. See, e.g., 73 Fed. Reg. 28,321, 28,340 (May 16, 2008) ("[S]ection 165 of the Act suggests that PSD requirements become effective for a new NAAQS upon the effective date of the NAAQS"); 70 Fed. Reg. 65,984, 66,043 (Nov. 1, 2005) ("[T]he obligation to implement PSD for the NAAQS was triggered upon the effective date of the NAAQS. . . ."); 52 Fed. Reg. 24,672, 24,682 (July 1, 1987) ("once the PM_{10} NAAQS becomes effective, EPA will be responsible for the protection of the PM_{10} NAAQS as well as the review of PM_{10} as a regulated pollutant."); 1997 Seitz Memorandum at 1 (JA XX) (noting statutory requirement that emissions from a new or modified major source not cause or contribute to violation of any NAAQS, and providing interim guidance on meeting NSR requirements related to the newly effective revised NAAQS); see also April 1, 2010 Page Memorandum at 2 (JA XX) ("EPA generally interprets the CAA and EPA's PSD permitting program regulations to require that each final PSD permit decision reflect consideration of

any NAAQS that is in effect at the time the permitting authority issues a permit.").[19]

The conclusion that "*any* . . . [NAAQS]" (emphasis added) means any NAAQS in effect at the time a PSD permit is issued follows directly from the plain language of the statute. See New Jersey v. EPA, 517 F.3d 574, 582 (D.C. Cir. 2008) ("[i]n the context of the [Act], the word 'any' has an expansive meaning") (citation and internal quotations omitted). At a minimum, EPA's view of the statute represents a reasonable interpretation that must be upheld as long as it is "a permissible construction of the statute." Chevron, 467 U.S. at 843.

Petitioners do not even attempt to demonstrate that it is unreasonable to interpret the Act to require that a new or revised NAAQS immediately apply to PSD permits. Instead, they simply pretend that EPA interprets the statute the other way around, such that a new or revised NAAQS does *not* apply until EPA says that it does. See, e.g., Pet. Br. at 47 (asserting EPA "declar[ed] the new NAAQS immediately effective"), 48-49 ("EPA has not always made new NAAQS immediately applicable to PSD permits."). The examples that Petitioners cite,

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[19] The Page memorandum postdates EPA's revision of the NO_2 NAAQS, and thus is not part of the administrative record. It is cited solely as evidence of EPA's longstanding interpretation of the statute and its implementing regulations, not as support for EPA's revision of the NAAQS.

however, merely prove that immediate applicability of a new or revised NAAQS is the rule, not the exception.

Petitioners point to EPA's implementation of the NAAQS for $PM_{2.5}$, asserting that EPA "deferred the PSD program" for this NAAQS for over ten years. Pet. Br. at 49. EPA did no such thing. To the contrary – the 1997 Seitz memorandum makes it clear that the $PM_{2.5}$ NAAQS was immediately applicable to PSD permitting decisions. Seitz Memorandum at 1 (JA XX). At that time, however, there were "significant technical difficulties" associated with monitoring, estimating $PM_{2.5}$ emissions, and modeling $PM_{2.5}$. Id. For purposes of PSD permits, EPA thus authorized permitting authorities to use PM_{10} levels as a surrogate for the newly effective $PM_{2.5}$ NAAQS. See id. at 1-2 (JA XX-XX); see also 73 Fed. Reg. 28,340 (1997 guidance authorized EPA to use PM_{10} program "as a surrogate for meeting $PM_{2.5}$ . . . requirements"). EPA's guidance addressed how compliance with the $PM_{2.5}$ NAAQS would be determined, not whether the NAAQS applied to PSD permitting decisions at all – in fact, there would have been no need for the guidance if the $PM_{2.5}$ NAAQS had *not* been immediately applicable.

Petitioners also point to EPA's 1987 implementation of the PM_{10} NAAQS. Pet. Br. at 49. Again, that rule merely demonstrates EPA's longstanding view that a new or revised NAAQS immediately applies to PSD permitting decisions unless EPA determines otherwise. EPA stated that "[o]nce the PM_{10} NAAQS becomes

effective, EPA will be responsible for the protection of the PM_{10} NAAQS as well as the review of PM_{10} as a regulated pollutant." 52 Fed. Reg. 24,682.[20] EPA went on to state that "PSD applicants requesting preconstruction review approval . . . must begin to address the new PM_{10} requirements unless they are eligible for grandfather status as described below." Id.

Petitioners argument that EPA erred by "declaring" the revised NAAQS immediately applicable to PSD permitting decisions, Pet. Br. at 47, thus inevitably fails. See generally id. at 46-55. The first problem with this argument is that EPA made no such declaration, and did not otherwise take final action to make the revised NAAQS applicable to PSD permitting decisions – as discussed above, that occurred by operation of law. Because there is no final agency action "declaring" the revised NAAQS applicable to PSD permitting decisions, Petitioners' challenge to that (nonexistent) action is beyond the jurisdiction of the Court. See 42 U.S.C. § 7607(b) (limiting Court's jurisdiction to review of final agency actions). For the same reason, Petitioners' request that the Court "vacate" the "portion of the . . . Rule" applying the revised NAAQS to PSD permitting decisions is nonsensical.

[20] EPA was referring to its role in administering preconstruction permitting requirements under the federal PSD program. See note 2, supra.

Pet. Br. at 56. There is no such "portion of the Rule"; again, the revised NAAQS applies to PSD permitting decisions by operation of law.

B. EPA Was Not Required To Delay The Applicability Of The Revised NAAQS.

At the same time as they argue that EPA allegedly erred in "declaring" the revised NAAQS immediately applicable to PSD permitting decisions, Petitioners also appear to argue that EPA was required to consider taking steps to somehow delay the PSD applicability of the revised NAAQS. See Pet. Br. at 49-53. Given the statutory language discussed above, Petitioners have not shown that EPA even had the discretion to adopt such a blanket delay; thus, their argument that EPA was somehow *required* to do so necessarily fails. There is certainly nothing in the statute that expressly directs EPA to consider delaying the PSD applicability of a new or revised NAAQS; thus, this case is distinguishable from Public Citizen v. Fed. Motor Carrier Safety Admin., 374 F.3d 1209 (D.C. Cir. 2004). As explained in the very passage cited by the Petitioners, Pet. Br. at 50-51, in that case the agency had failed to consider a "*statutorily mandated* factor." Public Citizen, 374

F.3d at 1216 (emphasis added).[21] Petitioners have identified no such statutory mandate here.

Nor can petitioners find such a mandate in the PSD provisions of the Act. See Pet. Br. at 51. Neither of the provisions that Petitioners refer to says anything at all about the NAAQS. 42 U.S.C. § 7475(c) requires EPA to act on PSD permit applications within a year. If EPA fails to act on a specific permit application in a timely manner, any party with standing may pursue its remedies at that point. Petitioners' unsupported speculation that EPA will inevitably fail in its duties is, however, wholly insufficient to establish that EPA was required – or even allowed – to issue a blanket delay of the PSD applicability of the revised NO_2 NAAQs.

42 U.S.C. § 7475(e)(3)(D) requires EPA to promulgate regulations specifying air quality models to be used in the PSD program. EPA has already

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[21] Petitioners also cite Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin., 429 F.3d 1136 (D.C. Cir. 2005). Pet. Br. 50. The basis for the Court's decision in that case was that the rule at issue was "so at odds with the record assembled by [the agency] that the action cannot stand." Advocates, 429 F.3d at 1140; see also id. at 1147. As discussed in Section I, the revised NAAQS is amply supported by the administrative record. Nat. Res. Def. Council v. EPA, 22 F.3d 1125 (D.C. Cir. 1994) (Pet. Br. at 53), also offers no aid to Petitioners. In that case, the Court concluded that EPA properly extended certain deadlines in order to ensure that States and EPA had the time allowed by Congress to complete certain tasks following preliminary steps that had themselves been delayed. Id. at 1135-36. Petitioners point to no parallel situation here.

done so, and those regulations specifically address analysis of NO_2 concentrations. See 40 C.F.R. Pt. p1, App. W 5.2.4. There is no statutory requirement that EPA revise those regulations each time it revises a NAAQS. EPA has, moreover, provided guidance on applying these regulations to the revised NAAQS. See infra at 59-60. Petitioners have again failed to demonstrate that this provision somehow authorizes, let alone requires, EPA to delay applicability of the revised NAAQS.

EPA does have the discretion to craft appropriate grandfathering provisions for PSD permit applications that have already been submitted as of the date a new NAAQS becomes effective. Petitioners have not, however, identified any permit applications that they contend should have been grandfathered, nor did they make any such argument to EPA during the comment period. Under Section 307(d)(7)(B), 42 U.S.C. § 7607(d)(7)(B), parties may not seek judicial review of issues they failed to raise with "reasonable specificity" during the comment period. The only exception is if it was "impracticable" to raise the issue at that time; even then, a party must first present the issue through a reconsideration petition to EPA, demonstrating why the issue could not have been raised and why it is "of central relevance to the outcome of the rule." Id. This Court enforces these requirements "strictly." NRDC v. EPA, 571 F.3d 1245, 1259 (D.C. Cir. 2009). Because Petitioners did not raise any grandfathering concerns during the comment period,

and have not since petitioned EPA on that basis, they cannot argue now that EPA should have grandfathered any particular permit applications.

Despite not having raised any grandfathering arguments previously, Petitioners base their arguments in part on EPA's decision to grandfather a PSD permit application by the Avenal Power Plant that was pending when the revised NO_2 NAAQS went into effect. Pet. Br. at 51-53. This decision postdates the revision to the NAAQS; thus, it is irrelevant to judicial review of that revision. See 42 U.S.C. § 7607(d)(7)(A) (record for judicial review "shall consist *exclusively*" of specified materials in rulemaking docket) (emphasis added); see also Camp v. Pitts, 411 U.S. 138, 142 (1973) (review of agency action to be based on record before agency at time it acted). It was also a highly-fact specific action based on Avenal's unique circumstances. Avenal's PSD permit application had been pending "well beyond the one-year deadline" when EPA established additional standards and criteria applicable to the PSD permitting program. Avenal Supplemental Statement of Basis ("SSB") at 2, 9 (JA XX, XX). Demonstrating compliance with these revised requirements would have further delayed the permitting process; thus, under the specific circumstances of the case, EPA determined that it should grandfather Avenal's permit application. SSB at 1, 5-6 (JA XX). EPA made it clear that its decision to grandfather the Avenal facility did not represent a change in EPA's view that as a general rule a new or revised

NAAQS is immediately applicable to PSD permitting decisions. See SSB at 2-3 (JA XX-XX); Avenal Response To Comments ("Avenal RTC") at 55 (JA XX).

Finally, Petitioners argue that the "tools" required to address compliance with the revised NO_2 NAAQS simply "are not available." Pet. Br. at 53. Contrary to Petitioners' assertion, EPA did not "acknowledge[]" that this is the case – the only thing EPA acknowledged on the page cited by Petitioners is that "a decision to promulgate a new short-term NO_2 NAAQS will clearly have implications for the air permitting process," which is hardly a remarkable proposition. 75 Fed. Reg. 6,525. And although EPA stated in Avenal that the analysis of one-hour NO_2 concentrations was taking more time than EPA anticipated when it asked Avenal to address this requirement, EPA never suggested that the analysis was not possible. Indeed, EPA specifically noted that it was "*not* grandfathering Avenal because the Agency believes [the analysis necessary to demonstrate compliance with the one-hour NO_2 NAAQS] is impossible or that Avenal is unable to complete such an analysis." Avenal RTC at 77 (JA XX) (emphasis added). EPA specifically disagreed with a commenter who alleged that adequate models for making the required demonstration were not available, explaining that it had approved the AERMOD dispersion model for PSD permit applicants. Avenal RTC at 79 (JA XX). EPA further explained that it had issued three guidance documents illustrating "how the AERMOD model may be used successfully to complete [the

required] analysis." Avenal RTC at 79 (JA XX). Petitioners have thus failed to demonstrate that the practical difficulties they regard as insurmountable even exist, let alone that they have been acknowledged by EPA.

C. EPA Appropriately Did Not Further Address Implementation.

The foregoing discussion assumes that Petitioners are arguing only that the revised NAAQS should not immediately apply to PSD permitting decisions. See Pet. Br. at 55. Petitioners' argument could, however, also be read as a challenge to some broader, unidentified implementation of the revised NO_2 NAAQS, or to EPA's approach of deferring implementation of the revised standard. See Pet. Br. at 47-48, 56. In either case, Petitioners' argument remains without merit.

As with EPA's purported "declaration" that the revised NAAQS is immediately applicable to PSD permitting, there is no final action for Petitioners to challenge. EPA may adopt regulations or take other steps to implement a new or revised NAAQS at the same time as it establishes that NAAQS. Alternatively, EPA may, as it did here, determine that no additional regulations are immediately necessary, and that it will issue regulations or guidance at a later date. EPA's brief statements in the preamble regarding potential future implementation of the revised NAAQS do not rise to the level of final agency action. See NRDC v. EPA, 559 F.3d 561, 565 (D.C. Cir. 2009) (declining to review conditional statements in preamble, on grounds that they did not amount to final agency action). Because

EPA did not take final action in the Rule to implement the revised NO_2 NAAQS, the Court by definition lacks jurisdiction over any claim that EPA erred in doing so.

Petitioners' claim that EPA did not respond adequately to comments on this issue, Pet. Br. at 47-48, is thus unfounded. EPA recognized the points that commenters raised regarding implementation. Response To Comments ("RTC") at 78-85 (JA XX-XX). Because these comments raised implementation issues that were not relevant to the Rule, EPA reasonably deferred addressing the substantive concerns raised in these comments until an appropriate time. See RTC at 84-85 (JA XX-XX) (stating EPA's intention to utilize current guidance and policies to implement the revised NAAQS for NO_2, with a commitment to review the need to provide additional technical and policy guidance following the promulgation of the NAAQS); see also id. at 79 (JA XX). Further response to these comments was not required under 42 U.S.C. § 7607(d)(6)(B) ("The promulgated rule shall also be accompanied by a response to each of the *significant* comments . . . submitted . . . during the comment period.") (emphasis added). And as anticipated, EPA has proceeded to issue guidance documents which specifically address how to model for the revised NO_2 NAAQS. See Notice Regarding Modeling for New Hourly NO_2 NAAQS (Feb. 25, 2010) (JA XX-XX); Applicability of Appendix W Modeling Guidance for the 1-Hour NO_2 [NAAQS] (June 29, 2010) (JA XX-XX);

Additional Clarification Regarding Application of Appendix W Modeling Guidance For the 1-Hour NO_2 [NAAQS] (March 1, 2011) (JA XX-XX).

In sum, Petitioners have failed to demonstrate anything unreasonable or unlawful in EPA's approach to the applicability and implementation of the revised NO_2 NAAQS.

CONCLUSION

For the foregoing reasons, the Petition for Review should be denied.

Respectfully submitted,
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DATED: October 28, 2011 (Initial Brief)

RESPONDENT'S CERTIFICATE OF COMPLIANCE WITH WORD LIMITATION AND TYPEFACE REQUIREMENTS

Respondent United States Environmental Protection Agency hereby represents that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 13,970 words, as counted by Microsoft Word, excluding the signature block and the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), and that it complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point type.

DATED: October 28, 2011

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CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing Brief for Respondents have been served through the Court's CM/ECF system on all registered counsel this 28th day of October, 2011.

DATED: October 28, 2011

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