ORAL ARGUMENT NOT YET SCHEDULED

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

No. 08-1200 (and consolidated cases)

STATE OF MISSISSIPPI, et al.,

Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

On Petition for Review of a Final Rule Issued by
The United States Environmental Protection Agency

FINAL BRIEF FOR RESPONDENT

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August 27, 2012

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

STATE OF MISSISSIPPI, *et al.*, Petitioners, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Respondent.	No. 08-1200 and consolidated cases

RESPONDENT'S CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel of record for Respondent United States Environmental Protection Agency ("EPA") submits this certificate as to parties, rulings and related cases.

A. Parties and Amici:

(i) Parties, intervenors, and amici who appeared below. Under Circuit Rule 28(a)(1)(A), the requirement to identify parties, intervenors, and amici who appeared below is inapplicable because the petitions seek review of informal agency rulemaking.

(ii) Persons who are parties, intervenors, and amici in this Court.

The parties and amicus to these consolidated cases are set forth in the

Certificate of Parties statement contained in the briefs filed by the Environmental Petitioners, State Petitioners, and Industry Petitioners.

B. Rulings Under Review:

Petitioners seek review of the final action taken by EPA at 73 Fed. Reg. 16,436 (March 27, 2008), entitled "National Ambient Air Quality Standards for Ozone."

C. Related Cases:

This case has not previously been before this Court or any other court. Petitioners are unaware of any related cases within the meaning of Circuit Rule 28(a)(1)(C).

/S/ Madeline Fleisher
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Dated: August 27, 2012

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TABLE OF ABBREVIATIONS

CASAC	Clean Air Scientific Advisory Committee
CD	Criteria Document
EPA	Environmental Protection Agency
FEV	Forced expiratory volume
IQA	Information Quality Act
NAAQS	National Ambient Air Quality Standards
OMB	Office of Management and Budget
PPM	Parts per million
RTC	Response to Comments
SP	Staff Paper

JURISDICTION

Jurisdiction exists under 42 U.S.C. § 7607(b).

STATUTES AND REGULATIONS

See the addendum filed with this brief.

STATEMENT OF ISSUES

1. Whether the Administrator of the United States Environmental Protection Agency ("EPA") reasonably adopted a revised eight-hour, 0.075 parts per million ("ppm") primary National Ambient Air Quality Standard ("NAAQS") for ozone?

2. Whether the Administrator reasonably adopted the revised secondary NAAQS?

3. Whether EPA's use of scientific information is reviewable for consistency with agency guidelines issued under the Information Quality Act, and if so, whether EPA acted consistently with those guidelines?

4. Whether EPA complied with 42 U.S.C. § 7408(a)'s direction for air quality criteria to "accurately reflect the latest scientific knowledge"?

STATEMENT OF THE CASE

In 2008, EPA revised the primary ozone NAAQS to 0.075 ppm, and set the secondary standard identical to the primary standard. 73 Fed. Reg. 16,436 (Mar. 27, 2008). EPA based its revision of the primary standard from its prior 0.08 ppm level on the latest scientific knowledge, including a large amount of new

information that had emerged since the Agency set the 0.08 ppm standard in 1997. EPA carefully evaluated this evidence to determine what conclusions it could draw about the public health effects of ozone and what uncertainties still remained, using a "weight of evidence" approach to assess how much confidence to place in the results of available studies.

The Administrator determined that there was direct clinical evidence demonstrating that ozone causes adverse effects in healthy people at levels down to 0.080 ppm; substantial evidence that asthmatics are likely to experience more serious adverse effects than healthy individuals; and epidemiological evidence showing statistically significant associations between ambient ozone and occurrences of serious adverse health effects such as hospital emergency department visits and hospital admissions in areas that would have met the 1997 standard of 0.08 ppm. EPA therefore decided to set a standard "appreciably below" 0.08 ppm to provide public health protection with an adequate margin of safety for both healthy individuals and those with asthma.

The Administrator selected a standard of 0.075 ppm, recognizing the continuing uncertainties about the effects of ozone below that level. This standard is challenged both by industry groups and one State that contend it is too stringent, and by several States and environmental and public health organizations that contend it is too lax.

BACKGROUND

I. Statutory Background

A. The Clean Air Act

The Clean Air Act, 42 U.S.C. §§ 7401-7671q ("CAA" or "Act"), is intended to "protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare." *Id.* § 7401(b)(1). NAAQS are a central element of the Act. CAA sections 108 and 109 require EPA to establish NAAQS for "criteria pollutants" that "cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare." *Id.* § 7408(a)(1)(A). Currently, there are NAAQS for six air pollutants: lead, particulate matter, ozone, carbon monoxide, sulfur dioxide, and nitrogen dioxide. The NAAQS establish permissible concentrations of these pollutants in the "ambient," or outside, air. States must then establish State Implementation Plans to attain and maintain the NAAQS within their borders. *Id.* § 7410.

The NAAQS process begins with the development of "air quality criteria," which must "accurately 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). EPA generally prepares a "Criteria Document," which contains rigorous reviews and assessments of the pertinent scientific studies and related information. Additionally, for this review EPA

conducted assessments providing quantitative estimates of ozone exposures and adverse health effects experienced by selected population groups, as well as adverse effects on vegetation. *See* EPA, Ozone Population Exposure Analysis for Selected Urban Areas (July 2007), JA 1178; EPA, Ozone Health Risk Assessment for Selected Urban Areas (July 2007), JA 1153; Abt Associates, Technical Report on Ozone Exposure, Risk, and Impacts Assessments for Vegetation (Jan. 2007), JA 703. EPA staff also prepare a "Staff Paper," an evaluative document that "bridges the gap" between the scientific review and the judgments required by the Administrator for standard-setting. *NRDC v. EPA*, 902 F.2d 962, 967 (D.C. Cir. 1990), *vacated in part on other grounds*, 921 F.2d 326 (D.C. Cir. 1991). ("*NRDC*"). These documents undergo extensive scientific peer review as well as public notice and comment. *See, e.g.*, 73 Fed. Reg. at 16,437-39.

Based on the air quality criteria, EPA promulgates "primary" and "secondary" NAAQS to protect against a pollutant's "adverse" effects on public health and welfare. 42 U.S.C. § 7409(b). "Primary" standards must be set at levels that, "in the judgment of the Administrator," are requisite to protect public health with "an adequate margin of safety." *Id.* 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." *Lead Indus. Ass'n v. EPA*, 647 F.2d

1130, 1154 (D.C. Cir. 1980) ("*LIA*"). Congress further defined public health broadly to include not just average healthy individuals but also sensitive people such as children who may be particularly vulnerable to air pollution. *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) ("*ALA*"). The "secondary" standards must protect public "welfare," which includes effects on soils, water, crops, vegetation, wildlife and climate, 42 U.S.C. § 7602(h), against "known or anticipated adverse effects." *Id.* § 7409(b).

The basic elements of NAAQS include: (1) the "indicator," which defines the chemical species or mixture to be measured; (2) the "form," which defines the air quality statistic to be compared to the level of the standard; (3) the "level," which defines the maximum permissible concentration of the pollutant; and (4) the "averaging time," which relates to the time period over which the level must be met. *See Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 516 (D.C. Cir. 2009) ("*AFB*").

EPA must set NAAQS without considering the cost of achieving them. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 471 (2001) ("*Whitman*"). In establishing the primary standards, EPA considers a number of factors, including the types of health evidence, the kind and degree of uncertainty, the nature and severity of health effects, and the size and nature of sensitive populations at risk. *See LIA*, 647 F.2d at 1161.

To ensure that NAAQS keep pace with advances in scientific knowledge, Congress also required that EPA review the criteria and NAAQS at five-year intervals, and revise them as "appropriate in accordance with [sections 108 and 109(b)]." 42 U.S.C. § 7409(d)(1). In its review, EPA must consider, and explain any significant departure from, the recommendations of the independent scientific review committee (the "Clean Air Scientific Advisory Committee" or "CASAC") established to advise the Administrator on air quality criteria and NAAQS. *Id.* §§ 7409(d)(2)(B), 7607(d)(3).

B. The Information Quality Act

The Information Quality Act ("IQA") directs the Office of Management and Budget ("OMB") to issue "guidelines" that provide "policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies . . . ." 44 U.S.C. § 3516, note (a).

OMB published guidelines implementing the IQA in 2002. *See* 67 Fed. Reg. 8452 (Feb. 22, 2002). These guidelines call on federal agencies to undertake three principal responsibilities: (1) to "adopt specific standards of quality that are appropriate for the various categories of information they disseminate"; (2) to "develop a process for reviewing the quality . . . of information before it is disseminated"; and (3) to "establish administrative mechanisms allowing affected

persons to seek" correction of information. *Id.* at 8458-59. The OMB guidelines state that "agencies must apply these standards . . . in a common-sense and workable manner." *Id.* at 8453.

In 2002, EPA issued its own IQA guidelines containing the Agency's "policy and procedural guidance for ensuring and maximizing the quality of the information we disseminate." Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the EPA at 3 (Oct. 2002) ("Guidelines"), JA 3283. The Guidelines set out three "performance goals," including that "[d]isseminated information should adhere to a basic standard of quality, including objectivity, utility, and integrity." *Id.* The Guidelines define "objectivity" as "whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased." *Id.* at 15, JA 3295. "Integrity" means "security . . . to ensure that the information is not compromised through corruption or falsification." *Id.* "Utility" means "the usefulness of the information to the intended users." *Id.* In addition, the Guidelines note that "influential" information that will have "a clear and substantial impact . . . on important public policies," *id.* at 19, JA 3299, should "have a higher degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed,

(3) the analytic methods applied, and (4) the statistical procedures employed." *Id.* at 21, JA 3301.

The Guidelines provide an administrative mechanism to seek correction of information. Guidelines 30-35, JA 3310-15. EPA also stated in the Guidelines that "[w]hen EPA provides opportunities for public participation by seeking comments on information, the public comment process should address concerns about EPA's information." *Id.* at 32, JA 3312. EPA specified that the Guidelines "are not a regulation and do not change or substitute for any legal requirements." *Id.* at 4, JA 3284.

II. EPA's Past Regulation of Ozone Pollution

Ozone is a powerful photochemical oxidant and lung irritant that occurs in the earth's lower atmosphere, where it is the principal component of smog. Ozone is not emitted directly into the air but results from chemical reactions between volatile organic compounds and nitrogen oxides (precursors) in the presence of sunlight and elevated temperatures. *Am. Petroleum Inst. v. EPA*, 665 F.2d 1176, 1181 (D.C. Cir. 1981) ("*API*"). Like other common air pollutants, ozone lacks a demonstrated "threshold": there is no known "bright line" below which it has been shown that there is no risk of health effects. *See API*, 665 F.2d at 1185; *NRDC*, 902 F.2d at 969.

EPA determines whether an ozone effect is "adverse" based on guidelines published by the American Thoracic Society, along with the advice of CASAC, focusing on whether a given effect interferes with an individual's normal activity or causes serious illness or injury. *See* 72 Fed. Reg. 37,818, 37,849/2-50/2 (July 11, 2007) ("2" refers to the column). EPA has identified a number of adverse health effects linked to ozone, including lung function decrements (generally measured by a breathing test to detect the percentage decrease in an individual's forced expiratory volume per one second ("FEV_1")); respiratory symptoms, such as cough, breathing discomfort, and wheezing; pulmonary inflammation and increased permeability that affect lung function; increased airway responsiveness to aggravating factors; and impairment of the lung's defenses against inhaled particles and microbes ("host defense"), which increases susceptibility to respiratory infection. *See* EPA, Review of the NAAQS for Ozone: Policy Assessment of Scientific and Technical Information at 3-4 to -5, 3-12 to -16, 3-52 (July 2007) ("Staff Paper" or "SP"), JA 755-56, 763-67, 803; 72 Fed. Reg. at 37,827/2. Ozone is also associated with more serious effects such as increased asthma medication use, emergency department visits, and hospital admissions. *See id.* at 37,827/2-29/3, 37,832/1-3.

EPA first promulgated NAAQS for photochemical oxidants in 1971 and revised them in 1979. 36 Fed. Reg. 8186 (Apr. 30, 1971); 44 Fed. Reg. 8202 (Feb.

8, 1979). EPA next revised the ozone NAAQS in 1997, when it replaced the former one-hour, 0.12 ppm primary standard with an eight-hour, 0.08 ppm standard (equivalent to 0.084 ppm under standard rounding conventions[1]), calculated based on the annual fourth-highest daily maximum eight-hour average concentration averaged over three years. *See* 62 Fed. Reg. 38,856, 38,873/2 (July 18, 1997). The switch from a one-hour to an eight-hour averaging time reflected new evidence showing that prolonged exposures to ozone at concentrations lower than that of the existing one-hour standard could cause serious adverse health effects. *Id.* at 38,861/2-3.

In determining the level for the 1997 primary standard, EPA considered the latest scientific knowledge, including clinical studies providing "clear evidence" that ozone causes adverse health effects at concentrations as low as 0.080 ppm. 61 Fed. Reg. 65,716, 65,727/3-28/3 (Dec. 13, 1996). The Administrator also took into account quantitative "[e]stimates of risk, in terms of the percentage of children likely to experience respiratory symptoms and decreases in lung function of concern . . . [and] estimates of exposures to the lowest concentration at which other, more uncertain effects have been observed." 61 Fed. Reg. at 65,729/1. The

[1] Because EPA allows ozone measurements to be rounded in determining compliance, an area with measured ozone levels at or below 0.084 ppm would still meet the 0.08 ppm standard. 72 Fed. Reg. at 37,853/1.

Administrator judged that a 0.08 ppm standard would provide the requisite public health protection. 62 Fed. Reg. at 38,867-68.

The Administrator set the 1997 secondary NAAQS equal to the primary standard as requisite to protect vegetation from ozone effects, judging that substantial uncertainties in the existing scientific knowledge prevented a conclusion that a lower standard or one in a seasonal form would provide any incremental benefits. *Id.* at 38,877/1, 38,878/1.

A number of parties sought review of the 1997 ozone NAAQS before this Court, along with the NAAQS for particulate matter ("PM") that EPA had promulgated at the same time, in *American Trucking Ass'ns, Inc. v. EPA*. The panel rejected several challenges to the ozone NAAQS. 175 F.3d 1027, 1040-45 (D.C. Cir. 1999) ("*ATA I*"), *reh'g granted in part*, 195 F.3d 4 (D.C. Cir. 1999) ("*ATA II*"). However, the panel remanded both the ozone and PM standards to EPA on the ground that CAA sections 108 and 109 constituted unconstitutional delegations of legislative power lacking an "intelligible principle" guiding their application. *ATA I*, 175 F.3d at 1034.

The Supreme Court reversed, holding that CAA section 109(b)(1) sufficiently limits EPA's discretion by requiring the Agency to set NAAQS at a level that is "requisite." *Whitman*, 531 U.S. at 475-76. The Supreme Court then remanded the case to this Court. The D.C. Circuit rejected all of the arguments

presented by petitioners on remand. *Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 378-80 (D.C. Cir. 2002) ("*ATA III*").

III. The 2008 Ozone Rulemaking

A. The Rulemaking Proposal

EPA initiated this review of the ozone NAAQS in September 2000 with a call for information for the preparation of a Criteria Document, exposure and risk assessment documents, and EPA Staff Paper. The Agency provided multiple opportunities for public and CASAC review of these documents, and made numerous changes to reflect CASAC and public comments. *See* 73 Fed. Reg. at 16,438. Based on the extensive new science discussed in these documents, the Administrator decided that the 1997 primary standard was not requisite to protect public health with an adequate margin of safety. *Id.* at 16,472/2-3. He therefore proposed a revised eight-hour standard in the range of 0.070 to 0.075 ppm,[2] in the same form as the 1997 standard. 72 Fed. Reg. at 37,878/1.

[2] The Administrator also decided to specify the level to the nearest thousandth ppm, based on improvements in measurement technology since the last review, when EPA had specified the standard to the nearest hundredth ppm. 73 Fed. Reg. at 16,475/2.

The Administrator also proposed revising the secondary standard, offering two alternatives: either a standard identical to the proposed primary standard or a cumulative, seasonal standard in the range of 7 to 21 ppm-hours.[3] *Id.* at 37, 905/1.

B. The Final 2008 Ozone Rule

On March 27, 2008, after receiving significant public comment on the proposal, 73 Fed. Reg. at 16,438/2, Administrator Johnson published a revised eight-hour, 0.075 ppm primary standard. He also issued a revised secondary standard identical to the new primary standard. *Id.* at 16,500/2.

1. Revision of the Primary Standard

a. Weight-of-the-Evidence Approach

In undertaking this review, EPA considered evidence of adverse health effects associated with ozone exposures as well as estimates of exposures and occurrences of health effects, "taking into account the nature and severity of the health effects, the size of the at-risk populations, and the kind and degree of the uncertainties associated with these considerations." 72 Fed. Reg. at 37,862/2-3; *see* 73 Fed. Reg. at 16,437/2. EPA's first step was to examine the "latest scientific knowledge" available regarding the public health effects of ozone, 42 U.S.C. § 7408(a)(2), looking to the Criteria Document, Staff Paper, CASAC advice and

[3] The unit of "ppm-hours" measures a plant's cumulative exposure to ozone as a "sum of weighted hourly concentrations, cumulated over the 12-hour daylight period (8 a.m. to 8 p.m.) during the consecutive 3-month period within the O_3 monitoring season with the maximum index value." 72 Fed. Reg. at 37,883/1-2.

recommendations, and public comments. 72 Fed. Reg. at 37,823/1. This scientific evidence consisted mainly of three types of studies: (1) clinical studies of human reactions to ozone exposures at varying levels and over varying amounts of time (also called "controlled human exposure" studies); (2) epidemiology studies examining occurrences of adverse health effects under actual ambient air conditions; and (3) animal toxicology studies investigating the biological mechanisms underlying ozone effects. As in 1997, the Administrator used a "weight of evidence" approach in analyzing this body of evidence to determine "the degree of confidence that various health effects are likely to be caused by exposure to O_3." 72 Fed. Reg. at 37,823/2-3.

Of the three types of evidence available, EPA gave the most weight to clinical studies, since they offer the most direct evidence of exposure-response relationships between ozone and various health endpoints. *Id.* at 37,823/2. Animal toxicology studies are subject to "the uncertainties of dosimetry differences and species sensitivity differences," and therefore EPA looked to those studies as demonstrating basic mechanisms of action for health effects of ozone exposure in humans. *Id.* Epidemiological studies may demonstrate mathematical associations but do not provide "direct evidence of a causal link between exposure to O_3 and the occurrence of health effects," and are subject to potential uncertainties stemming from factors such as the presence of confounding variables

(for example, other pollutants). *Id.*at 16,457/1. Therefore EPA weighed epidemiological evidence based on a number of criteria including: the *robustness* of the data after considering the effects of potential confounding factors (such as co-pollutants) or alternative models, 72 Fed. Reg. at 37,837/3; the *strength of the association* reported in the particular study, *id.*; the *consistency* of the epidemiological evidence with other epidemiological studies examining varying "persons, places, circumstances and times," *id.* at 37,823/3; and *coherence* across the same and similar health outcomes with clinical and toxicological studies providing *biological plausibility* for the observed effects. *Id.* at 37,838/1, 37,864/2; *see* 73 Fed. Reg. at 16,457/1.

b. At-Risk Groups

During the 1997 review, EPA identified individuals with asthma (and other lung diseases) as an at-risk "sensitive group" to be protected by the primary standard. The Agency reasoned that the same respiratory effects (such as lung function decrements and pulmonary inflammation) observed in clinical studies of healthy individuals would have a greater impact on those with already compromised respiratory symptoms and thus would be more likely to impair an individual's ability to engage in normal activity or to spur the need for medical treatment. 62 Fed. Reg. at 38,864/2; 61 Fed. Reg. at 65,720/1-2; *id.* at 65,722/1. In the Agency's 2008 review, citing significant new toxicological, clinical, and

epidemiological evidence, EPA concluded that asthmatics in fact experience greater responses than healthy individuals, not only greater impacts from the same responses. 72 Fed. Reg. at 37,846-48; *see generally* 73 Fed. Reg. at 16,445/1; SP 3-67 to -68, JA 818-19; EPA, Air Quality Criteria for Ozone and Related Photochemical Oxidants at 6-16 to -18 (Feb. 2006) ("Criteria Document" or "CD"), JA 373-75 (discussing new studies).

New clinical and toxicological studies provided important information about the role of ozone exposure in inducing increased airway responsiveness to aggravating factors, increased inflammatory responses, increased lung permeability, and impaired host defense in individuals with impaired baseline lung function (such as asthmatics), all of which would increase the likelihood of significant adverse consequences such as increased medication use, school absences, emergency department visits, and hospital admissions. 73 Fed. Reg. at 16,445/1-2; 72 Fed. Reg. at 37,830-32; CD 8-57 to -58, JA 663-64; SP 3-11 to -13, JA 762-64. Post-1997 epidemiological studies also showed associations between ozone exposure and increased respiratory symptoms, asthma medication use, emergency department visits, and hospital admissions, including large multicity panel studies of asthmatic children linking ozone to increased asthma medication

use.[4] 72 Fed. Reg. at 37,828-29, 37,847/3; SP 3-67, JA 818; CD 7-40 to -46, 7-51 to -55, JA 451-57, 462-66.

This evidence provided a coherent picture of mechanisms for ozone to exacerbate asthma, leading to serious adverse health effects, and led EPA to conclude that "it is likely that *more serious responses*, and *responses at lower levels*, would occur in people with asthma and other respiratory diseases." 72 Fed. Reg. at 37,863/3-64/1 (emphases added). Therefore, clinical and epidemiological studies of respiratory effects "that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O_3 exposure on asthmatics and other susceptible populations." *Id.* at 37,865/1.

c. New Health Effects Evidence

EPA's analysis of whether and, if so, how it would be appropriate to revise the 0.08 ppm standard first focused on new evidence that had arisen since the last review. As the Agency explained, the 1997 standard was set primarily based on clinical studies showing "lung function decrements, respiratory symptoms, and respiratory inflammation in humans, as well as epidemiology studies reporting excess hospital admissions and emergency department visits for respiratory

[4] In these panel studies, the subjects kept daily diaries of their symptoms, allowing "health effects to be modeled with each subject serving as their own control over time." CD 7-48, JA 459; *id.* at 7-51 to -52, JA 462-63 (describing particular panel studies).

causes." 73 Fed. Reg. at 16,440/1. EPA described an array of new evidence that had arisen since then. *See id.* at 16,440/1-2, 16,470-71.

i. Lung Function Decrements, Respiratory Symptoms, Pulmonary Inflammation, and Increased Airway Responsiveness

At the time of the last NAAQS review, there were statistically significant controlled human exposure studies demonstrating that an array of respiratory effects – including lung function decrements, respiratory symptoms, pulmonary inflammation, and increased airway responsiveness – are caused by ozone exposures down to 0.080 ppm. 73 Fed. Reg. at 16,445/1. Since then, more information has become available about the occurrence of such effects at and below 0.080 ppm.

The Adams Studies. First, two new controlled human exposure studies – the 2002 and 2006 Adams studies – examined effects of exposures down to 0.060 ppm in healthy subjects, producing results that "strongly suggest that exposure to 0.06 ppm O_3 causes small group mean FEV_1 decrements [*i.e.*, lung function decrements] in healthy adults with some individuals having notable effects." SP 3-9, JA 760; *see id.* at 3-6 to -8, JA 757-59 (explaining that in the 2002 and 2006 Adams studies, 7% of subjects experienced FEV_1 decrements greater than 10% at ozone exposures of 0.060 ppm over 6.6 hours, even where the group mean response was not large); *id.* at 3-9, JA 760 (noting that in the 2002 Adams study

20% of subjects exposed to ozone at 0.060 ppm experienced a FEV_1 decrement greater than 10%); CD 8-42, 8-69, JA 648, 675.

Since Adams had been examining health effects at each of six time points over 6.6 hours to assess the effects of different patterns of exposure, the Staff Paper further analyzed the 2006 Adams data based on a pre- to post-exposure comparison of effects of ozone versus filtered air. This analysis focused on the issue most relevant to setting the primary NAAQS: whether prolonged ozone exposure at 0.060 ppm has adverse health effects. SP 3-8, JA 759. The Agency found that the divergence of lung function responses to 0.060 ppm from the responses to filtered air "is suggestive of a significant effect on FEV_1." *Id.* Additionally, Adams' own 2006 analysis identified statistically significant respiratory symptom responses at that level. SP 3-9, JA 760 ("Adams (2006) reported that total subjective symptom scores (TSS) during the triangular 0.06 ppm exposure reached statistical significance (relative to preexposure at 5.6 and 6.6 hr . . . .)").

A scientist, Richard L. Smith, later offered a comment on the final Staff Paper in which he conducted a statistical reanalysis of the 2006 Adams data showing that healthy individuals experienced statistically significant lung function decrements at 0.060 ppm. Richard L. Smith, Public Comment to CASAC Ozone Review Panel March 5 2007 (Mar. 4, 2007) ("Smith Comment"), JA 1831. In light

of this comment, EPA subsequently verified Smith's results through a supplemental analysis of the 2006 Adams data. Memorandum from James S. Brown, EPA, to the Ozone NAAQS Review Docket (June 14, 2007), JA 1184; *see* 73 Fed. Reg. at 16,455/1; 72 Fed. Reg. at 37,828/2. This finding of statistical significance was based on a different statistical method than that used by Adams, who had relied on a statistical test, the Scheffé test, designed to minimize false positive findings of statistical significance (known as Type I errors) for the multiple comparisons he was conducting across multiple time points. Brown Mem. at 2, JA 1185. By contrast, Smith used a paired *t* test (commonly used in situations not involving the type of multiple comparisons with which Adams was concerned) to perform the analysis key to EPA's evaluation: a comparison of lung function pre- and post-exposure. Smith Comment at 3, JA 1834. He found that 0.060 ppm ozone exposures had statistically significant effects on lung function as compared to filtered air.[5] *Id.* In its reanalysis, EPA similarly concluded that "exposure to 0.06 ppm O_3 . . . causes a relatively small but statistically significant decrease (post- minus preexposure) in group mean FEV_1 responses compared to filtered air." Brown Mem. at 5, JA 1188. The magnitude of this response was

[5] Smith's analysis produced statistically significant results for both types of ozone exposures that Adams had studied – triangular exposures, where exposure concentration is increased and decreased linearly from a peak to produce an average exposure concentration for study, and square wave exposures, where the exposure concentration is constant throughout. Smith Comment at 3, JA 1186.

consistent with the trend in responses to exposures at 0.040 ppm and 0.080 ppm. *Id.*

Overall, EPA considered these results to be "very limited." 73 Fed. Reg. at 16,454/2. The Agency noted that these studies examined only 30 subjects each, 72 Fed. Reg. at 37,828/1, 37,858/1; only the 2006 study produced statistically significant results, *id.* at 37,828/2; and "the 0.060 ozone exposures and results have not been replicated," with the result that "some uncertainty exists and . . . further research is needed to clarify the issue." EPA, Response to Significant Comments on the 2007 Proposed Rule on the NAAQS for Ozone at 24 (Mar. 2008) ("RTC"), JA 3062. Additionally, Adams had not gathered data on health effects other than lung function decrements and respiratory symptoms, and for the other effects on which EPA was focused – inflammation, increased airway responsiveness, and impaired host defense – clinical studies had only shown adverse effects down to 0.080 ppm. 73 Fed. Reg. at 16,481/2. EPA therefore stated that the "percent of subjects that experienced FEV_1 decrements greater than 10% in this study of 30 subjects" could not "appropriately be generalized to the U.S. population." 73 Fed. Reg. at 16,454/2.

Epidemiology studies. Two new large U.S. epidemiological studies, as well as several smaller U.S. and international epidemiological studies, have demonstrated statistically significant associations between ozone exposure and

respiratory symptoms (*e.g.*, chest tightness and wheeze), as well as increased medication use, in asthmatic children. 73 Fed. Reg. at 16,445/2-3; 72 Fed. Reg. at 37,828-29, 37,865/1-2. These studies found such associations to be present even when conducted in geographic areas that met the 1997 standard of 0.08 ppm, or considering only days when ambient ozone levels were below 0.080 ppm. 73 Fed. Reg. at 16,445/2-3; 72 Fed. Reg. at 37,828-29. These effects were generally robust to adjustment for copollutants including particulate matter, a process that used statistical analyses to control for possible confounding factors that might also be responsible for the observed effects. *Id* at 37,829, 37,839; CD 7-53, JA 464.

Considering this evidence as part of the body of clinical, toxicological, and epidemiological evidence, EPA concluded that ozone exposure is causally associated with reduced lung function and other respiratory system effects, with a very high level of confidence, down to levels well below the then-current standard of 0.08 ppm. 72 Fed. Reg. at 37,845/1; *see generally id.* at 37,827-30, 37,875-76.

ii. Respiratory Hospital Admissions and Emergency Department Visits

EPA also found support for a causal relationship between ozone exposures and more serious adverse health effects in epidemiological studies that were controlled for confounding factors such as weather and copollutants. 72 Fed. Reg. at 37,832/1. The relevant new epidemiological evidence included studies showing significant associations between ozone and hospital admissions in the warm season

even in areas that would have met the 1997 standard of 0.08 ppm, including large, multi-city studies; studies of associations between ozone exposures and emergency department visits for various respiratory causes, especially asthma; and studies that continued to show associations between ozone exposure and health effects even when controlled for potential confounding effects. *Id.* at 37,832, 37,865-66.

EPA found this epidemiological evidence to be credible given its plausible biological basis as illustrated in clinical and animal toxicology studies. 72 Fed. Reg. at 37,832/1, 37,831; CD 7-175, 8-26, 8-77, JA 586, 632, 683. As EPA explained, effects observed in clinical and toxicological studies such as

> increased airway responsiveness, increased pulmonary inflammation, increased cellular permeability, and decreased pulmonary defense mechanisms . . . provide plausible mechanisms underlying observed associations with aggravation of asthma, increased medication use, increased school and work absences, increased susceptibility to respiratory infection, increased visits to doctors' offices and emergency departments, and increased admissions to hospitals.

73 Fed. Reg. at 16,471 n.20. EPA accordingly concluded that the associations between ozone and such health effects "extend down to O_3 levels well below the current standard." *Id.* at 16,444/2; *see id.* at 16,456/1 ("The biological plausibility of the epidemiological associations is generally supported by controlled human exposure and toxicological evidence of respiratory morbidity effects for levels at and below 0.080 ppm, but that biological plausibility becomes increasingly uncertain at much lower levels."); CD 8-77, JA 683.

iii. Mortality and Short-Term Ozone Exposure.

In the 1997 review, only limited evidence suggested a relationship between ozone and daily mortality. 72 Fed. Reg. at 37,835/1. Subsequent epidemiological evidence, including studies controlling for weather and copollutants, as well as large multi-city studies, have offered findings "highly suggestive" that "short-term O_3 exposure directly or indirectly contributes to non-accidental and cardiopulmonary-related mortality." 72 Fed. Reg. at 37,836/2; *see also id.* at 37,839/2, 37,866; CD 7-101 to -102, 8-78, JA 512-13, 684. New evidence linking ozone to cardiovascular morbidity effects also made this association more biologically plausible. 72 Fed. Reg. at 37,835. EPA did, however, note that there is currently only very limited knowledge regarding potential underlying mechanisms for mortality effects, and that "additional research is needed to more fully establish underlying mechanisms by which such effects occur." 73 Fed. Reg. at 16,447/1; *see also* 72 Fed. Reg. at 37,844. Ultimately, the Administrator identified the new mortality evidence as part of the body of evidence underlying his conclusion that revision of the 1997 standard was warranted, 73 Fed. Reg. at 16,470/3-72/1, but given the uncertainties regarding underlying biological mechanisms, the Administrator "did not focus on mortality as a basis for proposing that the current [1997] O_3 standard was not adequate." *Id.* at 16,460/2; *see also* CD 8-78, JA 684.

d. The Exposure and Risk Assessments

EPA put the scientific knowledge regarding ozone health effects "into a broader public health context" by conducting exposure and risk assessments. 72 Fed. Reg. at 37,823/3. These provided quantitative estimates under various alternative standards of the numbers and percentages of children, asthmatic children, and the general population in certain urban areas who would: (1) experience ozone exposures at and above various benchmark levels of ozone associated with adverse health endpoints ("exposures of concern"); and (2) experience certain adverse health endpoints based on alternative ozone standards. *Id.* at 37,823-24; *see generally id.* at 37,851-53, 37,857-59 (describing scope of both assessments).

For the exposure assessment, EPA projected how many individuals in, and what percentage of, these groups would be subject to exposures of concern at and above three benchmark levels: 0.080 ppm, 0.070 ppm, and 0.060 ppm. 72 Fed. Reg. at 37,824/1. The risk assessment provided quantitative risk estimates for the same groups for a range of respiratory morbidity effects, as well as non-accidental and cardiorespiratory-related mortality. 72 Fed. Reg. at 37,855-56. As part of this effort, EPA used a model to estimate "policy-relevant background" ozone concentrations – that is, the background ozone concentrations that would exist in the United States even without any anthropogenic emissions from the United

States, Canada, or Mexico – to be generally in the range of 0.015 to 0.035 ppm, depending on the area and month modeled.[6] 72 Fed. Reg. at 37,857; *see also* SP 2-48 to -55, JA 744-51. CASAC described the risk assessment as "well done, balanced and reasonably communicated." Letter from Dr. Henderson, CASAC Chair, to Administrator Johnson (Oct. 24, 2006), at 12, JA 1342 ("October 2006 CASAC Letter").

In describing the results of these assessments, EPA noted that although they provide important context in judging ozone's public health impacts, they do not present "a full picture of the O_3 exposures and O_3-related health risks posed nationally" because they do not include all relevant at-risk groups (omitting, for example, outdoor workers and children under age five) or all health effects linked to ozone exposure based on the body of scientific evidence. 73 Fed. Reg. at 16,447/1; *see also* 72 Fed. Reg. at 37,871/3. In particular, EPA recognized that the specific health endpoints modeled in the risk assessment are only part of a broader "'pyramid of effects' that include various indicators of morbidity that could not be included in the risk assessment (*e.g.*, school absences, increased medication use, emergency department visits) and which primarily affect members

[6] EPA concluded that its estimate of policy relevant background in the prior review – an average value of 0.04 ppm – was likely too high, based on more recent ozone measurements, and updated the estimate through the use of a newly available global model that appropriately reflects the spatial and temporal variability in policy relevant background ozone concentrations across the United States. SP 2-55, JA 751.

of at-risk groups." *Id.* at 37,868/2; *see also* SP 6-18 to -19, JA 1026-27 (explaining that ozone-related effects such as nonspecific airway responsiveness, decreased pulmonary defense mechanisms, and pulmonary inflammation are indicators of more serious morbidity effects, including increases in asthma medication use, school and work absences, doctor and emergency department visits, hospital admissions, susceptibility to respiratory infection, and potentially cardiovascular or chronic pulmonary effects); 73 Fed. Reg. at 16,471 n.20 (similar). Therefore, EPA considered the fact that the public health impacts of ozone are "clearly much larger than the quantitative" exposure and risk estimates indicate. 73 Fed. Reg. at 16,465/1 (citation omitted). Additionally, EPA noted that the results of the exposure assessment constitute a continuum, "with greater confidence and less uncertainty about the existence of health effects at the upper end and less confidence and greater uncertainty as one considers increasingly lower O_3 exposure levels." 72 Fed. Reg. at 37,853/3; *see also id.* at 37,859/2 (risk assessment).

e. The Administrator's Conclusions

EPA used all of the new information described above to "build[] upon the last review," 72 Fed. Reg. at 37,862/1, and concluded that the 0.08 ppm standard was *not* requisite to protect the public health with an adequate margin of safety. 73 Fed. Reg. at 16,470/3. In support of this determination, the Administrator relied on

the robust body of scientific evidence before him, which strengthened existing conclusions about the health effects of ozone and provided new evidence supporting increased confidence in the causal relationships underlying those effects at lower ozone levels than in the 1997 review. *Id.* at 16,470/3-71/1. The Administrator particularly cited new evidence including: (1) evidence demonstrating lung function decrements and respiratory symptoms in healthy individuals at ozone levels down to 0.080 ppm, with very limited clinical evidence of such effects at exposures well below the 1997 standard, along with new information about the susceptibility of individuals with asthma as likely to experience greater effects than healthy individuals; (2) epidemiological evidence of serious health effects in areas that likely would have met the 1997 standard; (3) epidemiological studies that show serious health effects even when days above 0.08 ppm are excluded; and (4) clinical and toxicological evidence providing considerable support for the biological plausibility of reported epidemiological evidence and for concluding that associations between such health effects and ozone levels extend below the level of the 1997 standard. 73 Fed. Reg. at 16,471/1-2. As "additional support to the evidence-based conclusion . . . that the" 1997 standard was not requisite, the Administrator also considered the results of the exposure and risk assessments in providing estimates of the exposures and risks remaining upon meeting the then-current standard, which he judged were

important from a public health perspective. *Id.* at 16,472/1; *see also id.* at 16,471/2-72/2; 72 Fed. Reg. at 37,870, 37,871/3, 37,879/1.

This judgment accorded with the recommendations provided by CASAC and in the EPA Staff Paper. CASAC unanimously concluded that:

> 1. There is no scientific justification for retaining the current primary 8-hr NAAQS of 0.08 parts per million (ppm), and
>
> 2. The primary 8-hr NAAQS needs to be substantially reduced to protect human health, particularly in sensitive subpopulations.

October 2006 CASAC Letter at 1-2, JA 1331-32; *see also* Letter from Dr. Henderson, CASAC Chair, to Administrator Johnson at 2 (Mar. 26, 2007), JA 1444. Likewise, the Staff Paper concluded that the adequacy of the 1997 standard had clearly been called into question by the overall body of evidence showing significant adverse health effects even below 0.08 ppm, particularly for at-risk groups such as asthmatics. 72 Fed. Reg. at 37,868/1.

Having judged that the 1997 standard was not requisite to provide the necessary public health protection, the Administrator had to determine what standard would protect public health with an adequate margin of safety. Considering "both the degree of additional protection that alternative levels of the standard might be expected to provide as well as the certainty that any specific level will in fact provide such protection," the Administrator proposed setting the primary standard in the range of 0.070 ppm to 0.075 ppm. *Id.* at 37,879/1-2.

In reaching this proposed decision, the Administrator judged that a standard of 0.080 ppm, though lower than the effective 1997 standard of 0.084 ppm, would still be at a level "at which the evidence provides a high degree of certainty about the adverse effects of O_3 exposure even in healthy people." 72 Fed. Reg. 37,879/1. He based that determination on evidence of adverse health effects in healthy individuals at ozone levels at and below 0.080 ppm, evidence that asthmatics are more susceptible to ozone effects than healthy people, and estimates of exposures of concern and health risks under a 0.080 ppm standard. *Id.* Further, the Administrator concluded that a standard above 0.075 ppm would still be "higher than what is requisite to protect public health, including the health of at-risk groups, with an adequate margin of safety." 73 Fed. Reg. at 16,478/1.

The Administrator also judged that a standard lower than 0.070 ppm would not be appropriate, given that there is only "very limited" clinical evidence at exposure levels below 0.080 ppm, while the great majority of the evidence below 0.080 ppm is epidemiological studies showing associations at those levels, but not direct evidence of a causal link. 72 Fed. Reg. at 37,879/1-2. The Administrator cited the "quite limited" nature of the clinical evidence, along with the mixed results of epidemiological studies, in concluding that evidence of causal associations "becomes increasingly uncertain at lower levels of exposure." *Id.* at 37,880/1. Given these considerations, the Administrator judged that such lower

standard levels "would likely be below what is necessary to protect public health with an adequate margin of safety." *Id.* at 37,880/2.

Ultimately, the Administrator decided that a primary eight-hour ozone standard of 0.075 ppm would be requisite to protect public health, including the health of at-risk groups such as asthmatics, with an adequate margin of safety. 73 Fed. Reg. at 16,482-83. He explained that a 0.075 ppm standard would provide "a significant increase in protection compared to the current standard, and is appreciably below 0.080 ppm, the level . . . at which adverse effects have been demonstrated." *Id.* at 16,483/2. The Administrator noted that, focusing on exposures at and above a benchmark of 0.070 ppm, such exposures are substantially reduced or eliminated for the vast majority of people in at-risk groups by a standard set at 0.075 ppm, with no appreciable difference, from a public health perspective, in the reductions of such exposures that would be associated with a standard set at 0.070 ppm. *Id.* at 16,481/3, 16,483/2. Weighing this evidence and estimates of public health effects alongside the uncertainties as to the public health benefits of preventing exposures at lower levels, Administrator Johnson concluded that, in his judgment, a standard of 0.075 ppm would draw the "appropriate balance . . . based on the entire body of evidence and information," while remaining "sufficient to protect public health with an adequate margin of safety." *Id.*

The Administrator acknowledged that this level was above the CASAC-recommended range of 0.060-0.070 ppm. *Id.* at 16,482/3. He observed that, without a bright line demarcating a known threshold ozone level responsible for adverse health effects, the choice of a requisite level is a policy judgment that rests on consideration of the strengths and limitations of the body of scientific evidence. *Id.* at 16,482-83. The Administrator explained that, in analyzing the body of evidence, he placed different weight than CASAC in two areas: "the role of the evidence from the Adams studies and the relative weight placed on the results from the exposure and risk assessments." *Id.* at 16,483/1. On the first point, he noted that CASAC had supported standards above 0.060 ppm, "indicating that they do not believe that the results of Adams studies mean that the level of the standard has to be set at 0.060 ppm." *Id.* at 16,483/1. As to the exposure and risk assessments, the Administrator reiterated the heavy weight he placed on the uncertainties associated with those assessments. *Id.*

2. Revision of the Secondary Standard

EPA conducted an "integrative synthesis" of the available evidence regarding the public welfare effects of ozone, in particular effects on vegetation and other ecosystem components. 73 Fed. Reg. at 16,485/2. The Agency also conducted quantitative and qualitative assessments of risks to vegetation from ozone exposure. *Id.* at 16,488/2. EPA explained that research since the last review

had provided important new information in the form of field-based exposure studies and controlled open top chamber studies. *Id.* at 16,485/2-3. The Agency observed that available evidence had reduced uncertainties since the last review both as to the levels of vegetation response at various ozone concentrations and as to ozone concentration measurements in rural areas (which tend to have fewer ambient air monitors). *Id.* at 16,494-95.

Based on this information, EPA determined that then-current air quality levels could cause significant impacts on vegetation, such as visible foliar injury, biomass loss from tree seedlings and mature trees, and crop yield reductions, and that such impacts would persist even in areas meeting the 1997 secondary standard. *Id.* at 16,487/3-88/1, 16,488/3-89/3, 16,494/2-3, 16,496/2. The Agency judged that these effects could be considered adverse "depending on the intended use of the plant and its significance to the public welfare." *Id.* at 16,496/2. EPA also anticipated that ozone would cause other adverse effects impacting the vigor of sensitive plant species, thus affecting overall ecosystem biodiversity and function. *Id.*

Given the "intended use" of some public lands that have been set aside by Congress and other governmental entities to protect their scenic value and natural ecosystems "for the enjoyment of future generations," and EPA's judgment that ozone exposures at the level of the 1997 standard would impair those uses, the

Agency concluded that revision of the 1997 secondary standard was warranted. *Id.* at 16,496/3. CASAC similarly viewed the 1997 secondary standard as no longer requisite in light of the available new information. October 2006 CASAC Letter at 6, JA 1336. At the same time, EPA noted significant remaining uncertainties about the extent and significance of crop yield effects, based on the lack of current data and the "extensive management" of crops to maximize yields. 73 Fed. Reg. at 16,497/1. CASAC also noted the "high uncertainties" in quantitative evidence regarding the effects of ozone concentrations on vegetation and ecosystems. October 2006 CASAC Letter at 6, JA 1336.

In assessing what revised standard would be requisite, EPA considered a standard in both the same form as the primary standard (an eight-hour standard), set between 0.060 and 0.080 ppm, and a cumulative, seasonal form (the "W126" form), set between 7 and 21 ppm-hours.[7] 72 Fed. Reg. at 37,882/3-83/1. The Agency noted that CASAC had recommended a somewhat lower range – a cumulative, seasonal standard of 7 to 15 ppm-hours – but cited "the uncertainty in determining the risk attributable to various levels of exposure to O_3" as grounds for the Administrator's policy judgment that a standard up to 21 ppm-hours could be reasonable. 72 Fed. Reg. at 37,903/2.

[7] The W126 function calculated the cumulative ozone exposure of plants in a given geographic area based on the sum of weighted hourly ozone concentrations during the 12-hour daylight period over three months of the ozone monitoring season. 72 Fed. Reg. at 37,883/1-3.

EPA had, in the last review, discussed the basis for a cumulative, seasonal form as the most biologically relevant form for protection against harmful effects on vegetation. 73 Fed. Reg. at 16,486/3 (citing 61 Fed. Reg. at 65,716). The Agency continued to have that view in this rulemaking. 73 Fed. Reg. at 16,493/3-94/1. However, as in 1997, the Administrator chose not to use a cumulative, seasonal form for the secondary standard. *Id.* at 16,499/3-500/1. Based on the significant uncertainties about the degree of risk associated with various ozone levels, and the consequent difficulty in determining whether the degree of protection provided by a cumulative seasonal standard would be "sufficient but not more than what is necessary," the Administrator instead chose to set the secondary standard identical to the revised primary standard. *Id.* at 16,500/1-2.

In support, the Administrator cited the Staff Paper's analysis of the extent to which alternative eight-hour standards would provide protection equivalent to various cumulative, seasonal standards, using 2002 to 2004 air quality data. *Id.* at 16,499/3; *see also id.* at 16,498/1; 72 Fed. Reg. at 37,883/1-2. The Administrator noted that this analysis indicated that a 0.075 ppm, eight-hour standard would significantly overlap with a standard based on the W126 form, "depending greatly on the W126 level selected and the distribution of hourly O_3 concentrations within the annual and/or 3-year average period." *Id.* at 16,499/3. The Administrator focused on a W126 level of 21 ppm-hours, at the top of the proposed range, citing

the "significant uncertainties that remain in the available body of evidence of O_3-related vegetation effects and in the exposure and risk analyses conducted for this review, and the difficulty in determining at what point various types of vegetation effects become adverse for sensitive vegetation and ecosystems." *Id.* The Staff Paper indicated that essentially no county meeting the revised 0.075 ppm primary standard would exceed this 21 ppm-hours level on a cumulative, seasonal basis. *Id.* at 16,500/1. Thus, the Administrator concluded a secondary standard set equal to the primary standard would protect public welfare from known or anticipated adverse effects. *Id.* at 16,500/2.

IV. This Litigation

After EPA promulgated the final 2008 Ozone NAAQS, multiple parties filed petitions for review in this Court challenging the rule. These petitioners comprise several industry petitioners and the State of Mississippi ("Industry Petitioners"), who contend that revision of the 1997 standard was not appropriate; and environmental and public health groups and 15 state petitioners, who contend that the 2008 standard is not adequately protective ("Environmental Petitioners" and "State Petitioners").

On March 9, 2009, EPA filed an unopposed motion requesting that the Court hold these cases in abeyance to allow time for the new Administrator to review the rule and determine whether it should be reconsidered. Doc. No. 1169527. This

motion was granted, and the abeyance was continued after EPA notified the Court of its decision to initiate a rulemaking to reconsider the 2008 Ozone NAAQS. Doc. No. 1226738.

EPA subsequently published notice of a proposed rule, in which the Agency proposed setting the primary standard at a level between 0.060 and 0.070 ppm and adopting a new secondary standard using a cumulative, seasonal average form. 75 Fed. Reg. 2938 (Jan. 19, 2010). Meanwhile, EPA also initiated its next review of the 2008 ozone NAAQS, required under CAA section 109(d)(1), shortly after the 2008 NAAQS were promulgated. 73 Fed. Reg. 56,581 (Sept. 29, 2008).

On September 12, 2011, EPA notified the Court that the draft final reconsideration rule the Agency had submitted for inter-agency review pursuant to Executive Order 12,866 had been returned to EPA for further consideration. Doc. No. 1329010, at 3. EPA explained to the Court that it no longer intended to take final action on the reconsideration rulemaking in the near future, but would instead be completing the reconsideration in conjunction with the next periodic review, and that it would therefore be appropriate for the Court to issue a briefing schedule for these cases. The Court did so on February 17, 2012.[8] Doc. No. 1359125.

[8] The February 17, 2012 Order also granted EPA's motion to dismiss a separate case that had been brought by several petitioners in this action, challenging EPA's deferral of the reconsideration rulemaking. *Am. Lung Ass'n v. EPA*, No. 11-1396. The Court held that it did not have jurisdiction to review that non-final action. Doc. No. 1359125 at 2.

STANDARD OF REVIEW

The 2008 Ozone NAAQS is subject to judicial review under CAA § 307(d)(9), which provides that the Court may reverse any action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 7607(d)(9). The "arbitrary or capricious" standard presumes the validity of agency action, and a reviewing court is to uphold the action if it satisfies minimum standards of rationality. *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 520-21 (D.C. Cir. 1983); *Ethyl Corp. v. EPA*, 541 F.2d 1, 34 (D.C. Cir. 1976). Where EPA has considered the relevant factors and articulated a rational connection between the facts found and the choices made, its regulatory choices must be upheld. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also LIA*, 647 F.2d at 1158 ("[W]here there is evidence in the record which supports [the Administrator's] judgments, this court is not at liberty to substitute its judgment for the Administrator's.").

These principles are particularly applicable in review of EPA's NAAQS decisions, since such decisions present "complex questions of science, law, and social policy," which necessarily involve judgments "at the very 'frontiers of scientific knowledge.'" *LIA*, 647 F.2d at 1176 (quoting *Ethyl Corp.*, 541 F.2d at 24). Courts must be at their most deferential when reviewing aspects of an agency decision that rest on an evaluation of complex scientific data within the agency's

technical expertise. *See, e.g.*, *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983); *Ethyl Corp.*, 541 F.2d at 36 ("[The court] must look at the [agency's] decision not as the chemist, biologist or statistician that [it is] qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality."). It is not the court's "function to resolve disagreement among the experts or to judge the merits of competing expert views." *LIA*, 647 F.2d at 1160. "That the evidence in the record may also support other conclusions, even those that are inconsistent with the [EPA] Administrator's, does not prevent [the court] from concluding that his decisions were rational and supported by the record." *Id.*

"[W]here, as here, the statute is '*precautionary*' in nature, the evidence 'uncertain or conflicting' and the 'regulations designed to protect the public health,' the court 'will not demand rigorous step-by-step proof of cause and effect.'" *NRDC*, 902 F.2d at 968 (quoting *Ethyl*, 541 F.2d at 28). Thus, EPA may draw conclusions from "suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as 'fact,' and the like." *Id.* (quoting *Ethyl*, 541 F.2d at 28).

Nor is EPA required to follow any particular paradigm of decisionmaking. *Id.* at 973-74; *LIA*, 647 F.2d at 1161-62. Recognizing that the final choice of a

standard is a "'quintessential policy judgment within the discretion of EPA,'" a court may not reverse if a careful review of the record shows that "the Administrator has provided an explanation of why [she] chose one method rather than another, and this explanation and [her] choice are not irrational." *LIA*, 647 F.2d at 1162 (citation omitted).

SUMMARY OF ARGUMENT

Setting a NAAQS expressly requires exercise of the Administrator's scientific and policy judgment, especially for a pollutant such as ozone that has no demonstrated effects threshold. With respect to the primary standard, EPA has identified a methodology to guide it in that task: the "weight of evidence" approach. EPA reasonably analyzed the available evidence using that approach to assess the factors relevant to judging the public health impacts of ozone: the nature and severity of the health effects, the size of the at-risk populations, and the kind and degree of the uncertainties associated with these considerations.

Industry, Environmental, and State Petitioners' attacks all rest on picking out bits and pieces of evidence they consider to be favorable to their arguments, but they fail to consider that evidence in light of the whole body of scientific evidence in the record. Most importantly, each set of parties discounts the importance of uncertainty in weighing the studies they discuss. Industry Petitioners dismiss all evidence that is less than completely certain, essentially arguing that it merited no

weight in the Administrator's decision. In doing so, they fail to consider the body of evidence as a whole, and also disregard EPA's obligation to incorporate an adequate margin of safety into the primary standard to address risks that are not yet precisely understood or quantified. Industry Petitioners' allegations that EPA did not accurately summarize the scientific information before it, meanwhile, are belied by the record of the Agency's detailed account of all of the available evidence.

Environmental and State Petitioners, on the other hand, contend that the 0.075 ppm standard is not requisite based on certain evidence regarding the effects of ozone below 0.080 ppm, and that EPA was required to protect against such effects, no matter how uncertain. In both cases, EPA's reasoned consideration of the strengths and weaknesses of the cited evidence, amply supported by the record, merits the Court's deference.

As for the secondary standard, Environmental and State Petitioners similarly argue that the evidence can only support their scientific and policy judgment, despite the Administrator's explanation of the uncertainties that caused him to reach different conclusions. The Court should defer to EPA's reasoning regarding the uncertainty remaining in the latest science on the known and anticipated public welfare effects of ozone, and the Administrator's policy judgment as to the significance of those impacts on the public welfare.

ARGUMENT

I. EPA'S DETERMINATION THAT THE 1997 STANDARD IS NO LONGER REQUISITE WAS NEITHER ARBITRARY NOR CAPRICIOUS.

A. EPA Reasonably Concluded that the 1997 Standard Should Be Revised.

Given the lack of evidence of a bright-line threshold in the health effects of ozone, 73 Fed. Reg. at 16,477/2, the selection of a requisite standard necessarily required that the Administrator balance the different types of evidence based on their relative strengths and uncertainties, exercising his policy judgment. *ATA III*, 283 F.3d at 360 ("The lack of a threshold concentration below which these pollutants are known to be harmless makes the task of setting primary NAAQS difficult, as EPA must 'select ... standard level[s] that ... reduce risks sufficiently to protect public health' even while recognizing that 'a zero-risk standard is [not] possible.'" (citation omitted; alterations in original)); *see* 42 U.S.C. § 7409(b)(2) (providing that the choice of standard is "in the judgment of the Administrator"). This judgment must be upheld as long as it is the result of reasoned decisionmaking that acknowledges the uncertainties in setting a NAAQS for a non-threshold pollutant. *API*, 665 F.2d at 1185. Industry Petitioners argue that EPA's decision to revise 1997 primary NAAQS fails under this standard. Industry Br. 19. However, the Administrator's determination that a 0.08 ppm standard was not requisite was well within the bounds of reasonableness.

There are two significant points as to which none of Petitioners challenge the Administrator's judgment. First, the Administrator found that available evidence showed that asthmatics suffer greater effects from ozone exposure than do healthy individuals, and at lower levels. *See supra* 15-17. Consequently, the Administrator reasonably determined that this evidence meant that studies of ozone effects in healthy subjects would likely underestimate risks to asthmatics. 72 Fed. Reg. at 37,865/1; 73 Fed. Reg. at 16,450/1. Second, the Administrator rationally interpreted clinical studies to support a clear causal relationship between ozone and adverse health effects in healthy individuals at levels down to 0.080 ppm. *Id.* at 16,466; *see* 72 Fed. Reg. at 37,827-31.

A third important factor in the Administrator's decision that revision was warranted was epidemiological evidence showing significant adverse health effects below the level of the 1997 standard. The Administrator considered a number of new epidemiological studies and judged that they demonstrated statistically significant associations between ozone exposures and an array of adverse health effects – including serious effects such as increased asthma medication use in children with moderate to severe asthma, hospital admissions, and emergency department visits. 73 Fed. Reg. at 16,450/1-2; SP 3-17 to -19, JA 768-70. This new evidence included two large panel studies reporting statistically significant associations with respiratory symptoms and increased asthma medication use,

along with several other single-city studies showing robust positive associations. 73 Fed. Reg. at 16,445/2-3. The Administrator also highlighted several new large, multi-city studies that found associations with respiratory-related hospital admissions. *Id.* at 16,446/1. *See generally* 72 Fed. Reg. at 37,842 (chart aggregating results of available epidemiological studies). These findings were generally robust even when controlled for the possible confounding effects of other pollutants such as particulate matter. 73 Fed. Reg. at 16,445-46, 16,458-59. Most importantly, several of these studies specifically looked at areas meeting the 1997 standard, or subsets of days when ozone levels were below 0.080 ppm, and still found statistically significant associations. *Id.* at 16,445/3, 16,446/1, 16,471/1-2. The Administrator reasonably judged the findings of these studies to be biologically plausible in light of available clinical and toxicology studies, particularly those that linked ozone exposure to aggravation of asthma and increased susceptibility to respiratory infection. *Id.* at 16,471/2, 16,444/2; SP 3-19, JA 770. He also regarded the epidemiological data as consistent and coherent across a large number of various types of studies. 73 Fed. Reg. at 16,479/2-3.

Each of the above conclusions was consistent with the assessment in the Staff Paper and CASAC's independent appraisal of the evidence, further supporting the rationality of the Administrator's analysis based upon the evidence available in 2008. *See* CD 8-73 to -82, JA 679-88; SP 6-46 to -82, 6-85 to -87, JA

1054-60, 1093-95; October 2006 CASAC Letter at 3-5, JA 1333-35. Administrator Johnson also found support for his conclusions in the exposure and risk assessments, which showed that if the 1997 standard was left in place, significant proportions of sensitive populations such as children and asthmatics would still be exposed to ozone at levels associated with adverse health effects such as lung function decrements, respiratory symptoms, and hospital admissions, as well as a broader "pyramid of effects." 73 Fed. Reg. at 16,471/2-72/1.

Weighing this body of evidence, the Administrator determined that there was a "high degree of certainty about the adverse effects of O_3 exposure even in healthy people" at levels down to 0.080 ppm. *Id.* at 16,476/3. He thus reasonably determined that the primary standard should be "set at a level appreciably below 0.080 ppm." *Id.* at 16,480/2-3. This approach would protect "sensitive citizens" in accordance with the Administrator's obligation to provide an "adequate margin of safety." *Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617-18 (D.C. Cir. 2010) ("*CBR*"). In the words of *Whitman*, the Administrator judged that the existing standard of 0.08 ppm would not be "sufficient" to protect public health with an adequate margin of safety based on the strong evidence that ozone causes such effects in healthy people at concentrations down to 0.080 ppm and in asthmatics at even lower levels. 531 U.S. at 473; 73 Fed. Reg. at 16,483/2.

B. EPA's Approach to Determining the Requisite Primary Standard Was Consistent with the Requirements of the Clean Air Act.

Industry Petitioners attack the legal validity of EPA's primary standard, arguing that the Administrator's decision to revise improperly rested on a bare finding that a 0.075 ppm standard would provide "increased protection" as compared to the 1997 standard. Industry Br. 25. This argument has neither a legal nor a factual basis.

Section 109(b)(1) does not direct EPA to utilize any particular means to determine the requisite NAAQS; rather, EPA must simply select a level that is "not higher or lower than necessary . . . to protect the public health with an adequate margin of safety." *Whitman*, 531 U.S. at 476; *see also NRDC*, 902 F.2d at 971; *LIA*, 647 F.2d at 1161-62. EPA retains significant discretion in making that public health policy judgment, and is simply required to "engage in reasoned decisionmaking" in reaching its conclusions. *ALA*, 134 F.3d at 392; *see also LIA*, 647 F.2d at 1146-47.

Such reasoning often involves comparison of the levels of protection offered by proposed standards. Although Industry Petitioners cite *Farm Bureau* as criticizing EPA's "analysis of the relative protection" of alternative secondary NAAQS, in fact that decision faulted EPA because its "analysis demonstrate[d] nothing about the relative protection offered by the different standards" – in other words, because EPA had not conducted a *reasonable* comparison between the

alternative standards under consideration. *AFB*, 559 F.3d at 530. As always, the focus of judicial review is simply whether EPA has articulated a reasoned basis for its assessment of alternative standards. *See, e.g.*, *id.* at 527 (upholding EPA's decision to rely primarily on its evaluation of the body of scientific evidence rather than a quantitative risk assessment in comparing the public health protection offered by alternative particulate matter primary standards, since the Agency offered a reasoned explanation for doing so); *ATA III*, 283 F.3d at 374 (similar).

EPA took such a reasoned approach here. Contrary to Industry Petitioners' suggestion, EPA did not merely decide to revise the 1997 standard based on an unqualified finding of "increased protection." Rather, EPA also considered the *nature and severity* of the public health impacts that a lower standard would offer protection against; the *size of the at-risk population groups* experiencing those impacts; and the *kind and degree of uncertainties* associated with evidence of ozone effects in determining whether revision of the 1997 standard would be appropriate. 72 Fed. Reg. at 37,862/2-3; *see also* 73 Fed. Reg. at 16,437/2.

First, EPA focused significant effort on determining how much confidence to place in evidence linking adverse health effects to particular levels of ozone exposure. Specifically, EPA had a "high degree of certainty" that ozone causes adverse health effects at exposure levels down to 0.080 ppm, including serious health effects such as emergency department visits and hospital admissions, 73

Fed. Reg. at 16,476/3, supporting to the Administrator's judgment that revision of the 1997 standard was warranted given the degree and certainty of public health protection provided by such revision. *Id.* at 16,476/2-3. By contrast, the Administrator expressly declined to set a standard lower than 0.075 ppm – even though doing so would provide increased protection against some exposures at lower levels – because there remained important uncertainties about whether ozone exposures at those lower levels are causally linked to adverse health effects. *Id.* at 16,483/2. The Administrator thus did not make an arbitrary choice to seek increased protection against ozone exposures unmoored from any consideration of whether those exposures would result in public health impacts. Rather, he exercised his judgment based on a reasoned analysis of whether additional protection against lower ozone exposures was necessary to avert adverse public health effects with an adequate margin of safety.

C. EPA Reasonably Determined that the Record Warranted Revision of the 1997 Standard.

Industry Petitioners' complaints regarding EPA's determination that the 1997 standard must be revised are rooted in their contention that "little has changed" since the 1997 NAAQS – in essence, that the available scientific information about the health effects of ozone exposure is the same, and therefore the "requisite" standard should also remain the same. Industry Br. 26. However, the Administrator reasonably explained why his judgment was different than the

conclusion reached in 1997, based on the greatly expanded body of scientific information.

1. Industry Petitioners Fail to Recognize the Role of Uncertainty in the 1997 and 2008 Reviews.

Industry Petitioners inaccurately describe the basis for the 1997 primary standard. They ignore EPA's "weight of evidence" approach, which relies on an integrated assessment of *all* of the evidence at hand as well as an evaluation of relevant uncertainties, rather than the perfunctory cataloguing of health effects that Industry Petitioners perform. This failure leads Industry Petitioners to wrongly disregard the role of uncertainty in the 1997 and 2008 reviews, overlooking the significant impact of new evidence on EPA's certainty regarding ozone's adverse health effects at various levels, even as to those effects that EPA did give some weight in setting the 1997 standard.

Industry Petitioners list several categories of evidence that EPA considered in 1997 and the population groups that the Agency considered to be sensitive. Industry Br. 8-10. Based on a superficial tally, they assert that this 1997 evidence matches the evidence available today. *Id.* at 28-37. What Industry Petitioners fail to convey is that in the prior review EPA found that effects were more certain at some levels than at others, and that some effects were more serious than others. When EPA assessed the latest scientific knowledge available for the present review, it found the weight of the evidence had changed significantly.

In 1997, EPA had direct causal evidence in the form of clinical studies linking ozone to lung function decrements and respiratory symptoms down to levels of 0.08 ppm. 62 Fed. Reg. at 38,863-64; 61 Fed. Reg. at 65,728/1. For some sensitive individuals, these symptoms were "sufficiently severe and extended in duration to be considered adverse." 62 Fed. Reg. at 38,864/1. EPA considered these clinical studies to offer "[t]he strongest and most quantifiable exposure-response information," 61 Fed. Reg. at 65,719/3, but contrary to Industry Petitioners' assertion, the Agency did not simply "assume at that time that lung function decrements and symptoms could occur below the 0.08 ppm level." Industry Br. 32. Rather, EPA recognized that there were important uncertainties in extending such results "below the lowest-observed-effects levels to an estimated background level of 0.04 ppm" that were not reflected in the quantitative risk assessment. 61 Fed. Reg. at 65,726/1.

In 1997, there was also clinical evidence of more serious effects, including increased airway responsiveness, lung inflammation, and increased susceptibility to respiratory infection down to 0.08 ppm. *Id.* at 65,719/2, 65,720-21. Additionally, limited epidemiological evidence showed associations between ozone and hospital admissions and emergency department visits even when considering only concentrations below the prior one-hour, 0.12 ppm standard. *Id.* at 65,720/3, 65,727-28. However, EPA differentiated these epidemiological results

from the "clear, causal relationships" demonstrated by clinical studies, noting that the former studies did not "conclusively demonstrate[]" causal associations. *Id.* at 65,722/2. More generally, EPA acknowledged that these more serious effects were "less certain" at lower levels, especially without a quantified exposure-response relationship. 62 Fed. Reg. at 38,868/2, 38,860/3.

The uncertainties in 1997 about effects below 0.08 ppm – especially more serious health effects – played an important role in EPA's selection of a primary standard. In considering exposure and risk assessments indicating that a standard below 0.08 ppm *would* reduce estimates of ozone exposures and associated health effects, *id.* at 38,864/3, EPA nevertheless focused on limiting "exposures of concern . . . at and above 0.08 ppm, eight-hour average, *at which a range of health effects have been observed in controlled human studies* . . . ." *Id.* at 38,860/2 n.5 (emphasis added); *see also* 61 Fed. Reg. at 65,729/3 (emphasizing clinical findings of health effects at 0.08 ppm as corroborating epidemiological studies "reporting similar symptomatic and functional effects associated with exposures to ambient levels of O_3 that broadly span this clinical lowest-observed-effects level"). The Administrator therefore rejected a standard of 0.07 ppm, even though the exposure and risk assessments projected such a standard would provide increased public health protection. 62 Fed. Reg. at 38,868/2-3.

ATA III included a close review of EPA's reasons for choosing a 0.08 ppm rather than a 0.07 ppm level for the 1997 primary standard: the failure of any CASAC member to recommend a standard below 0.08 ppm, the "transient and reversible" nature of the health effects that are most certainly linked to ozone exposures at low concentrations, the lesser certainty of more serious adverse health effects at low concentrations, and the proximity of 0.07 ppm to estimated peak background levels of 0.04 ppm. 283 F.3d at 377. Though questioning some elements of EPA's asserted rationale, the Court did endorse EPA's choice of standard as the product of "reasoned decision making." *Id.* at 379. The "[m]ost convincing" foundation for EPA's decision was "the absence of *any* human clinical studies at ozone concentrations below 0.08," which "amply support[ed] EPA's assertion that the most serious health effects of ozone are 'less certain' at low concentrations" and "provid[ed] an eminently rational reason to set the primary standard at a somewhat higher level, at least until additional studies become available." *Id*.

This Court's endorsement of EPA's 1997 reliance on concerns about certainty supports the view that even risks of which the Agency was aware in that last review may carry *more* weight now in light of new evidence "provid[ing] increased confidence . . . that indicators of respiratory morbidity such as emergency department visits and hospital admissions are causally related to O_3

exposures," along with new information about ozone effects on people with asthma and ozone effects in areas meeting the 1997 standard. 73 Fed. Reg. at 16,471/1-2. Thus, Industry Petitioners' contention that EPA's "increased confidence" about effects evidence from 1997 "merely confirms the 1997 NAAQS was 'requisite'" is unavailing. Industry Br. 34. As EPA reasonably explained, "with similar risks, increased certainty in the risks presented by O_3 implies greater concern" than in 1997 about public health impacts. 73 Fed. Reg. at 16,466/3; *see also id.* at 16,467/1-2.

In sum, EPA reasonably considered the amount of uncertainty with respect to serious adverse health effects, and how that degree of uncertainty had changed since 1997, as part of its overall assessment of the body of evidence. *Cf. LIA*, 647 F.2d at 1161 (approving EPA margin of safety analysis focusing on "such factors as the amount of uncertainty involved, the size of the population affected, and the severity of the effect"). Significant deference to the Agency's judgment is due in an arena where Congress acknowledged questions of scientific certainty would often arise, and charged EPA with the task of weighing the "latest scientific knowledge" in assessing future public health impacts. 42 U.S.C. § 7408(a)(2); *see also* H.R. Rep. No. 94-1175, at 34 (1976) ("a substantial element of judgment, including making comparative assessment of risks, projections of future possibilities, establishing margins of safety and margins of error, extrapolating

from limited data, etc., are necessary and permissible under the Act in order to protect public health").

2. EPA Reasonably Determined That Newly Available Evidence Warranted a Lower Primary Standard.

Industry Petitioners' assertion that EPA "fail[ed] to compare what was known or assumed in 1997" with the evidence available in this review is simply false. Industry Br. 29. EPA expressly considered in this review how its knowledge compared "to what was known at the time of the last review," 73 Fed. Reg. at 16,471/1, and clearly distinguished between the evidence available in each review. *See, e.g.*, *id.* at 16,440/2-3; 72 Fed. Reg. at 37,862-66. Critically, EPA has done what Industry Petitioners have not: it has specified how the body of evidence supports the Administrator's conclusions about the nature and certainty of public health impacts of ozone exposures at various levels, and thus provided a reasoned explanation of why the evidence newly available for this review supported a different judgment about the requisite ozone standard than in 1997.

In 1997, EPA identified important uncertainties about the occurrence of adverse health effects at levels below 0.08 ppm. *See supra* 50-52; *see also ATA III*, 283 F.3d at 379. In this review, EPA found that new evidence had *lessened* these uncertainties. 73 Fed. Reg. at 16,471/1-2. This new information including new evidence that ozone more seriously affects asthmatics than healthy individuals; stronger epidemiological evidence of serious adverse health effects at

and below 0.080 ppm; and new but very limited clinical evidence of ozone effects at levels down to 0.060 ppm. *Id.*; *supra* 15-23. Each of these pieces of evidence is amply supported by the record, and together they offered a reasonable basis for deciding that a standard below 0.080 ppm was necessary.

a. EPA Reasonably Weighed Important New Evidence Regarding the Response of Asthmatic Individuals to Ozone Exposure in Deciding to Revise the 1997 Primary Standard.

As described *supra* 15-17, EPA concluded based on new clinical and epidemiological evidence that "it is likely that *more serious responses*, and *responses at lower levels*, would occur in people with asthma and other respiratory diseases" as compared to healthy individuals. 72 Fed. Reg. at 37,863-64 (emphasis added). Therefore, clinical and epidemiological studies of respiratory effects "that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O_3 exposure on asthmatics and other susceptible populations." *Id.* at 37,865/1.

This conclusion went beyond EPA's treatment of asthmatics as an at-risk group in 1997. Then, EPA considered that ozone effects of the same magnitude could have a greater public health impact on people with asthma because they started off with poor lung function; thus, the Agency deemed FEV_1 decrements between 10% and 20% to be adverse in asthmatics, whereas only FEV_1 decrements above 20% would be considered adverse in healthy individuals. 61 Fed. Reg. at 65,722/3.

But in 1997 EPA did not consider that asthmatics might in fact suffer greater *effects* to begin with, or that effects might occur at lower *levels* than those associated with effects in the general population. *See* 73 Fed. Reg. at 16,464/2 ("At the time of the last review . . . there was little evidence that [asthmatics] were more responsive than healthy individuals in terms of the magnitude of pulmonary function decrements or symptomatic responses."); 62 Fed. Reg. at 38,868/2 (including children and asthmatics as undifferentiated subsets of general population that would benefit from a standard of 0.08 ppm in 1997 NAAQS Rule). The evidence indicating that asthmatic individuals might actually experience greater *responses* than healthy individuals when exposed to the same ozone levels was a new development. Not only might an asthmatic be more affected by a 10% lung function decrement than a healthy person, but also, where a healthy subject experienced a 10% lung function decrement at a given exposure level, an asthmatic might suffer a 15% or even 20% decrement; the same principle applies to other respiratory effects such as increased airway responsiveness. *See* 72 Fed. Reg. at 37,846/3; CD 6-16 to -17, JA 373-74; SP 3-67 to -68, JA 818-19. Additionally, this increased knowledge about more serious responses in asthmatics provided biological plausibility for epidemiological evidence linking ambient ozone levels to respiratory effects and associated health endpoints, thus increasing the Agency's confidence in those epidemiological studies. 72 Fed. Reg. at 37,826/1-2, 37,847/3.

Overall, the new evidence that asthmatics experience greater effects from ozone exposures and effects at lower levels, as compared to healthy individuals, supported EPA's increased understanding that ozone poses greater health risks than previously believed.

Industry Petitioners ignore these details, viewing the designation of a "sensitive population" as a simple on-off switch that was flipped in 1997 and can no longer affect EPA's judgment about the ozone's public health effects. Industry Br. 37. Such a narrow approach would be inconsistent with EPA's task of fully considering "the kind and extent of all identifiable effects on public health" from a pollutant, 42 U.S.C. § 7408(a)(2), and accounting for them in ensuring the protection of sensitive groups. *See ALA*, 134 F.3d at 389 ("NAAQS must protect not only average healthy individuals, but also 'sensitive citizens'"); *see also CBR*, 604 F.3d at 617-18.

b. EPA Reasonably Placed Significant Weight on New Epidemiological Studies Showing Associations Below 0.080 ppm.

Industry Petitioners grossly mischaracterize the 1997 NAAQS by asserting that EPA "conclude[d] that respiratory effects leading to hospital visits could occur down to background levels." Industry Br. 33. The sole basis for their assertion is an EPA statement that it is possible, given the lack of evidence of any effects threshold for ozone, that ozone "may elicit a continuum of biological responses

down to background concentrations." 62 Fed. Reg. at 38,863/3 (quoted in Industry Br. 33). This cursory description misses, once again, the careful weighing of uncertainties in which EPA was engaged. EPA does not consider effects as either uncertain or certain, with no room in between; under the "weight of evidence" approach, many factors go into determining the strength of evidence linking ozone to a given health endpoint at a given ambient level. *See supra* 14-15.

Though in 1997 EPA lacked evidence of a threshold for ozone effects and therefore recognized that the continuum of risk could extend "*potentially* down to background levels," there remained uncertainty about risks at ozone levels below 0.08 ppm, particularly as to more serious health effects. 62 Fed. Reg. at 38,873/1 (emphasis added)); *see also id.* at 38,868/2; 61 Fed. Reg. at 65,726/1 (noting uncertainty in extrapolating evidence of responses to ozone exposures below the lowest level at which such effects were observed in clinical studies, 0.08 ppm). That uncertainty was significantly reduced in several respects by evidence newly available in this review. The more than 200 epidemiological studies conducted since the prior review have provided a consistent, coherent, robust, and biologically plausible set of evidence that specifically supports associations between ozone and serious health effects even in areas meeting the 1997 standard and at levels *below* 0.080 ppm. *See supra* 21-23.

In particular, this new evidence included two new large, multi-city studies of asthmatic children reporting significant lung function decrements, increased respiratory symptoms, and increased asthma medication use, including at levels below 0.080 ppm and even when the results were adjusted to account for the potential confounding effects of co-pollutants. *See* 73 Fed. Reg. at 16,445-46 (discussing Mortimer (2002) and Gent (2003)). These studies thus provided robust results regarding increased asthma medication use, a health endpoint that had not been extensively explored at the time of the 1997 review. *See* 61 Fed. Reg. at 65,728/2 (noting only that "inflammatory responses *could* adversely affect asthmatic individuals by resulting in increased medication use" (emphasis added)). They also helped fill out a coherent body of evidence of a range of respiratory-related morbidity effects in areas that would have likely met the 1997 standard and at levels below 0.080 ppm, including important new studies supporting a link between exposures below the 1997 standard and emergency department visits and hospital admissions. 73 Fed. Reg. at 16,470/3, 16,450; *see generally* 72 Fed. Reg. at 37,842 (chart aggregating results of available epidemiological studies); SP 3-9 to -12, 6-11 to -14, JA 760-63, 1019-22 (reviewing new epidemiological evidence since prior review).

EPA appropriately placed more weight on this new evidence than it had on the far less developed epidemiological evidence, focused on higher ozone levels,

that was available in 1997. The Agency did recognize that epidemiological studies are not direct evidence of a causal relationship. 73 Fed. Reg. at 16,457/1. But the Administrator reasonably judged that the significantly expanded epidemiological evidence available in this review, when weighed as part of the entire body of evidence including clinical and toxicological evidence supporting the biological plausibility of serious ozone health effects at levels below the level of the current standard, was sufficient to reduce uncertainties about the causal relationship between ozone and more serious health effects at levels below 0.080 ppm. *Id.* at 16,457/1, 16,450/2; *see also, e.g.*, CD 8-12, JA 618 (noting stronger toxicology evidence since last review).

Industry Petitioners' assertions about continuing uncertainties regarding epidemiology studies of school absences, cardiovascular effects, and mortality constitute a red herring, incorrectly suggesting that EPA considered each of these effects in isolation as the only new information since 1997. *See* Industry Br. 34-35. EPA properly considered the evidence regarding these effects as part of the body of evidence, along with a long list of other scientific information, *see* 73 Fed. Reg. at 16,440/2, in accordance with its obligation to weigh all of the "latest scientific knowledge" relevant to setting a NAAQS. 42 U.S.C. § 7408(a). EPA also acknowledged the limitations of this information, as Industry Petitioners themselves point out. Industry Br. 34-35. Accordingly, the Agency reasonably did

not make any of these effects the focus of its decision to revise the 1997 standard, instead emphasizing studies of different health endpoints like increased asthma medication usage and hospital admissions.[9] *See supra* 19-21; 73 Fed. Reg. at 16,440/2, 16,460/2. EPA thus took evidence regarding school absences, cardiovascular effects, and mortality into account as part of a much larger, cohesive body of evidence regarding the pyramid of health effects associated with ozone exposure – a body of evidence that EPA found to be stronger, as a whole, than the information available in 1997. *E.g.*, *id.* at 16,470/3-71/1.

Finally, Industry Petitioners' argument that EPA cannot lower the ozone standard because it should have already accounted for any uncertainties present in 1997 by incorporating a margin of safety into the NAAQS is one that this Court should not countenance, for a number of reasons. Industry Br. 35. To do so would improperly prevent EPA from re-weighing existing uncertainties in light of new evidence. It would also preclude different Administrators from reaching different judgments on the evidence before them. Finally, holding that the 1997 standard provides a sufficient margin of safety to encompass all new evidence would prevent EPA from ever revising a NAAQS again, since by Industry Petitioners' lights every NAAQS should already have a margin of safety that prospectively

[9] Although EPA did discuss its increased certainty regarding the possible mortality effects of ozone as important new evidence, 73 Fed. Reg. at 16,450/1-2, the Agency clearly stated that such mortality evidence was not the focus of its decision to propose revision of the 1997 standard. *Id.* at 16,460/2.

addresses all uncertain health effects – a result that is plainly inconsistent with Congress's command for EPA to review new scientific information and, as appropriate, revise the NAAQS at five-year intervals. *See* 42 U.S.C. §§ 7408(a), 7409(d)(1). This argument also rests on a misunderstanding of the nature of the margin of safety; it is not some specific quantitative reduction in the NAAQS level to account for all uncertainty, but rather an overarching obligation for EPA to "err on the side of caution" in considering public health risks that have not been "quantified or precisely identified as to nature or degree." *ATA III*, 283 F.3d at 369.

c. EPA Reasonably Decided What Weight to Give New Clinical Evidence Regarding Health Effects of Ozone Exposures Down to 0.060 ppm.

The Adams studies, in which some healthy individuals experienced lung function decrements and respiratory symptoms at ozone levels down to 0.060 ppm, constituted the principal new clinical evidence available since the last review, when such effects had only been observed at levels down to 0.080 ppm. *See* 72 Fed. Reg. at 37,827/3-28/2. Industry Petitioners misconstrue both the role of these studies in the Administrator's decision and the level of deference owed to EPA's interpretation of the Adams data.

As outlined above, EPA did not blindly "assume[] at that time [the prior ozone NAAQS review] that lung function decrements and symptoms could occur

below the 0.08 ppm level, for both typical and more sensitive individuals."[10] Industry Br. 32 (footnotes omitted). Rather, the Agency acknowledged the increasing uncertainty of health effects at levels below the lowest-observed-effect levels in clinical studies, 0.08 ppm. *See* 61 Fed. Reg. at 65,726/1; *supra* 50-51. Although the Adams studies were "very limited," they did provide support for the biological plausibility of epidemiological evidence of health effects below 0.080 ppm, which the Administrator took into account as part of the expanded body of evidence since 1997.[11] *See* RTC 29, JA 3067 ("[B]iological plausibility becomes increasingly uncertain especially below 0.060 ppm, the lowest level at which effects were observed in controlled human exposure studies."); 72 Fed. Reg. at 37,870/1; SP 6-58, 6-61, JA 1066, 1069. This Court acknowledged in reviewing the 1997 standard that such "additional studies" could provide EPA with more certainty about the effects of ozone at levels below 0.08 ppm. *ATA III*, 283 F.3d at 379.

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[10] Industry Petitioners also mention that the 1997 record included evidence that some healthy individuals "had experienced FEV decrements as large as 50% when exposed to ozone concentrations as low as 0.08 ppm." Industry Br. 32 (citing 62 Fed. Reg. at 38,860/2). While true, this is irrelevant; while that evidence supported EPA's judgment that exposures at 0.08 ppm could cause adverse health effects, it did not pertain to the effects of exposures below 0.08 ppm.

[11] The Administrator also took into account new evidence regarding the health effects of ozone exposure on asthmatics in assessing the epidemiological evidence. Industry Petitioners ignore this aspect of the Administrator's reasoning, which is discussed *supra* 43-44.

Industry Petitioners also cursorily suggest that Dr. Adams was right about the correct interpretation of the data from his studies and EPA was wrong. Industry Br. 32. That is exactly the type of "battle of the experts" in which this Court has declined to engage. In *Lead Industries Ass'n*, this Court explained that its function in reviewing a NAAQS is not "to resolve disagreement among the experts or to judge the merits of competing expert views." 647 F.2d at 1160. The Court "must look at the [agency's] decision not as the chemist, biologist or statistician that [it is] qualified neither by training nor experience to be, but as a reviewing court exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality." *Ethyl Corp.*, 541 F.2d at 36. Therefore, the Court's "task is the limited one of ascertaining that the choices made by the Administrator were reasonable and supported by the record. That the evidence in the record may also support other conclusions, even those that are inconsistent with the Administrator's, does not prevent us from concluding that his decisions were rational and supported by the record." *LIA*, 647 F.2d at 1160 (internal citation and footnote omitted). Here, EPA reached different conclusions than Dr. Adams regarding the import of his data because the Agency considered a different question than Dr. Adams did, and did so using a different analytical approach, offering a reasoned explanation for both choices as more appropriate to EPA's task of considering the effect of prolonged ozone exposures. *See supra* 19-21.

Finally, Industry Petitioners' focus on their disagreement about the import of the Adams data regarding average lung function decrements at 0.060 ppm is misplaced. Industry Br. 30. EPA was also concerned with the occurrence of sizable *individual* effects even where the group mean decrement was small. Individual effects are important because it is well-established that there is significant, replicable inter-subject variability in ozone health effects – in other words, some individuals consistently experience greater effects than others in response to ozone exposures. 72 Fed. Reg. at 37,828/3; SP 3-5, JA 756. Therefore, as EPA explained, the evidence from Adams regarding individual lung function decrements greater than 10 percent – the level judged to be adverse for asthmatics – was "the most important finding from this study in terms of public health implications" in terms of evaluating potential risks to the more "sensitive or susceptible parts of the population." 73 Fed. Reg. at 16,454-55.

In sum, the Adams studies did provide some new information that contributed to EPA's overall assessment of the body of scientific evidence regarding the health effects of ozone, even if the Agency did consider the studies to be limited as direct evidence of a causal relationship between lung function decrements and ozone exposures at and above 0.060 ppm.

D. EPA Reasonably Declined to Conduct a Direct Quantitative Comparison Between the 1997 Risk Assessment and the Current Risk Assessment.

1. EPA Is Not Obligated to Regulate Based on Quantitative Risk Estimates.

Although EPA opted to perform a risk assessment in both this review and the 1997 review, that choice did not bind EPA to conduct a direct comparison of the resulting risk estimates. As this Court explained in *Farm Bureau*, the same reasonableness standard generally governing EPA's setting of a NAAQS applies to its choice of methodology. 559 F.3d at 521 (holding that EPA use of one analytical approach in the prior review "did not thereby commit . . . [the Agency] irrevocably" to the same approach in later reviews). EPA's discretion includes the ability to adopt any rationally chosen methodological approach, since "[t]he choice between . . . possible approaches is a policy choice of the type that Congress specifically left to the Administrator's judgment." *LIA*, 647 F.2d at 1162; *see also NRDC*, 902 F.2d at 973 (rejecting petitioners' argument that the court should impose a specific methodology for EPA to follow in determining the requisite NAAQS under CAA section 109). Thus, "if the relevant facts have changed [since a prior review] or the EPA has reasonably made a different policy judgment, then it need only explain itself and we will defer." *Id.*

In particular, the D.C. Circuit has firmly rejected the idea that, in setting a NAAQS, EPA is obligated to "establish a measure of the risk to safety it considers

adequate to protect public health," *NRDC v. EPA*, 902 F.2d at 973, especially in light of "the uncertainty of the data upon which the Administrator need[s] to rest his assessment." *Id.* at 974; *see also ATA III*, 283 F.3d at 369 (affirming that the Administrator may look beyond quantified risks in selecting the requisite standard, since to hold otherwise "would compel EPA to leave hazardous pollutants unregulated unless and until it completely understands every risk they pose, thus thwarting the Clean Air Act's requirement that the Agency err on the side of caution by setting primary NAAQS that" provide an adequate margin of safety). Therefore, Industry Petitioners' argument that the 2008 primary standard must rise or fall based on a comparison between the risk assessments in this review and the 1997 review is unavailing. EPA reasonably chose an alternative analytical method – a careful qualitative consideration of the differences between its 1997 and 2008 analyses and an explanation of how that new information altered the weight it gave existing evidence or suggested wholly new conclusions. *See supra* 42-45.

2. EPA Offered a Reasoned Explanation for Its Decision Not to Directly Compare the 1997 and 2008 Quantitative Risk Estimates.

Industry Petitioners next maintain that EPA acted arbitrarily in refusing to be bound by its 1997 quantitative risk estimates as the once and future measure of the "risks . . . 'requisite' to protect public health." Industry Br. 41. This argument is unavailing. EPA offered three separate, reasonable bases for declining to conduct

a direct comparison of the 1997 and 2008 risk estimates as part of its decision on whether to revise the 1997 primary standard. 73 Fed. Reg. at 16,466/3-67/2.

First, EPA explained that such a comparison would not be useful because the risk estimates did not fully capture the body of evidence underlying the Administrator's consideration of the requisite standard in either 1997 or 2008. *Id.* at 16,467/2. Industry Petitioners' argument wrongly assumes that the quantified risk estimates from 1997 wholly encompass "the risk levels associated with the 0.08 ppm standard that EPA found in 1997, and this Court affirmed in 2002, to be 'requisite.'" Industry Br. 39. In fact, EPA explained that "quantitative risk estimates were not the only basis for EPA's decision in setting a level for the O_3 standard in 1997, and they do not set any quantified 'benchmark' for the Agency's decision to revise the O_3 standard at this time." 73 Fed. Reg.at 16,467/2.

Rather, in both 1997 and 2008, EPA viewed the risk assessment within the larger context of the Agency's level of certainty about the causal effects of ozone exposure at lower levels. In 1997, while the risk assessment played a more important role, the Administrator also carefully considered the uncertainties underlying the inputs to the risk assessment; ultimately those uncertainties led her not to choose a lower, 0.07 ppm standard that the risk estimates indicated would offer increased protection against adverse health effects. 62 Fed. Reg. at 38,868/2**;** *see supra* 50-51. The 2008 risk assessment played a lesser role, with the

Administrator relying primarily on the body of scientific evidence to determine a standard, and also emphasizing the exposure assessment over the risk assessment as a better tool to capture the full array of public health risks, both quantified and unquantified. 73 Fed. Reg. at 16,482/2-3, 16,452/1-2. And in both reviews, EPA pointed out that its risk assessments did not offer a full picture of the public health impacts of alternative ozone standards, since they offered quantitative estimates of only portions of the "pyramid of effects" caused by ozone for selected population groups in limited geographic areas. 62 Fed. Reg. at 38,866/1; 73 Fed. Reg. at 16,467/2. Therefore, in both 1997 and 2008 EPA used the risk assessment as a means to put evidence about the effects of ozone in a broader public health context, *see* 73 Fed. Reg. at 16,477/2; 61 Fed. Reg. at 65,723/1, *not* as the sort of absolute measure of "tolerable" risk that Industry Petitioners urge. Industry Br. 39.

Second, EPA responded to commenters seeking a comparison of risk estimates by noting that such a comparison would fail to account for "EPA's increased level of confidence in the associations between short-term O_3 exposures and morbidity and mortality effects," an important qualitative element of the Administrator's consideration. 73 Fed. Reg. at 16,467/1. The quantitative risk estimates are meaningless unless accompanied by a proper qualitative consideration of "the degree of confidence that the Agency has that the observed health effects are causally linked to O_3 exposure at those levels." *Id.*

Industry Petitioners attempt to counter this critique with their argument that, if the risk estimates in both 1997 and 2008 were uncertain, then they cannot support EPA's judgment regarding the requisite standard. Industry Br. 44. This one-dimensional view only illustrates Industry Petitioners' continued failure to recognize that a large part of EPA's task in setting NAAQS is to recognize sources of uncertainty and to reasonably account for them. EPA did so in 1997, as this Court held in affirming the Agency's choice of a 0.08 ppm standard based on its consideration of both the 1997 risk assessment and the lack of clinical evidence below 0.08 ppm. *ATA III*, 283 F.3d at 379-80. EPA has also done so here, continuing to use risk estimates as a method for putting evidence of ozone effects in a public health context, while still understanding how recognized uncertainties in the underlying evidence may limit the usefulness of such estimates in judging the public health impacts of ozone at low levels. *See* 73 Fed. Reg. at 16,481/1-82/2.

Finally, EPA noted that a direct comparison would not produce any relevant information, since the 2008 risk assessment had incorporated the latest science through improvements in both the model inputs and the model itself since 1997. These changes included:

- a different geographic scope (both in terms of the cities chosen and the areas modeled for each of those cities);

- a wider range of annual air quality data (a "typical" air quality year in 1997, versus a recent three-year set of air quality data in 2008);
- different population groups (*e.g.*, outdoor children in 1997 versus all school age children and asthmatic children in 2008); and
- additional health endpoints based on new epidemiological evidence (for example, EPA included respiratory symptoms in asthmatic children as a new health endpoint in 2008).

Id. at 16,466/3-67/1. Indeed, one of the sets of comments cited by Industry Petitioners, Industry Br. 39, particularly noted that "since the methodology EPA used to calculate risks in 2006 differs markedly from the methodology used in 1997, it is somewhat misleading to directly compare the risk figures." Exxon Mobil Comments at 62, JA 2726.

Industry Petitioners attempt to skirt this problem by conducting their own ad hoc comparison of selected elements of the two risk assessments that they assert remain similar in scope.[12] Industry Br. 41-45. Their approach – considering on equal terms the risk estimates for hospital admissions of asthmatics; lung function decrements in children; respiratory symptoms in children; and exposures and risks

[12] Notably, Industry Petitioners do not offer any citation to comments that raised these alleged similarities between the 1997 and 2008 risk estimates. *See* Industry Br. 41-45. To the extent these particular issues were not raised in comments, and thus could not be considered and responded to by EPA, they are waived. *See Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297-98 (D.C. Cir. 2004).

in outdoor workers – is expressly a product of the ease of comparison of these selected health endpoints, rather than any judgment about the full body of evidence regarding these effects, or their particular relevance to EPA's decision to revise the 1997 primary standard. Industry Br. 41. Therefore, Industry Petitioners can offer little meaningful discussion of any increase or decrease in the public health risks that EPA considered in deciding to revise the 1997 primary standard. Accordingly, EPA reasonably rejected this sort of piecemeal comparison in responding to industry comments. EPA responded to those comments – which suggested an isolated comparison of the risk estimates regarding lung function decrements – by explaining that such a comparison would "fail to account for differences in additional and more severe health endpoints not covered in the 1997 assessment, as well as the fact that there are somewhat different and more urban areas included in the current assessment." 73 Fed. Reg. at 16,467/1.

Industry Petitioners also imply that higher risk estimates were due in some part to EPA's change in its estimate of nonanthropogenic background ozone levels, from a single national estimate of 0.04 ppm in 1997 to a range of levels from 0.015 ppm to 0.035 ppm, depending on location and time, in 2008. Industry Br. 40-41. That complaint is irrelevant unless EPA's estimations of background ozone levels

are unreasonable, an argument Industry Petitioners do not make.[13] In fact, the change in EPA's background level estimates resulted from the Agency's switch to a peer-reviewed model able to simulate long-range ozone transport that allowed EPA to capture variations in background ozone levels across location and time. SP 2-54, JA 750; RTC 94, JA 3106. EPA was not obligated to adhere to its now-outdated approach from 1997 simply to allow for quantitative comparability between reviews, given that the Agency offered a reasoned decision for changing to a better method for estimating background levels.[14]

3. Industry Petitioners' Attempted Risk Comparison Does Not Undermine EPA's Rationale for Not Comparing the 1997 and 2008 Risk Assessments.

Even assuming that Industry Petitioners' haphazard comparison has any theoretical validity, their purported comparisons are problematic for the very reasons outlined by EPA. As noted previously, EPA did have increased

[13] Industry Petitioners allege in a footnote (40 n.10) that the proper estimate of background ozone levels is 0.05 ppm to 0.066 ppm, based on monitoring data from remote sites. The Court should disregard this assertion; Industry Petitioners offer no substantive argument as to why EPA's chosen methodology for estimating background ozone levels – which was based on a sophisticated model that specifically accounted for long-range transport of ozone to remote monitoring sites, calibrated against real-world observations – was not reasonable. *See* RTC 94, JA 3106.

[14] Furthermore, Industry Petitioners' discussion about the interaction between background levels and risk estimates for mortality says nothing about the risk estimates for respiratory morbidity effects, which were the focus of the Administrator's decision to revise the 1997 standard. 73 Fed. Reg. at 16,460/2.

confidence and knowledge in 2008 about the risks of hospital admissions, respiratory symptoms in children, lung function decrements, and many other relevant health effects. S*upra* 15-24, 42-45. Industry Petitioners' conclusion that the quantitative risk estimates regarding these health endpoints did not change from 1997 to 2008 is therefore a non-sequitur; with respect to the Administrator's overall assessment of this aspect of ozone's public health impacts, the risk assessment simply was not the driver of EPA's decision that a standard below 0.080 ppm is now necessary.[15] 73 Fed. Reg. at 16,482/3 (noting "primary consideration" of body of scientific evidence, and supportive role of exposure and risk assessments); RTC 76, JA 3096. That is why EPA decided a direct comparison of the 1997 and current risk estimates would not be useful in determining the requisite standard. Therefore, the Agency's decision not to compare its quantitative risk estimates was reasonable and merits the Court's deference.

E. EPA Reasonably Utilized the Latest Scientific Knowledge in Determining the Requisite Primary Ozone Standard.

CAA section 108(a)(2) directs EPA to issue air quality criteria (on which the NAAQS is based under section 109(b)(1)) that "accurately reflect the latest

[15] Industry Petitioners do not make any argument that the exposure estimates remain the same between the 1997 and 2008 reviews, an important omission given EPA's explanation that the exposure assessment can capture important information about health risks that cannot be quantified in the risk assessment. 73 Fed. Reg. at 16,482/2-3, 16,452/1-2.

scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." 42 U.S.C. § 7408(a)(2). Industry Petitioners suggest that the Criteria Document for the 2008 NAAQS did not contain "accurate[]" or "useful" information, and that therefore the primary standard was promulgated in violation of section 108(a)(2). However, both Industry Petitioners' arguments that the information relied upon by EPA was not consistent with section 108, and their implication that EPA failed to reasonably utilize that information, are unavailing.

1. Industry Petitioners Offer No Basis for Imposing Any Heightened Standard of Review Regarding the Information in the Criteria Document.

First, Industry Petitioners assert that the statutory terms "accurately" and "useful" should be given their plain meaning. While we agree that the dictionary definition of a statutory term can be useful in discerning Congress' intent, that definition cannot be considered outside of the statutory context in which the word is used. *Dolan v. U.S. Postal Service*, 546 U.S. 481, 486 (2006) ("The definition of words in isolation . . . is not necessarily controlling in statutory construction."). Here, in the course of a purported plain language interpretation of section 108, Industry Petitioners take the word "accurately" out of context and thereby twist its meaning. Citing a dictionary definition of "accurate" as "free from error" or

"exact," they contend that "Congress required EPA to consider and rely upon all scientific information that is . . . free from error (accurate)." Industry Br. 47. But in the actual text of section 108, it is not the *scientific knowledge* cited in the Criteria Document that must be "accurate[]"; rather, it is the *criteria* that must be accurate in reflecting the "latest scientific knowledge."[16] 42 U.S.C. § 7408(a)(2); *see also API*, 665 F.2d at 1185 ("We need not find that each study discussed in the criteria document is accurate and reliable . . . .").

Moreover, section 108(a)(2) requires the Criteria Document to "accurately *reflect*" the latest scientific knowledge. 42 U.S.C. § 7408(a)(2). The word "reflect" does not require EPA to simply reproduce each and every relevant study; rather, it is defined more broadly as "to give back or exhibit as an image, likeness, or outline." Merriam-Webster Dictionary Online, http://www.merriam-webster.com/dictionary/reflect (last visited June 26, 2012). Thus, while section 108 obliges EPA to summarize and assess the latest science without misrepresenting it as a factual matter, it does not limit EPA to a mere restatement of the results of scientific studies without independent analysis. Rather, EPA's

[16] No court has ever required that EPA establish that the science it considers in the Criteria Document is absolutely "free from error," particularly in the sense of eliminating all uncertainty. As this Court has acknowledged on multiple occasions, "some uncertainty about the health effects of air pollution is inevitable," and EPA must act *despite* such uncertainty in promulgating NAAQS under CAA sections 108 and 109. *LIA*, 647 F.2d at 1154.

analysis remains subject to review only to determine whether it represents reasoned decisionmaking. As this Court explained in *API*, "[t]he proper function of the court is not to weigh the evidence anew and make technical judgments; our role is limited to determining if the Administrator made a rational judgment." 665 F.2d at 1185.

Additionally, Industry Petitioners must fail in their attempt to import any *additional* legal test into section 108 based on EPA's IQA Guidelines. This Court lacks jurisdiction to entertain any Industry Petitioners claim asserting a violation of the Guidelines themselves; as every court to address the issue has held, the Information Quality Act "creates no legal rights in any third parties." *Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006); *e.g.*, *San Luis & Delta-Mendota Water Auth. v. Salazar*, 760 F. Supp. 2d 855, 964 (E.D. Cal. 2010) (holding that agency's IQA guidelines do not "set forth any 'judicially manageable standards' against which the presentation, use, or analysis of data can be measured" and thus there is no right to judicial review of claims of agency failure to comply with the guidelines); *In re Operation of the Missouri River System Litig.*, 363 F. Supp. 2d 1145, 1174 (D. Minn. 2004) (similar).

EPA likewise explained in issuing its own Guidelines that they are merely guidance and do not impose any sort of legally enforceable standard:

> Our Guidelines reflect EPA's best effort to present our goals and commitments for ensuring and maximizing the quality of information

> we disseminate. As such, they are not a regulation and do not change or substitute for any legal requirements. They provide non-binding policy and procedural guidance, and are therefore not intended to create legal rights, impose legally binding requirements or obligations on EPA or the public when applied in particular situations, or change or impact the status of information we disseminate, nor to contravene any other legal requirements that may apply to particular agency determinations or other actions.

Guidelines 4, JA 3284. Therefore, this Court lacks jurisdiction to consider any claim that EPA somehow violated the IQA itself in the course of promulgating the 2008 ozone NAAQS.

Moreover, the *in pari materia* doctrine cited by Industry Petitioners as a basis for using the Guidelines in reviewing the ozone NAAQS is unavailing; that canon is rooted in the idea that "a legislative body generally uses a particular word with a consistent meaning in a given context." *Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972). Here – even if one stretches this doctrine so far as to infer that in using the term "utility" in a general statute regarding agency dissemination of information in 2000, Congress intended to "shed light" on the meaning of the term "useful" in a provision of the Clean Air Act enacted 30 years earlier – the IQA itself merely directs federal agencies to issue guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency," but leaves open the question of the meaning of the words "quality, objectivity, utility, and integrity." 44 U.S.C. § 3516, note (b)(2)(A). In other words, the IQA did *not* specifically "set forth what

agencies must do to ensure the accuracy and usefulness of the data and analyses used for regulatory decisionmaking." Industry Br. 48. Thus, in determining what section 108(a)(2) might require, the Information Quality Act provides no independent basis for the Court to depart from its longstanding approach of simply requiring EPA to demonstrate that the NAAQS are the product of reasoned decisionmaking.

2. EPA Accurately Summarized the Latest Scientific Knowledge in the Criteria Document and Drew Rational Conclusions from That Knowledge in Determining the Requisite Ozone NAAQS.

Industry Petitioners' allegations regarding flaws in the accuracy and utility of the Criteria Document are not supported by the record. They contend that EPA "inaccurately characterized the results of some studies and relied heavily on other studies without acknowledging their weaknesses." Industry Br. 49. Even if the IQA Guidelines do serve as a valid gloss on section 108(a)(2)'s directive that EPA prepare a Criteria Document that "accurately reflect[s] the latest scientific knowledge useful" to determining the requisite NAAQS, EPA did in fact gather "accurate, reliable and unbiased information" and analyze it "using sound statistical and research methods." Guidelines 21, JA 3301 (cited in Industry Br. 21). In none of the examples cited by Industry Petitioners did EPA omit or mischaracterize any relevant scientific information.

To the extent Industry Petitioners actually seek to dispute the *conclusions* that EPA drew from the available scientific information, neither the IQA nor section 108 provides grounds for such a challenge. This Court "owe[s] deference to an agency's determination regarding the reliability of scientific evidence," *ATA III*, 283 F.3d at 374, and should not allow Industry Petitioners to evade that standard of review by engaging in a battle of the experts here under the guise of an argument about information quality. *LIA*, 647 F.2d at 1160. Rather, the Court's "task is the limited one of ascertaining that the choices made by the Administrator were reasonable and supported by the record." *Id*. Both the IQA and section 108 relate only to EPA's dissemination and summarization of scientific information, not EPA's analysis of or judgments based on that information, and therefore they do not lessen the deference due to the Agency's scientific judgment.

a. EPA's Use of the Adams Studies Was Based on an Accurate Description of Their Results in the Criteria Document and a Valid Statistical Analysis of the Underlying Data.

Industry Petitioners principally argue that EPA's independent examination of the 2002 and 2006 Adams studies and consideration of comments on the import of those studies, which led the Agency to conclude that the 2006 study showed statistically significant responses to ozone exposures down to 0.060 ppm, does not accurately reflect the latest scientific knowledge. Yet Industry Petitioners never explain *why* EPA's discussion of the Adams study was not accurate or objective,

other than to complain that EPA itself failed to explain how its analysis, "which did not undergo any independent peer review . . accurately reflect[s] the 'latest scientific knowledge' over the findings of the author himself, which were subject to peer review." Industry Br. 51; *see id.* at 53. Contrary to Industry Petitioners' claim, EPA accounted for its view of the data resulting from its focus on a different inquiry than Adams, for purposes of which it used a different analytical method. *See supra* 19-21; 73 Fed. Reg. at 16,455/1. CASAC indicated its support for the use of the analytical method and statistical test utilized by Richard Smith in his comment and by EPA in the Brown Memorandum in a March 5, 2007 teleconference. *See* 73 Fed. Reg. at 16,455/1-2. EPA never misrepresented Adams' data or his conclusions, and the Agency used accepted statistical methods that it transparently explained and offered for public comment in both the Staff Paper and the Brown Memorandum. *See* Guidelines 15, 20-21, JA 3295, 3300-01. In sum, the Criteria Document – and all of EPA's subsequent discussion of the 2006 Adams study – did accurately reflect that study's contents as a factual matter.

Industry Petitioners cite the fact that Adams' original analysis did not find statistically significant links between ozone and respiratory effects at levels below 0.080 ppm, a conclusion that EPA reexamined using different analytical methods. Industry Br. 50-51. However, the Criteria Document, Staff Paper, and subsequent

EPA analysis all stand as valid analyses of the Adams data based on accepted statistical methods.

CASAC specifically urged EPA to consider the Adams data in the Criteria Document, as did Adams himself and the entity that funded his study, the American Petroleum Institute. Letter from Dr. Henderson, CASAC Chair, to Administrator Johnson at 5 (Feb. 10, 2006) ("February 2006 CASAC Letter"), JA 1207; RTC 97-98, JA 3109-10. While Industry Petitioners construe CASAC's request as support for Dr. Adams' specific conclusions and methods, Industry Br. 52, in fact CASAC stated only:

> Panelists considered the need for new study data reflecting controlled human exposures to low ozone concentrations, e.g., less than 0.08 ppm. A paper on this subject [the 2006 Adams study] . . . has recently been accepted for publication . . . . The Panel was given a preprint of that paper and considered it of sufficient importance that the Panel recommended that the Agency include this information in the Ozone AQCD and in their consideration of standards in their Ozone Staff Paper.

February 2006 CASAC Letter at 5, JA 1207.

Accordingly, EPA included the 2006 Adams study in the Criteria Document and Staff Paper. As outlined *supra* 19-21, EPA examined the 2006 data for pre- versus post-exposure effects, as opposed to the comparisons over several interim points during the exposure that Adams had conducted, since the former issue was most relevant to determining what ozone standard would be requisite to protect public health. In doing so, EPA noted that "the lack of an overlap in the range of

responses" to filtered air versus 0.060 ppm ozone "is suggestive of a significant effect on FEV_1." SP 3-8, JA 759. EPA also noted that Adams had found statistically significant respiratory system effects at 0.060 ppm in the 2006 study, and that in the 2002 Adams study, some of the subjects had experienced notable effects (an FEV_1 decrement of greater than 10%). *Id.* at 3-8 to -9, JA 759-60. All were accurate statements regarding Adams' data.

EPA's statistical reanalysis of the Adams data in the Brown Memorandum also reflected Adams' data and explained the Agency's bases for reaching different conclusions. Since this different statistical approach to analyzing the Adams data was not raised until comments on the final Staff Paper, *supra* 19, EPA's full statistical analysis did not appear in the Criteria Document. However, the public was able to offer comment on the Brown Memorandum and did do so. *See, e.g.*, RTC 20-23, JA 3058-61. EPA then further explained its views of the Adams studies in response to public comments on this issue, including Adams' own comments regarding the propriety of analyzing the 2006 data using a different statistical test (contrary to Industry Petitioners' allegation that EPA ignored such comments). RTC 20-23, 26-28, JA 3058-61, 3064-66; *see* Industry Br. 51 n.16.

Having accurately described the Adams data in the Criteria Document, EPA was not barred by any part of section 108(a)(2) (or the EPA Information Quality Guidelines) from using the information in that document in a reasonable way to

inform the Administrator's judgment regarding the standard requisite to protect the public health with an adequate margin of safety. Furthermore, EPA reasonably responded to all of the substantive critiques of its analysis offered in comments. As EPA's response detailed, its conclusions regarding the Adams data were based on "a standard statistical test . . . which is appropriate for the type of comparison made." RTC 22, JA 3060. EPA also acknowledged the lesser statistical power of the 2006 Adams study, *see* Industry Br. 52, which had only 30 subjects, and in fact cited that issue as a reason for its view that it would be inappropriate to generalize the Adams results to the entire U.S. population. 73 Fed. Reg. at 16,478/3, 16,454/2. Although Dr. Adams or Industry Petitioners may disagree with EPA's conclusions, that disagreement does not render the Agency's conclusions arbitrary or capricious given that EPA provided a reasonable explanation for its interpretation of the Adams data, consistent with the advice of CASAC.

b. EPA's Use of Ambient Air Quality Measurements in Conjunction with Epidemiological Data Was Reasonable and Consistent with Section 108(a)(2).

Industry Petitioners also criticize EPA's purportedly lopsided reliance on ozone exposure measurements based on ambient air quality monitors rather than personal exposure monitors. Industry Br. 54. Their argument has no basis in the record; in fact, EPA considered the available data from both sources and utilized that data consistently with the Agency's established weight-of-evidence approach.

Industry Petitioners' assertion that the "overwhelming view . . . is that ambient ozone measurements do not provide reliable estimates of personal exposure for use in time-series studies" is misleading. Industry Br. 54. As noted in the Criteria Document, there are multiple studies showing that personal ozone exposures are "well correlated with monitored ambient O_3 concentrations." CD 7-9, JA 420. A number of the studies cited by Industry Petitioners, meanwhile, do not relate to ozone at all. *See* Industry Br. 54 nn.17, 18, 20, 21.

In any case, EPA acknowledged studies on both sides of the debate, and thoroughly described and considered the fact that ambient air quality monitors – which measure ozone levels at fixed outdoor locations – may not always provide an accurate measure of individuals' exposure to ozone given variations in time spent outdoors and in varying locations. *See* CD 3-75, JA 296; *also id.* at 7-6 to -10, JA 417-21; SP 3-39 to -42, JA 790-93; 72 Fed. Reg. at 37,839/1. However, personal exposure information is relatively scarce, and therefore EPA has relied on measurements of ambient ozone levels as a surrogate, based in large part on the conclusion of a number of studies that ambient ozone measurements *are* a reliable surrogate for personal exposure for purposes of assessing the results of epidemiological studies.[17] SP 3-42, JA 793. That judgment merits deference from

[17] CASAC raised no general objection to EPA's utilization of ambient air data; the CASAC statement cited by Industry Petitioners regarding potential exposure error is limited solely to the issue of the association between mortality and ozone

the Court in light of EPA's reasoned explanation that although ambient measurements may not precisely capture personal exposure levels, they do track personal exposure in a predictable and useful way, particularly in showing concentration-response relationships that can be utilized for risk assessments even if the personal exposure measurements are not exact.[18] SP 3-42, JA 793; RTC 83, JA 3103. Finally, EPA did not consider the results of studies reliant on ambient exposure data in isolation; the Agency also looked to controlled human exposure studies showing direct relationships between ozone exposure and adverse health effects at given exposure levels. *E.g.*, 73 Fed. Reg. at 16,456/1.

While EPA may not have discussed each and every study cited by Industry Petitioners, the Agency did accurately summarize and account for studies reflecting both significant associations and no associations between personal and ambient ozone exposures in assessing evidence based on ambient ozone measures. This was sufficient to support EPA's reasoned decision, given that the Agency's obligation is merely to prepare criteria that "reflect" the "latest scientific

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exposure at very low levels. Letter from Dr. Henderson, CASAC Chair, to Administrator Johnson at 3-4 (June 5, 2006), JA 1327-28; 73 Fed. Reg. at 16,457/3-58/1.

[18] If anything, the "bias" introduced by relying on ambient measurements, Industry Br. 55, is most likely to *under*-predict the effects of ozone because ambient measurements consistently *over*estimate the exposure level at which adverse health effects measured in epidemiological studies are occurring. RTC 39, JA 3077.

knowledge," not to restate the results of every last study without exercising its independent judgment in weighing the available evidence.

c. EPA Accurately Assessed Both Studies that Showed an Association Between Ozone Exposure and Adverse Health Effects and Those that Did Not, and Accurately Described Findings on the Potential Impact of Confounding Factors in Epidemiological Studies.

EPA fully acknowledged the existence of certain studies cited by Industry Petitioners that showed no association between ozone and adverse health effects. RTC 55-56, JA 3093-94; CD 7-71 to -78, JA 482-89. Therefore, the Agency's summary in the Criteria Document did accurately reflect the evidence. EPA simply gave these studies different weight than Industry Petitioners would like when viewed as part of the entire body of evidence.

Industry Petitioners' first point on this issue relates to the state of current science: that "recent epidemiological studies have focused almost entirely on particulate matter . . . . creat[ing] a bias in the published studies, which may not accurately reflect the effects of ozone." Industry Br. 58. EPA did acknowledge possible uncertainties resulting from confounding factors such as other pollutants, SP 3-42 to -44, JA 793-95; 73 Fed. Reg. at 16,358/3-59/1, but explained that these studies had continued to show significant results even when controlled for possible confounding by particulate matter. *See, e.g.*, 72 Fed. Reg. at 37,828-29; CD 7-79 to -80, JA 490-91. While the quoted paper states that these particulate matter

studies "do not pay sufficient attention to optimizing analytic approaches and sensitivity analyses," Moolgavkar at 2, JA 1864, if Industry Petitioners believe these studies insufficiently controlled for particulate matter confounding, that is a substantive critique that they could and should have raised in comments so that EPA could respond. Meanwhile, the debate regarding the weight that should be given to these studies has nothing to do with whether the Criteria Document has accurately summarized them.

CASAC's concerns regarding the relationship between particulate matter and mortality likewise do not cast doubt on EPA's discussion of the epidemiological evidence. *See* Industry Br. 59-60. As noted above, mortality risks were not the focus of the Administrator's decision to revise the 1997 standard, in large part because EPA recognized the continuing uncertainties in the epidemiological studies of mortality. *See supra* 24; 72 Fed. Reg. at 37,836/1-2. However, the isolated nature of CASAC's comment highlights the fact that, as a general matter, CASAC voiced no objection to EPA's handling of the issue of confounding.

Once again, Industry Petitioners have not demonstrated that EPA ever misrepresented or omitted important evidence. Since EPA reasonably accounted for epidemiology studies that did not show statistically significant results, and for

possible confounding by other pollutants, the Court must defer to the Agency's reasoned scientific judgment.

In sum, the record developed for the 2008 decision demonstrates that EPA accurately described the science, including its strengths and weaknesses, and reasonably determined that the primary ozone standard could not be left at 0.08 ppm and still be considered requisite to protect public health with an adequate margin of safety. Industry Petitioners' petitions must therefore be denied.

II. ENVIRONMENTAL AND STATE PETITIONERS FAIL TO SHOW THE 0.075 PPM PRIMARY STANDARD IS ARBITRARY OR CAPRICIOUS.

A. The Administrator Reasonably Judged a 0.075 ppm Standard to Be Requisite to Protect the Public Health with an Adequate Margin of Safety.

Based on the scientific evidence and the exposure and risk assessments regarding evidence of adverse health effects at ozone levels at and below 0.080 ppm, as described *supra* 15-27, the Administrator decided to revise the 1997 standard to "appreciably below" 0.08 ppm. 73 Fed. Reg. at 16,480/2-3. He ultimately "judge[d] that the appropriate balance to be drawn, based on the entire body of evidence and information available in this review, is a standard set at 0.075." *Id.* at 16,483/2. Environmental and State Petitioners assert that this standard was too high to provide the requisite public health protection. Environmental Br. 13-14; State Br. 13-14. But the Administrator provided a

reasoned explanation of his weighing of the record evidence to support his judgment that a standard below 0.075 ppm would be more stringent than necessary.

The Administrator determined that a standard below 0.075 ppm would not be requisite due to uncertainties about health effects at lower levels. He did consider the Adams studies as additional, "very limited" new evidence of adverse health effects at levels down to 0.060 ppm in healthy individuals, but did not regard that data as sufficient "to support a primary focus at this level." 73 Fed. Reg. at 16,476/1-2. He also weighed the epidemiological evidence of serious adverse health effects – including increased asthma medication use, emergency department visits, and hospital admissions – at ozone levels below 0.080 ppm, while acknowledging that epidemiological studies do not provide direct evidence of a causal association between adverse health impacts and ozone exposure at a particular level. *Id.* at 16,476/3, 16,479/2-3. Given that this evidence left important uncertainties about the causal relationship between ozone and adverse health effects at lower concentrations, the Administrator concluded that setting a primary standard below 0.075 ppm would be likely to provide more protection than necessary against public health impacts. *Id.* at 16,483/2. EPA thus accounted for all of the evidence cited by Environmental and State Petitioners as mandating a

lower standard, and reasonably balanced the body of evidence in a manner consistent with the "weight of evidence" approach.

This analysis was mirrored in the Administrator's consideration of the exposure assessment. Given the evidence of adverse public health impacts down to 0.080 ppm, he placed less weight on "exposures of concern" down to the benchmark level 0.070 ppm, but still considered such exposures since the evidence of adverse effects at 0.080 ppm relates to healthy individuals rather than sensitive groups such as asthmatics. 73 Fed. Reg. at 16,481/2. The Administrator placed "very little weight" on exposures down to 0.060 ppm given the "very limited scientific evidence" at that exposure level. *Id.* at 16,481/2-3. The exposure assessment estimated that a 0.075 ppm standard would eliminate or substantially reduce the incidence of exposures at the 0.070 and 0.080 ppm benchmark levels, *id.* at 16,483/2, and that a 0.070 ppm standard would not provide "appreciably different" protection against exposures at those benchmark levels as compared to a 0.075 ppm standard. *Id.* at 16,482/2.

The Administrator placed less weight on the risk assessment, again based on the important uncertainties regarding the causal relationship between ozone exposures and adverse health effects. *Id.* at 16,482/2. However, he did note that the risk assessment indicated that a 0.075 ppm standard would significantly reduce

risks of adverse health effects in sensitive groups as compared to the 1997 standard. *Id.*

B. EPA Reasonably Weighed Evidence of Adverse Health Effects Below 0.080 ppm in Setting the Primary Standard at 0.075 ppm.

Fundamentally, both Environmental and State Petitioners' arguments that the primary ozone standard is arbitrary and capricious rest on the premise that EPA ignored "a wealth of evidence" that they contend proves that ozone causes adverse health effects at and below 0.075 ppm. Environmental Br. 16; *see also* State Br. 17-18. However, the Administrator clearly considered the entire body of evidence, and balanced it consistently with the weight-of-evidence approach.

1. EPA Reasonably Placed Limited Weight on the Adams Studies.

EPA provided a reasoned explanation for giving "very limited" weight to the Adams studies, an explanation that merits this Court's deference as the product of the Agency's expert judgment. *ALA*, 134 F.3d at 392.

The Agency candidly acknowledged Environmental and State Petitioners' main points: that the Adams studies provide evidence of lung function decrements in some healthy individuals at ozone levels down to 0.060 ppm, and that the 2006 Adams study provide statistically significant evidence of lung function decrements and respiratory symptoms at 0.060 ppm. *See, e.g.*, 73 Fed. Reg. at 16,454/1-2. Because of that evidence, the Administrator did give some weight to the Adams

results, as part of the evidence of the biological plausibility of epidemiological studies showing adverse health effects at ozone levels below 0.080 ppm. *See supra* 63.

However, the Administrator determined that this clinical evidence was too limited to warrant the heavy weight assigned to it by Environmental and State Petitioners. 73 Fed. Reg. at 16,478/3. EPA noted several sources of possible uncertainty regarding the Adams studies. Both the 2002 and 2006 studies involved only 30 subjects each. *See* SP 5-19, JA 928; 72 Fed. Reg. at 37,858/1 (characterizing data from 30 subjects as "very limited"). In conducting their own analysis of pre- versus post-exposure effects in the two studies, EPA staff found results that "strongly suggest[ed]" – but did not prove beyond all possible doubt, as Petitioners appear to assert – "that exposure to 0.06 ppm O_3 causes small group mean FEV_1 decrements in healthy adults with some individuals having notable effects." SP 3-9, JA 760; *see also id.* at 6-7, JA 1015. Although EPA's subsequent reanalysis in the Brown Memorandum did find statistically significant results for the 2006 Adams study, it did not do so for the 2002 study as Environmental Petitioners suggest. Environmental Br. 5. Furthermore, as EPA noted, the results of the 2006 study had not been replicated, leaving EPA with only one study of 30 subjects on which to base its conclusions regarding the impacts of exposures at 0.060 ppm on the population generally. RTC 24, JA 3062.

Additionally, although Adams' data provided information about lung function decrements and respiratory symptoms occurring below 0.080 ppm, there was clear evidence of other adverse effects in healthy people – inflammation, increased airway responsiveness, and impaired host defenses – *only down to 0.080 ppm*. SP 6-59, 6-77, JA 1067, 1085. (By contrast, in 1997, 0.080 ppm was the lowest-observed-effects level for all five of these health outcomes. 61 Fed. Reg. at 65,729/2-3.) The Administrator considered this a factor in determining how to weigh the potential health risks of exposures at *and below* 0.080 ppm:

> The Administrator recognizes that the 0.080 ppm benchmark level represents a level at which several health outcomes, including lung inflammation, increased airway responsiveness, and decreased resistance to infection have been shown to occur in healthy adults. The Administrator places great weight on the public health significance of exposures at and above this benchmark level given the greater certainty that these adverse health responses are likely to be observed in a significant fraction of the at-risk population.

73 Fed. Reg. at 16,481/2; *see also* SP 6-60, JA 1068 (recommending a standard ranging up to "somewhat below" 0.080 ppm, the lowest-observed-effects level for pulmonary inflammation, increased airway responsiveness and impaired host-defense capabilities).

The Administrator therefore, within his discretion, reasonably placed greater weight on the clinical evidence of health effects at 0.080 ppm in considering this body of evidence as a whole. 73 Fed. Reg. at 16,481/2; *see also id.* at 16,454/2 (disagreeing with commenters "that the percent of subjects that experienced FEV_1

decrements greater than 10% in this study of 30 subjects can appropriately be generalized to the U.S. population").

Environmental Petitioners assert that the Administrator's treatment of the Adams studies fails under a "substantial evidence" test. Environmental Br. 19. Notably, this Court has declined to second-guess EPA's technical judgments under such a standard, as long as the Administrator has made a "rational judgment" based on the record. *API*, 665 F.2d at 1185; *see also LIA*, 647 F.2d at 1146 n.29. Therefore, the Court still must defer to the Administrator's judgment where it is the product of reasoned decisionmaking.

Although Environmental Petitioners contend that the Administrator did not have sufficient reason to consider the Adams studies to be uncertain given that there were no other studies at 0.060 ppm showing an *absence* of effects or refuting the Adams results, Environmental Br. 19, those are not the only factors that EPA may consider in evaluating a scientific study. The Administrator articulated several other reasons – outlined *supra* 93-95 – as a basis for his judgment that the Adams studies were too limited to allow for a primary focus on 0.060 ppm as an exposure of concern, and it is *that* explanation that the Court must review for rationality.[19]

[19] As discussed further *infra* 115-18, Environmental Petitioners' appeal to CASAC's recommended range of 0.060 to 0.070 ppm as undermining the rationality of EPA's choice of a 0.075 ppm standard is unavailing. Even CASAC

Environmental Petitioners acknowledge that the Adams studies had not been replicated, creating a basis for some uncertainty. However, they view that fact as insufficient to support "a finding that the results are not reliable." Environmental Br. 20. They contend that, given that there were two sets of data reported by Adams, from 2002 (based on data from a 1998 experiment) and 2006, "findings of significant breathing impairment at 0.060 ppm were replicated." *Id.* Foremost, Environmental Petitioners incorrectly indicate that both of these studies produced statistically significant results. *Supra* 19-21; *see* Environmental Br. 5. Additionally, this argument does not account for the Administrator's other bases for considering the Adams studies to be only very limited evidence. *Supra* 93-95. Nor have Environmental or State Petitioners identified any relevant factors that EPA failed to consider in deciding how much weight to give the Adams studies.

The Court should not give credence to Environmental Petitioners' assertion that EPA has previously given greater weight to evidence of these types. Environmental Br. 21. The fundamental flaw with that approach is that, in each NAAQS rulemaking, EPA assesses the body of evidence *as a whole*. *See* 73 Fed. Reg. at 16,439/3; 44 Fed. Reg. at 8209/3 (Administrator determines requisite standard "after weighing *all* the medical evidence bearing on ozone," including

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did not view the Adams studies as eliminating all uncertainty regarding the impacts of ozone at levels down to 0.060 ppm, and therefore recommended a standard anywhere up to 0.070 ppm as reasonable.

both inconclusive and conclusive studies (emphasis in original)). Since no single study is ever judged in isolation, but rather alongside other evidence, pointing to one study as the basis for an EPA decision out of context – as Environmental Petitioners do, *see* Environmental Br. 21 – will often fail to capture the full reasons for the Agency's decision. *Cf.* 44 Fed. Reg. at 8207/3-08/1 (giving weight to non-significant results of "key" study cited by Environmental Petitioners as exclusive basis for 1979 ozone NAAQS in part because "the two most sensitive subjects sustained *markedly impaired* respiratory function and exercise ventilatory patterns" at 0.15 ppm); *id.* at 8209/1-2, 8216/3 (also expressing concern about other studies showing effects at levels down to 0.10 ppm).

EPA considered the Adams studies in full, but simply came to a different conclusion than that urged by Environmental or State Petitioners in deciding how much weight to place on this evidence. It is well-established that a reasoned explanation on the technical question of how much confidence to place in the results of a scientific study merits an "extreme degree of deference" from the Court, *AFB*, 559 F.3d at 519 (citation and internal quotation marks omitted), even if "the evidence in the record may also support other conclusions." *LIA*, 647 F.2d at 1160. The Court must therefore defer to the Administrator's assessment of the evidence on this point.

2. EPA Reasonably Weighed the Epidemiological Studies as Evidence of Associations, But Not Direct Causal Evidence.

Environmental Petitioners' citations to epidemiological studies showing adverse health effects below 0.075 ppm and to the results of the exposure and risk assessments, Environmental Br. 21-22, are also unavailing. EPA has reiterated on multiple occasions its cognizance "of the uncertainties related to whether the observed associations between O_3 concentrations at levels well below 0.080 ppm and the health outcomes reported in the epidemiological studies reflect actual causal relationships." 73 Fed. Reg. at 16,470/2; *see generally* 72 Fed. Reg. at 37,838-40 (discussing possible sources of uncertainty regarding epidemiology evidence). Therefore, EPA weighs epidemiological studies as part of the entire body of evidence, examining such factors as their biological plausibility, overall consistency, strength of associations, robustness, and coherence in determining how much confidence they warrant. 72 Fed. Reg. at 37,823/3, 37,837-38.

Based on these factors, the Administrator did consider the epidemiological studies as significant evidence of adverse health effects at ozone levels below 0.080 ppm. *See, e.g.*, 73 Fed. Reg. at 16,476/3. However, the Administrator's assessment of the weight of the epidemiological evidence logically depended on the ozone level in question, and the existence of other evidence supporting the causal nature of associations at those levels. He accordingly concluded that "evidence of a causal relationship between adverse health outcomes and O_3

exposures became increasingly uncertain" given that several relevant health effects had been observed only down to 0.080 ppm, and the Adams data at 0.060 ppm was "very limited." *Id.* at 16,479/3. Additionally, EPA noted other possible uncertainties at lower levels:

> Further, at lower levels, it becomes increasingly uncertain as to whether the reported associations are related to O3 alone rather than to the broader mix of air pollutants present in the ambient air. EPA notes that the multi-city time series studies evaluated in this review do not resolve this issue. It also becomes increasingly uncertain as to whether effect thresholds exist but can not be clearly discerned by statistical analyses. Thus, when considering the epidemiological evidence in light of the other available information, it is reasonable to judge that at some point the epidemiological associations can not be interpreted with confidence as providing evidence that the observed health effects can be attributed to O3 alone.

RTC 29, JA 3067. On these grounds, the Administrator rejected the view that the epidemiological evidence was sufficient to support a standard as low as 0.060 ppm. *Id.;* 73 Fed. Reg. at 16,479/3.

Environmental Petitioners cite only a single example of a judgment on causality at levels below 0.080 ppm: the Staff Paper statement that ozone exposure at 0.060 ppm was likely to cause adverse effects in sensitive groups. Environmental Br. 26 (citing SP 6-61, JA 1069). While the Court may consider the Staff Paper in reviewing the Administrator's decision to "determin[e] whether the EPA has adequately addressed the relevant considerations and reasonably reached its conclusions," *AFB*, 559 F.3d at 521, it remains within the discretion of

the Administrator to make the policy judgments necessary to set standards at the "frontiers of scientific knowledge." *LIA*, 647 F.2d at 1146-47 (internal quotation marks and citation omitted); *see also id.* at 1155 n.50. In reviewing such policy judgments, "where no factual certainties exist or where facts alone do not provide the answer," the courts look to see whether the Administrator has explained "the reasons why he chooses to follow one course rather than another." *Id.* at 1147 (quoting *Indus. Union Dep't, AFL-CIO v. Hodgson*, 449 F.2d 467, 475-76 (D.C. Cir. 1974)). Here, the Administrator concluded that the Adams results were too limited to warrant a primary standard below 0.075 ppm, and offered record-based reasons for that decision as outlined above. While the Administrator placed less weight on the Adams studies than CASAC or the Staff Paper had, *see* 73 Fed. Reg. at 16,483/1; SP 6-7, JA 1015, the rational grounds for that exercise of his judgment merit this Court's deference. *LIA*, 647 F.3d at 1158 ("[T]he Administrator . . . . has explained his factual findings and policy judgments, and there is an adequate basis in the record for these decisions. No more is required of him.").

Environmental Petitioners' main critique of EPA's rationale – that "nowhere did EPA find or show that the uncertainty was 'too great' to justify disregarding the adverse effects shown," Environmental Br. 25 – is unavailing; this Court specifically affirmed EPA's position in *ATA III* that it need not specify any "threshold amount of scientific information or degree of certainty" in setting a

NAAQS. *ATA III*, 283 F.3d at 369. As always, the Administrator is simply required to set forth a reasoned decision, which he did here in stating that he had decided to set the primary standard at 0.075 ppm based on the uncertainties of the body of evidence at lower exposure levels. 73 Fed. Reg. 16,483/2; *id.* at 16,478/1 ("[T]he Administrator judged that the increasing uncertainty of the existence and magnitude of additional public health protection that standards below 0.070 ppm might provide suggested that such lower standard levels would likely be below what is necessary to protect public health with an adequate margin of safety.").

Thus, this is not like the cases cited by Environmental Petitioners, which concern circumstances where EPA had failed to articulate the role of uncertainty in its reasoning or had not offered a reasoned basis for finding that uncertainty exists. In *Massachusetts v. EPA*, the Supreme Court faulted EPA for failing to reach any final decision as to whether greenhouse gases endanger public health under 42 U.S.C. § 7521(a)(1), where EPA did not determine that "the scientific uncertainty is so profound that it precludes EPA from making a reasoned judgment" on that issue. 549 U.S. at 534. Here, EPA did make a final decision about what primary NAAQS is requisite and how uncertainties affected that decision. Similarly, in *State Farm*, the Supreme Court criticized EPA's reasoning in asserting "substantial uncertainty" where the agency had failed to consider evidence that seemed to provide further relevant information. 463 U.S. at 52-54. Where EPA bases a

decision on the presence of uncertainty, the Agency must – as always – "explain the evidence which is available, and . . . offer a 'rational connection between the facts found and the choice made.'" *Id.* at 52 (citations omitted). Here, EPA reasonably accounted for all the evidence cited by Environmental and State Petitioners but still found uncertainty about ozone effects at lower exposure levels because of the nature of that evidence, such that a standard below 0.075 ppm would be more stringent than necessary. However, *Massachusetts v. EPA* and *State Farm* offer no ground for requiring EPA to go beyond this traditional standard to include some particular additional phrasing – such as a statement that uncertainty is "too great,"[20] Environmental Br. 25 – as a sort of regulatory incantation in order to render its reasoning valid.

Environmental Petitioners' cited examples of situations where EPA has set NAAQS relying only on epidemiological studies (the 2006 particulate matter NAAQS and the 2008 lead NAAQS) are also inapposite. Foremost, it is impossible to equate two wholly different sets of epidemiological evidence, given that EPA assesses the strength of such epidemiological evidence with close attention to the specific details of the studies and possible confounding factors,

[20] *ATA III*, cited by Environmental Petitioners, quoted the Administrator's statement that "inherent scientific uncertainties are too great to support" lower levels for the NAAQS, but nowhere indicated that such particular phrasing was necessary to support the Administrator's decision. 283 F.3d at 367 (internal quotation marks omitted).

along with the overall consistency of the evidence. *See* 72 Fed. Reg. at 37,823/2-3. And the assertion that EPA did not rely on anything besides epidemiological evidence is inconsistent with EPA's approach of considering the whole body of evidence in each NAAQS review. *Id.* The NAAQS cited by Environmental Petitioners in fact considered the epidemiological evidence in combination with the other available scientific information, in line with EPA weight-of-evidence approach. *See, e.g.*, 71 Fed. Reg. 61,144, 61,180/2 (Oct. 17, 2006) ("[T]he weight of the dosimetric, limited toxicologic, and atmospheric science evidence, taken together, lends support to the plausibility of the $PM_{10-2.5}$-related effects reported in the urban epidemiologic studies."); 73 Fed. Reg. 66,964, 66,976/2, 66,984 n.56 (Nov. 12, 2008) (citing laboratory animal studies as important in substantiating the epidemiological evidence).

3. EPA Reasonably Weighed the Results of the Exposure and Risk Assessments in Light of Its Varying Levels of Certainty About the Underlying Causal Relationships.

EPA's weighting of the exposure assessment was based on its consideration of the strength of the evidence underlying these assessments. EPA used the exposure assessment to estimate population exposures to various benchmark levels of concern. *See* 72 Fed. Reg. at 37,851/3. However, the conclusions that the Administrator could draw from this information were only as strong as the Administrator's certainty that exposures at a given level would cause adverse

health effects. EPA recognized those uncertainties as affecting its confidence in the results of the exposure assessment at lower ozone levels. *See* 72 Fed. Reg. at 37,853/3 ("In considering the concept of exposures of concern, it is important to balance concerns about the potential for health effects and their severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower O_3 levels.").

Since, as outlined above, the Administrator considered the Adams studies to be very limited causal evidence regarding exposures at 0.060 ppm, he reasonably placed very little weight on 0.060 ppm as a benchmark exposure of concern. 73 Fed. Reg. at 16,481/2-3. The risk assessment was also based in large part on epidemiological data, 72 Fed. Reg. at 37,824/2, and subject to the same uncertainties. *See* 73 Fed. Reg. at 16,467/2. Accordingly, Environmental and State Petitioners' repeated allegations that the 0.075 ppm primary standard will allow tens of thousands more asthmatic children to suffer lung function decrements every year, Environmental Br. 29 and State Br. 24, omit an important consideration: the Administrator viewed such risks as increasingly uncertain as ozone exposure levels decreased, and therefore did not rely on those specific estimates of health effects. 73 Fed. Reg. at 16,483/2, 16,459/1. This Court has already deferred to similar reasoning with respect to the particulate matter

NAAQS, and it should do the same here. *ATA III*, 283 F.3d at 374; *see also AFB*, 559 F.3d at 527-28 (similar).

4. EPA Reasonably Weighed the Totality of the Evidence.

Environmental Petitioners assert that EPA failed to properly weigh the totality of the evidence in judging that there were important uncertainties about the public health impacts of ozone at lower levels. Environmental Br. 29-33. To the contrary, the Administrator considered each piece of evidence raised by Environmental Petitioners and articulated his reasons for finding greater uncertainty in the body of evidence than they do. *Supra* 92-105.

C. EPA Reasonably Provided an Adequate Margin of Safety in the Primary Standard by Erring on the Side of Caution.

1. EPA Explained How the 2008 Primary Ozone Standard Provided an Adequate Margin of Safety.

Environmental and State Petitioners both contend that EPA did not offer any explanation of how the 0.075 ppm standard would provide an adequate margin of safety. Environmental Br. 33; State Br. 20-24. This argument is belied by a full review of the Administrator's reasoning, which at many points addressed the need to protect against uncertain risks that is at the heart of the margin-of-safety requirement.

For the NAAQS to provide an adequate margin of safety, EPA must "regulate not only the known dangers to health, but may 'err' on the side of

overprotection by setting a fully adequate margin of safety." *API*, 665 F.2d at 1186; *see also ATA III*, 283 F.3d at 369 (describing margin-of-safety requirement as obligating EPA to "err on the side of caution" where a "pollutant's risks cannot be quantified or precisely identified as to nature or degree"). However, the choice of how to do so is "a policy choice of the type that Congress specifically left to the Administrator's judgment." *LIA*, 647 F.2d at 1162. In particular, the Administrator need not "identify[] a 'safe level' and then apply[] an additional margin of safety." *ATA III*, 283 F.3d at 368. He may instead "take into account margin of safety considerations throughout the process as long as such considerations are fully explained and supported by the record." *Id.* (citation and internal quotation marks omitted); *see also NRDC*, 902 F.2d at 973-74.

That is what the Administrator did here. As stated in the final rule, the margin of safety is "intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting" and "provide a reasonable degree of protection against hazards that research has not yet identified," considering both types of uncertainty as "components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty." 72 Fed. Reg. at 37,820/1. The Administrator identified several factors as relevant to this analysis: "the nature and severity of the health effects involved, the size of the population(s) at risk, and

the kind and degree of the uncertainties that must be addressed." *Id.* at 37,820/1; 73 Fed. Reg. at 16,437/2.

In accordance with this approach, the Administrator set a primary ozone NAAQS designed not only to address health risks from exposures down to 0.080 ppm, the level at which he judged there to be strong evidence that ozone causes adverse effects in healthy people, but also to address risks to sensitive groups and risks at levels where the available body of evidence was less certain. Thus, instead of setting the standard just below 0.080 ppm, the Administrator set it "appreciably below" that level to account for risks to individuals with asthma.[21] 73 Fed. Reg. at 16,480/2-3. Similarly, in weighing the exposure and risk assessments, the Administrator focused on a benchmark exposure of concern of 0.070 ppm in determining that a standard of 0.075 ppm is requisite to protect both healthy and asthmatic individuals against health risks even below the level at which adverse health effects had been demonstrated in healthy subjects. *See* 73 Fed. Reg. at 16,441/1; *see also id.* at 16,483/2 ("At a level of 0.075, exposures at and above the benchmark of 0.080 ppm are essentially eliminated, and exposures at and above the benchmark of 0.070 are substantially reduced or eliminated for the vast majority of people in at-risk groups."). The Administrator did not ignore

[21] Even a standard of 0.080 ppm would have represented a reduction from the 1997 standard, which was effectively a 0.084 ppm limit given applicable rounding conventions. *See supra* 10 n.1.

exposures at 0.060 ppm, but decided to place very little weight on them, while noting that they would be reduced by a primary standard of 0.075 ppm. 73 Fed. Reg. at 16,481/3. As a whole, these steps resulted in a margin of safety judged by the Administrator to be adequate to protect against risks to both healthy and asthmatic individuals at levels below 0.080 ppm, even though those risks had not been "precisely identified as to nature or degree." *ATA III*, 283 F.3d at 369.

The Administrator also explained why a lower level was not needed to provide an adequate margin of safety, citing "the increasing uncertainty of the evidence and magnitude of additional public health protection" at such low levels. 73 Fed. Reg. at 16,478/1; *see id.* at 16,483/2 (citing uncertainty about health effects below 0.075 ppm as basis for not choosing a standard of 0.070 ppm). Accordingly, the Administrator judged that the evidence was too uncertain to warrant more protection from such risks than would be provided by a standard of 0.075 ppm. *Id.* at 16,476/1-2, 16,478/3-79/1, 16,481/3. In doing so, the Administrator carried out his statutory charge to set a standard that in his judgment is not "more than necessary" to provide requisite public health protection with an adequate margin of safety. *Whitman*, 531 U.S. at 473.

CASAC's statement in its 2007 letter that it viewed the Staff Paper's discussion of the margin of safety as insufficient is irrelevant in light of this record evidence showing that the Administrator did "err on the side of caution" in setting

the primary standard.[22] *See* 2007 CASAC Letter (cited in State Br. 21). As CASAC itself has recognized, there is a gap between the scientific evidence and those "public health and welfare policy judgments" that are "required of the EPA Administrator." October 2006 CASAC Letter at 2; *see also AFB*, 559 F.3d at 521. The Administrator exercised that judgment in settling on his preferred approach for providing an adequate margin of safety, which was consistent with this Court's direction to "err on the side of caution" in setting the primary standard. *ATA III*, 283 F.3d at 369.

Nor does the decision in *Farm Bureau*, that EPA had not offered a reasonable explanation of how the primary annual $PM_{2.5}$ standard it selected would provide an adequate margin of safety for sensitive populations against risks from fine particles, pertain here. 559 F.3d at 525-26; *see* State Br. 20-23. That holding rested on two important facts: first, that EPA had unreasonably discounted two relevant studies; and second, that EPA had entirely failed to address how the standard would adequately reduce certain risks to subpopulations that it had recognized as particularly vulnerable to particulate matter. 559 F.3d at 525-26. By contrast, here the Administrator explained the limited weight he was giving the Adams studies, and their limited role in his determination. The Administrator also

[22] In arriving at a recommended primary range, the Staff Paper spoke to the same factors later considered by the Administrator in selecting a standard with an adequate margin of safety. SP 1-2 to -3, JA 733-34; *see id.* at 6-5 to -41, JA 1013-49.

took account of risks to asthmatics in setting the 0.075 ppm standard. *See supra* 27-32.

The Administrator has no obligation to follow some particular script or adopt any specific method in selecting a margin of safety. Rather, he need only "err on the side of caution" where, as here, a pollutant's risks cannot be quantified or precisely identified. *ATA III*, 283 F.3d at 369. Here, the Administrator did so, and that approach is evident in his extended discussion of protection against the less certain risks below 0.080 ppm for both healthy and asthmatic individuals.

2. EPA Reasonably Considered All of the Record Evidence in Setting an Adequate Margin of Safety.

Environmental and State Petitioners also contend that EPA substantively failed to provide an adequate margin of safety in the primary ozone standard. However, they advance a position that has no basis in the Clean Air Act or this Court's precedent: that the margin-of-safety requirement obliges the Administrator to set a primary standard that addresses *all* possible risks, no matter how much uncertainty attends them. State Br. 18; Environmental Br. 33. Moreover, Environmental and Industry Petitioners' argument is flawed as a factual matter because they fail to acknowledge the Administrator's explanation of how a 0.075 ppm standard would provide an adequate margin of safety for at-risk groups as well as healthy people, by protecting against exposures below 0.080 ppm, the level

at which the Administrator was highly certain ozone exposure causes adverse health effects in healthy individuals.

EPA did not fail in its obligation to provide an adequate margin of safety merely because it determined to give little weight to evidence of adverse health effects at 0.060 ppm. The Administrator determined, as discussed *supra* 93-95, that that evidence was too uncertain to merit a primary focus on exposures at 0.060 ppm. That reasoned judgment is within the Administrator's discretion. As this Court has recognized, for pollutants such as ozone that lack a demonstrated threshold, EPA cannot eliminate all risks except by setting the primary standard at zero; the decisions, however, have abjured any requirement that EPA take such an extreme step. *ATA III*, 283 F.3d at 360; *see also LIA*, 647 F.2d at 1156 n.51; H.R. Rep. No. 95-294, at 127 (rejecting idea that primary NAAQS "should be set at zero or background levels" in order "to protect against all known or anticipated effects" for non-threshold pollutants). Instead, EPA must select a standard that "reduce[s] risks sufficiently to protect public health." *ATA III*, 283 F.3d at 360 (citation and internal quotation marks omitted).

This Court has therefore expressly held that EPA *can* judge the occurrence of adverse public health impacts to be too uncertain to merit further protection, as the Agency did here in deciding not to eliminate or further reduce exposures down to 0.060 ppm. For example, in *ATA III*, EPA set the particulate matter primary

standard at 15 μg/m^3, "just below the range of mean annual PM2.5 concentrations [16 to 21μg/m^3] observed in studies showing a statistically significant association between fine particulate matter and health effects." 283 F.3d at 372; *see id.* at 366-67. In doing so, EPA recognized that there was the possibility of health risks at lower concentrations, based on non-significant study results showing correlations at annual concentrations down to 11 μg/m^3, but deemed that evidence to be "highly uncertain." *Id.* The Court held that it did not have "any basis for concluding that EPA's decision was unreasonable or unsupported by the record." *Id.* at 372. Here, EPA used a similar approach, setting the standard "appreciably below" the ozone level at which the Agency believed there were established health risks for healthy individuals. 73 Fed. Reg. at 16,482/3; *id.* at 16,480/2-3.

Likewise, in *Farm Bureau*, this Court affirmed EPA's decision not to utilize recent data from two studies in setting the primary annual $PM_{2.5}$ standard. 559 F.3d at 526. EPA explained that it was uncertain about the import of that recent data regarding the effects of annual $PM_{2.5}$ exposures, given the possibility that the effects could be the result of historic, rather than contemporaneous, exposures. *Id.* Given the Agency's explanation of its reasons for not relying on that evidence and the need to set a standard that is not higher than necessary to protect public health, the Court held that EPA had not failed to provide an adequate margin of safety. *Id.* at 526-27 (citing *ATA III*, 283 F.3d at 372). Thus, both *ATA III* and *Farm Bureau*

support the Administrator's judgment here that some risks from ozone exposure are uncertain enough that they do not require an even lower standard to provide an adequate margin of safety.

Another case relied upon State Petitioners, *American Lung Association*, held EPA's analysis to be unreasonable not because the Agency had declined to protect against highly uncertain risks, but because EPA had in fact deemed the effects in question – repeated exposures to sulfur dioxide bursts – to be "significant" but had failed to offer a reasonable explanation for why it did not take them into account as public health impacts relevant to setting a requisite primary standard. 134 F.3d at 392. There was no question about the certainty of these effects, and indeed the Court treated EPA's decision as to whether to consider the effects to be a relevant public health impact as a threshold question not relating to the issue of how EPA should provide an adequate margin of safety. *Id.* at 392-93. That is a far cry from the present situation, where EPA considered the public health risks at issue and offered a reasonable rationale for why it did not believe evidence of adverse health effects at levels down to 0.060 ppm was certain enough to merit more than limited consideration in the Agency's analysis of the requisite standard to protect public health with an adequate margin of safety. *See supra* 92-105.

Additionally, EPA did account for sensitive groups in setting the standard. State Petitioners assert that selecting a standard "just below the level at which [the

Administrator] concluded harm occurs to healthy individuals" is insufficient in light of the evidence regarding asthmatics' greater sensitivity to ozone. State Br. 18. However, the Administrator did *not* set the standard at or "just below" the level at which such harm occurs; rather, he expressly adopted a standard he judged to be "*appreciably* below" 0.080 ppm, to provide a "*significant* increase in protection compared to the current standard." 73 Fed. Reg. at 16,483/2 (emphasis added). That additional protection was specifically aimed at accounting for the effects of ozone on sensitive populations such as individuals with asthma. 73 Fed. Reg. at 16,480/2-3.

EPA's explanation thus accounted for all of the relevant evidence cited by Environmental and State Petitioners. They clearly disagree with the weight that the Agency gave to those considerations. However, those are questions subject to EPA's scientific and public health policy judgment, to which this Court must defer as long as EPA has reasonably explained its judgment. *AFB*, 559 F.3d at 521.[23]

[23] In its corrected brief, at pages 13-15, Amicus Province of Ontario argues that the 2008 primary ozone standard is arbitrary and capricious because it fails to adequately protect sensitive groups, is contrary to *Farm Bureau*, and departs from CASAC's recommendations. As explained above and further below, EPA reasonably responded to these issues, which State and Environmental Petitioners also raise. The other issues raised by Amicus – regarding ozone standards in the Province of Ontario and other countries and their purported metric and bases (at 1-5 & 7), regarding trans-boundary pollution impacts on Ontario (at 7-12), and regarding the "Foreign Relations Law of the United States" and the "U.S.-Canada Ozone Annex" (at 15-16) – were not raised by any of the parties in these consolidated petitions for review, and thus should not be considered by the

D. EPA Reasonably Explained Its Decision to Set a Standard Above CASAC's Recommended Range.

The requirement imposed by CAA section 307(d)(3) is straightforward: if EPA sets a NAAQS outside the range recommended by CASAC, the Agency must explain its departure. 42 U.S.C. § 7607(d)(3). As this requirement suggests, however, the traditional arbitrary-and-capricious standard of review remains the same. This Court recognized in *Farm Bureau*, where the Administrator had declined to rely on a quantitative risk assessment in setting the particulate matter NAAQS despite the fact that both CASAC and the Staff Paper considered the risk assessment to be reliable, that "[e]ven so we must defer to the EPA's assessment of 'scientific data within its technical expertise' as long as the agency has examined the data and adequately explained itself." 559 F.3d at 527 (citation omitted). Since in that case EPA had "considered all aspects of the problem [and] catalogued its concerns," the Court upheld the Agency's choice despite its departure from CASAC's recommendation. *Id.* Here, EPA has likewise provided a reasoned explanation for its departure from the CASAC-recommended range of standards, and the Court should similarly affirm its decision.

Court. *Michel v. Anderson,* 14 F.3d 623, 625 (D.C. Cir. 1994); *e.g., Eldred v. Reno,* 239 F.3d 372, 378 (D.C. Cir. 2001) (citing cases), *reh'g denied*, 255 F.3d 849, 851 (2001) (citing cases), *aff'd*, 537 U.S. 136 (2003); *Snyder v. Phelps,* 580 F.3d 206, 216 (4th Cir. 2009*), aff'd,* 131 S.Ct. 1207 (2011). Moreover, these other issues are based largely on documents outside the administrative record for judicial review in this case (*e.g.*, Amicus 3-12), and thus should not be considered for this reason as well.

CASAC cited an array of evidence in support of its recommendation of a standard in the range of 0.060 to 0.070 ppm, which it transmitted to EPA in its October 2006 letter. Like EPA, CASAC recognized new evidence regarding both the relationship between ozone and respiratory morbidity and the increased sensitivity of asthmatics. October 2006 CASAC Letter at 3, JA 1333. This evidence included: (1) several new epidemiological studies providing more evidence of adverse health effects at concentrations below the level of the 1997 standard, "backed-up by evidence from controlled human exposure studies that also suggest that the current primary ozone NAAQS is not adequate to protect human health (Adams, 2002; McDonnell, 1996)"[24]; (2) the Adams studies, providing evidence of adverse lung function effects in healthy individuals at 0.060 ppm; (3) the fact that asthmatics had "been found to be more sensitive and to experience larger decrements in lung function in response to ozone exposures than would healthy volunteers; and (4) "the broad range of epidemiologic and controlled exposure studies cited" in items (1) and (2), which showed associations between ozone exposure and health endpoints such as school absences, emergency department visits, hospital admissions, medication usage, and mortality. October 2006 CASAC Letter at 3-4, JA 1333-34. Based on this evidence, CASAC

[24] The cited McDonnell study was one of the controlled human exposure studies showing lung function decrements caused by ozone exposures at levels down to 0.08 ppm. *See* SP 3-6 to -7, JA 757-58.

unanimously advised that the 1997 standard of 0.08 ppm was not adequate, that it must be substantially reduced to provide increased protection, especially for sensitive subpopulations, and that the primary standard should be set somewhere in the range of 0.060 to 0.070 ppm. *Id.* at 5, JA 1335.

Although CASAC, like EPA, considered the entire body of evidence as a whole, this description makes clear the key role that the Adams studies played in CASAC's recommendation – as evidence supporting the plausibility of epidemiological studies linking ozone to a number of adverse health effects at levels below the 0.080 ppm standard in items (1) and (4), and as direct evidence of ozone effects down to 0.060 ppm in item (2). Therefore, as the Administrator explained, the significantly lesser weight that he placed on the Adams studies provided a rational justification for him to set the primary standard higher than CASAC recommended. 73 Fed. Reg. at 16,483/1. Moreover, the Administrator's alternative weighting of the Adams studies reflected CASAC's own view that the Adams studies were not of such weight that the standard had to be set at 0.060 ppm; otherwise CASAC presumably would not have recommended a *range* for the primary standard that included levels well above 0.060 ppm. *See id.* at 16,483/1. CASAC also cited the results of the risk assessment as showing reduction in adverse health effects continuing down to a standard of 0.064 ppm, the lowest concentration considered. October 2006 CASAC Letter at 4, JA 1334. In

accordance with the Administrator's views on Adams, he noted that he did not place as much weight on risk estimates at that level as CASAC appeared to, based on his own judgment as to the certainty of the health evidence underlying the risk assessment. 73 Fed. Reg. at 16,483/1.

Where, based on uncertainties in the data, CASAC has recommended setting the standard somewhere in the range between 0.060 and 0.070 ppm, did the Administrator act arbitrarily and capriciously by judging the uncertainty to be greater than CASAC had and thus setting the final primary standard above the top of CASAC's recommended range? Given the Administrator's reasoned explanation of his view of the relevant uncertainties, the answer must be "no."

III. EPA REASONABLY EXPLAINED ITS DECISION TO SET A REVISED SECONDARY OZONE STANDARD, AND PETITIONERS' CHALLENGES PROVIDE NO BASES TO UPSET THAT DECISION.

A. Industry Petitioners' Challenge

Industry Petitioners challenge the revised secondary standard solely on the ground that it allegedly is "'at least in part based on'" the primary standard. Industry Pet. Br. 60-61 (quoting *ATA I*, 175 F.3d at 1040). They argue therefore that if the primary standard is declared unlawful, the secondary standard must also be set aside and remanded. *Id.* On this logic alone, since Industry's challenge to the revised primary standard must be rejected for the reasons explained *supra* 42-89, so also must their challenge to the revised secondary standard be rejected.

Moreover, EPA set out its reasons why, independent of the revised primary standard, the 1997 secondary standard must be revised, *see* 73 Fed. Reg. at 16,496-47, and why 0.075 ppm using the eight-hour form for that revision is requisite to protect public welfare. *See* 73 Fed. Reg. at 16,399/3-16,500. Industry Petitioners did not challenged these findings or explanation in their opening brief, and they may not do so now. *United States v. Van Smith*, 530 F.3d 967, 973 (D.C. Cir. 2008) (arguments first raised in reply brief are waived). The revised secondary standard, therefore, should be upheld regardless of the Court's ruling on Industry Petitioners' challenge to the revised primary standard.

B. Environmental and State Petitioners' Challenges

1. EPA Reasonably Concluded that a Revised Secondary Standard is Needed.

The Environmental and State Petitioners agree with EPA's conclusion that the 1997 secondary standard of 0.08 ppm using the eight-hour form must be revised to afford greater public welfare protection for ozone-induced adverse effects on sensitive vegetation and natural ecosystems. The Administrator based his decision upon new evidence demonstrating that adverse vegetation effects are expected to occur at exposures that would remain after meeting the 1997 secondary standard. 73 Fed. Reg. at 16,496/2. These effects include visible injury to leaves (foliar injury) and the loss of seedling growth and the mature tree biomass, *id.*; *see id.* at 16,486/1, which in turn may impair the ability of affected species to

withstand other environmental stresses, such as those from pests, temperature and disease. *Id.* at 16,492/2. For example, numerous new chamber and field studies indicate that such effects will occur to important ozone-sensitive species at ozone levels in areas just meeting the prior 0.08 secondary standard. *Id.* at 16,485/3-16,486. Tree species affected include aspen, ponderosa pine, black cherry, red oak and red maple. *Id.* at 16,488/3-89/2. The effects over time may affect the long-term survival and reproduction of individual affected trees and "ultimately the abundance of sensitive tree species in forest stands." *Id.* at 16,489/2. The Administrator concluded that such effects also impact the wildlife habitat and health of the forested ecosystem that depends upon such affected species. *Id.* at 16,496/2-3.

The Administrator judged these effects adverse to public welfare based upon the intended use of the affected resources and ecological receptors. *Id.* at 16,496/3; 72 Fed. Reg. at 37,889/3-90/1. Thus the Administrator concluded, for example, that such effects on trees in forests as well on the wider natural ecosystem they support are adverse to protected public lands and to the scenic wildlife and wilderness values such lands are designed to protect. 73 Fed. Reg. at 16,496/3. The Administrator's determination that a revised secondary standard was needed was based on his evaluation of the strengths and weaknesses of this

information as well as CASAC's recommendation that additional protection was necessary and the public comments received. *See id.* at 16,496-97.

2. The Administrator Reasonably Explained His Reasons For Not Adopting a Cumulative, Seasonal Form for the Revised Secondary Standard.

Environmental and State Petitioners' primary point of departure from EPA's decision is that, in setting the revised secondary standard, EPA employed the same eight-hour form as the prior secondary standard instead of adopting a cumulative, seasonal form that sums weighted hourly ozone concentrations over the course of a three-month growth season. These Petitioners note that a standard using a cumulative, seasonal form would have better reflected scientific information on biologically relevant exposures, and that CASAC itself recommended that EPA adopt such a form. Environmental Br. 37-38; State Br. 27.

EPA concurs that a cumulative, seasonal form more directly matches the underlying scientific data regarding biologically relevant exposures that pose adverse vegetation and ecosystem effects than does an eight-hour form. 73 Fed. Reg. at 16,493/3-16,494/1, 16,500/1. The Administrator thus did not rule out or fail to consider setting a revised secondary standard based upon such a form. He disagreed, however, that this "better match" dictates that *only* a revised secondary standard defined through a cumulative, seasonal form would be requisite to protect public welfare. *Id.* To the contrary, the Administrator assessed the revision of the

secondary standard more holistically than Petitioners advocate here, by considering the form in connection with its level, the differences in protection expected from the alternatives considered, and the uncertainties associated with each alternative, in judging what standard would be requisite to protect public welfare.

For example, the Administrator considered EPA's analysis showing "significant overlap" in areas with air quality expected to just meet a 0.075 ppm with an eight-hour form (i.e., the revised primary ozone standard) and areas just meeting selected levels using a cumulative, seasonal form. *Id.* at 16,499/3. This informed the Administrator's judgment that a revised secondary standard set at the same level and form as the revised primary standard would provide significant, increased protection for vegetation over the existing secondary standard. *Id.* at 16,499/3. The Administrator also identified a target level of protection in terms of a cumulative, seasonal standard. Based on the uncertainties in the evidence and in determining the existence and degrees of adversity, the Administrator focused on the level of 21 ppm-hours, at the upper end of the proposed range of levels. *Id*. at 16,499-500. Based on an analysis of currently monitored counties, a cumulative, seasonal form at the proposed level of 21 ppm-hours "would be unlikely to provide additional protection in any areas beyond that likely to be provided by the revised primary standard." *Id.* at 16,500/1. In balancing the need to provide sufficient but not more than necessary protection, the Administrator evaluated the risk of under-

protection from using a standard with an eight-hour form. He identified this as a potential risk for currently unmonitored areas that might have air quality associated with high cumulative, seasonal levels, but without high eight-hour averages associated with the eight-hour form. Though noting this potential risk, the Administrator explained that the number and size of such areas and the degree of risk were difficult to determine. *Id.* He also considered the potential risk of impermissibly providing *more* protection than was necessary, which would arise from moving to a secondary standard with a new form under circumstances where there was significant uncertainty in determining the risk associated with various exposure levels, the appropriate degree of protection, and the uncertainty in predicting exposure and risk patterns. *Id.*

The Administrator also explained his reasons for departing from CASAC's advice. While he concurred with CASAC that a cumulative, seasonal standard is the most biologically relevant way to relate exposures to plant growth, the Administrator disagreed that this outweighs the "significant uncertainties in determining or quantifying" risks among varying levels of ozone exposure and the degree of protection afforded by any specific level at which a cumulative, seasonal standard might be set, and the "associated potential for error" in determining such a standard that would be requisite. *Id.* Given these uncertainties, the Administrator concluded that a cumulative, seasonal standard "would result in

uncertain benefits beyond those afforded by the revised primary standard and therefore may be more than necessary to provide the requisite degree of protection." *Id.* at 16,500/1-2. At the same time, the Administrator concluded that a revised secondary standard set at the level and form of the revised primary standard "would be sufficient to protect public welfare from known or anticipated adverse effects," even without the addition of a cumulative, seasonal standard. *Id.* at 16,500/2.

State Petitioners fault the Administrator's explanation for not adopting a seasonal, cumulative standard, arguing that in comparing alternative levels for a cumulative, seasonal standard to a secondary eight-hour standard at 0.075 ppm, the Administrator should have given greater weight to a comparison at a level below 21 ppm-hours. State Br. 30-31. The Administrator, however, explained that 21 ppm-hours was within the range he proposed for a cumulative, seasonal average, 73 Fed. Reg. at 16499/3-500/1, and he further explained the importance of this level in terms of protection. For example, extensive studies on representative domestic agricultural crops indicated that 50 percent of the studied cases would be protected from greater than 10 percent yield loss with a standard at a level of 21 ppm-hour using a cumulative, seasonal form. 72 Fed. Reg. at 37,889/2-3. This level of protection also has significant implications in natural forests, such as those in national parks, since losses ranging up to 40% in seedling biomass at exposures

above this level have been demonstrated for important tree species. *Id.* at 37,891/3; *see also* 73 Fed. Reg. at 16,487/3 (approximate biomass loss in tree seedlings associated with 21 ppm-hour). Such adverse effects on forests are important because "[i]mpacts on seedlings may potentially affect long-term tree growth and survival, ultimately affecting the competitiveness of O_3-sensitive tree species and genotypes within forest stands." 72 Fed. Reg. at 37,891/3. EPA further considered the important geographical regions where O_3 would exceed this level. *Id.* at 37,892/2-3.

Moreover, the Administrator explained that he "focused his consideration" in this comparison on 21 ppm-hours from within the range given

> the significant uncertainties that remain in the available body of evidence of O_3-related vegetation effects in the exposure and risk analyses conducted for this review, and the difficulty in determining at what point various types of vegetation effects become adverse for sensitive vegetation and ecosystems . . . .

73 Fed. Reg. at 16,499/3. These uncertainties are well documented in the record.[25]

In sum, the record does note support State Petitioners' arguments that the Administrator failed adequately to explain his reasoning or that he "skew[ed] the analysis," as they contend. State Br. 30-31. Rather, their arguments are at their

[25] *E.g.*, 72 Fed. Reg. at 37,887/2 (uncertainties in relating visible foliar injury symptoms to other vegetation effects); RTC 117, JA 3117 (uncertainties in judging the degree of adversity associated with visible foliar injury effects); 72 Fed. Reg. at 37,894 (uncertainties in relating results for tree seedling biomass loss to that of mature trees); RTC 118, JA 3118 (uncertainties in judging what level of tree seedling loss is adverse).

core disagreements with the Administrator's judgment in weighing the relative strengths and weaknesses of the relevant scientific information, a matter in which the Agency is entitled to an "'extreme degree of deference.'" *AFB*, 559 F.3d at 519 (citation omitted); *LIA*, 647 F.2d at 1160. Moreover, the Agency did examine the results of comparisons of numbers of areas with air quality expected to just meet an eight-hour standard at 0.075 ppm (i.e., the revised primary ozone standard) and areas just meeting levels lower than 21 ppm-hours, including those within the range CASAC recommended for a cumulative, seasonal standard. 73 Fed. Reg. at 16,499/3. As explained above, the Administrator rejected these lower levels of a cumulative, seasonal form as a basis for the proper focus of comparison given the significant uncertainties and the associated likelihood that such a lower standard would be more protective than necessary.

For these same reasons, the Administrator's comparison does not suffer the defects of the approach rejected in *Farm Bureau*, as State Petitioners assert (at 32). In that case, the Court concluded that EPA simply failed to explain why it relied upon one comparison over others when concluding that a revised secondary particulate matter standard different than the primary was not necessary. 559 F.3d at 530 ("EPA failed to explain . . . ."). Unlike that situation, and as discussed above, not only did the Administrator here explain that he focused on the level of protection afforded at 21 ppm-hours with a cumulative, seasonal standard, but he

also explained his reasons for his focus on that level in his comparison rather than focusing on lower levels and other comparisons. He also explained his ultimate conclusion that such a standard "would be unlikely to provide additional protection in any areas beyond that likely to be provided by the revised primary standard." *Id.* at 16,500/1.

The Environmental Petitioners (at 35-36) fault EPA's balance of the relevant considerations, arguing that EPA failed to identify the particular level of uncertainty to justify not setting a requiste level. The Administrator did not, however, claim that uncertainty precluded him from setting a secondary standard requisite to protect public welfare; rather as explained above uncertainty was one of the factors he considered in setting the requisite standard. Moreover, EPA is under no obligation to quantify or specify a threshold level of uncertainty in its decision-making. Indeed, this Court has consistently rejected parallel efforts by industry petitioners challenging EPA's NAAQS decisions. For example, this Court in *ATA III* affirmed EPA's position that it need not specify any "threshold amount of scientific information or degree of certainty" in setting a NAAQS. *ATA III*, 283 F.3d. at 369 ("we have expressly rejected the notion that the Agency must 'establish a measure of the risk to safety it considers adequate to protect public health every time it establishes a [NAAQS]'" (citation omitted); *see supra* 100-01. Thus, less certainty, due for example from a lack of direct evidence, "provid[es] an

eminently rational reason" to set a NAAQS at a higher level. *ATA III*, 283 F.3d at 379.

Environmental Petitioners also contend that EPA failed to identify a "target level" of welfare protection before setting a level for the revised secondary standard, Environmental Br. 36, and that this renders the Administrator's explanation inadequate under *Farm Bureau*. That decision and its particular circumstances are inapposite. In that case, CASAC and staff recommended a range for a secondary particulate matter NAAQS. 559 F.3d at 528. In rejecting that range, EPA argued in part "that it need not determine what level of visibility protection is requisite to protect the public welfare," *id.* at 530, a proposition the Court rejected. *Id.* In contrast, here the Administrator explained why he focused on the degree of protection afforded by a level of 21 ppm-hours, and why he concluded that a revised secondary eight-hour standard set at 0.075 ppm is requisite to protect public welfare.

Moreover, *Farm Bureau* did not categorically reject the use of comparisons of air quality between areas to inform the Administrator's judgment of the protections provided by alternative standards, but rather found flaws in the particular comparisons at issue, involving inconsistencies in air quality data used, and on that basis concluded that the comparisons said nothing about the relative protections afforded by the alternatives. 559 F.3d at 530. It was in this context

that the Court faulted as arbitrary EPA's reliance upon those comparisons. Neither do we agree with Petitioners' apparent reading of *Farm Bureau* to sanction only one particular approach to standard-setting, or to require that EPA identify a separate "requisite" level of protection for each welfare effect considered. To the contrary, EPA must retain discretion to consider and balance the often differing and incomplete forms of information available about the different public welfare effects, and their relative strengths and weaknesses, without the imposition of artificial obstacles to its decision-making. The Administrator's judgments must be based on reasoned decision-making, but the case law does not impose the kind of restriction Petitioners' favor on the tools available to the Administrator in reaching such judgments. *See, e.g., LIA*, 647 F.2d at 1180 (the Administrator "properly concentrated his attention on whether the welfare effects of lead exposure justified promulgation of a more stringent secondary standard"); *see id.* at 1162 ("[t]he choice between . . . possible approaches is a policy choice of the type that Congress specifically left to the Administrator's judgment"); *NRDC*, 902 F.2d at 973 (refusing to impose a specific methodology for EPA to follow in determining the requisite NAAQS); *ATA II*, 283 F.3d at 379 (upholding the Administrator's choice of level because it was the product of "reasoned decision-making").

3. The Administrator Did Not Fail to Consider Public Welfare Effects of Alternative Eight-Hour Standards at Levels Below 0.075 ppm.

The State and Environmental Petitioners next contend that the record demonstrates that adverse effects to vegetation will occur at levels below 0.075 ppm with an eight-hour form for the revised secondary standard, indicating that EPA should have adopted a more protective standard. Environmental Br. 38; State Br. 29. To the extent Petitioners argue that EPA should have adopted a lower level for the secondary standard using an eight-hour form, that argument is waived. This argument was not raised during the comment period and therefore cannot be raised for the first time in this Court as a basis to challenge EPA's decision. 42 U.S.C. § 7607(d)(7)(B); *NRDC v. EPA*, 571 F.3d 1245, 1259 (D.C. Cir. 2009) (we "'enforce[] this provision strictly'") (citation omitted).

Moreover, even though effects remain below 0.075 ppm, that is no basis to upset the Administrator's decision. The possibility that the evidence in the record "may also support other conclusions, even those that are inconsistent with the Administrator's," does not undercut the Administrator's decision as long as he offers a plausible explanation for his judgment. *LIA*, 647 F.2d at 1160. As set forth above, the Administrator explained his focus on the level of protection afforded at 21 ppm-hours and his balance of evidence of potential effects at lower

levels and their associated uncertainties in judging the revised secondary standard that is requisite to protect public welfare.

4. The Administrator's Consideration of Comments by OMB Can Not Displace his Reasoned Explanation as the Basis for Judicial Review.

Citing the requirement that the Administrator set secondary standards that are "in his judgment" requisite to protect public welfare, 42 U.S.C. § 7409(b)(2), the State Petitioners contend that EPA's decision, "[t]o the extent that" it is based upon the views of personnel within the Office of Management and Budget, or even those of the President, is entitled to no deference and is contrary to the Act. State Br. 32-35. This argument conflates Administrator Johnson's consideration of those views with the alleged abdication of his responsibility to exercise his judgment and explain the basis for his decision. Indeed, State Petitioners argue only in the conditional ("[t]o the extent that . . ."), underscoring the lack of a basis for their charge.

As an initial matter, it is not remarkable that OMB, or the President, might express views on draft regulations or that the Administrator would consider those views in determining how to exercise his judgment. Indeed, Congress upon enacting the Clean Air Act fully expected that OMB and the various agencies within the government *would* provide EPA with comments and that EPA *would* consider them; thus, Congress established specific docketing and record

requirements for this purpose that apply to significant rulemakings such as those in which the Agency sets or revises NAAQS. *See, e.g.*, 42 U.S.C. §§ 7607(d)(1)(A), (d)(4)(B)(ii), (d)(7). Here, the Administrator frankly acknowledged the views he considered. 73 Fed. Reg. at 16,497/2-3. There is, however, no error in this. The proper issue is whether the Administrator articulated a rational basis for his decision that is reasonably supported by the record. That is the sole basis upon which the Court must judge the Administrator's decision under the applicable standard of review. *Id.* § 7607(d)(9)(A). Thus, though Administrator Johnson's decision may comport with the recommendations then provided by OMB and the President, so long as the Administrator reasonably explained his decision under the applicable standard of review, it must be upheld. *See*, *e.g.*, *Catawba County, N.C. v. EPA*, 571 F.3d 20, 28-29, 37-43 (D.C. Cir. 2009) (upholding EPA's justification for using OMB-based boundaries in defining certain nonattainment areas for particulate matter NAAQS). As set out above, Administrator Johnson adequately explained the basis for his decision. 73 Fed. Reg. at 16,497/2-3 ("While the Administrator fully considered the President's views, the Administrator's decision, and the reasons for it, are based on and supported by the record in this rulemaking.").

State Petitioners' efforts to cast the explanations offered by others as those of the Administrator must, therefore, fail. Contrary to State Petitioners' suggestion

(at 33-34), the Administrator plainly did not base his decision on the revised secondary standard *solely* on the grounds that it offers "added protection" over the prior standard. *See supra* 124-29. Nor did he base it on costs of implementation, as State Petitioners also suggest. *E.g.*, 73 Fed. Reg. at 16,437/2 (recognizing costs of implementation may not be considered). In sum, the Court should reject State Petitioners' arguments and should instead evaluate the reasoning and explanation provided by the Administrator himself for his judgments on the secondary standard.

IV. THE COURT SHOULD REJECT THE STATE PETITIONERS' REQUEST THAT IT ISSUE A SCHEDULE ON REMAND.

State Petitioners contend that if the Court remands EPA's 2008 ozone NAAQS, as they request, the Court should not vacate those standards, because doing so would leave only the less protective 1997 ozone NAAQS in place. While EPA believes a remand is not warranted, if the Court disagrees, the Agency concurs that vacatur would not be appropriate.

EPA opposes, however, the State Petitioners' request that if a remand is issued the Court also issue a remedial order requiring EPA to "issue proposed ozone NAAQS by October 2013 and to promulgate NAAQS by July 2014." State Br. 40. Here, State Petitioners appear to refer to EPA's nondiscretionary duty, under 42 U.S.C. § 7409(d)(1), to conduct a periodic review, every five years, of new scientific information and the NAAQS and at that time to adopt any revised or

new standards as may be appropriate. EPA initiated that review shortly after issuing the 2008 revised ozone NAAQS, and informed the Court, in papers filed in connection with a separate petition for review that has been dismissed for lack of jurisdiction, that EPA intends to issue a notice of proposed rulemaking in October 2013 and a final rule in July 2014 to complete the Agency's statutorily mandated review of the 2008 ozone NAAQS.[26]

State Petitioners appear to seek an order requiring EPA to complete this ongoing rulemaking, arguing that EPA's intended schedule for that rulemaking may change. Absent such an order from this Court, State Petitioners contend, they will have no "meaningful remedy [to] address[] the inadequate standards." State Br. 37. This Court, however, lacks jurisdiction over EPA's ongoing periodic review of the 2008 Ozone NAAQS. Rather, the Clean Air Act citizen suit provision places in the federal district courts the authority to compel agency action if EPA fails to perform a nondiscretionary duty, such as EPA's statutory periodic review of NAAQS. 42 U.S.C. § 7604(a)(2); *Am. Lung Ass'n v. Reilly*, 962 F.2d 258 (2d Cir. 1992); *see Massachusetts v. EPA*, 415 F.3d 50, 53 (D.C. Cir. 2005), *reversed on other grounds*, 549 U.S. 497 (2007). Congress has authorized direct

[26] *See* EPA's Motion to Dismiss (dated Dec. 8, 2011) (attached Declaration of Regina McCarthy ¶ 5), filed in *American Lung Association, et al., v. EPA, et al.*, No. 11-1396 (D.C. Cir.). The Court dismissed that petition for review on February 17, 2012, for lack of jurisdiction over EPA's the non-final decision to defer its voluntary rulemaking on reconsideration. Order, in No. 11-1396.

challenges of deferrals of nondiscretionary actions in the courts of appeal only where such deferrals are part of a final decision reviewable in the court of appeals, 42 U.S.C. § 7607(b)(2), and that is plainly not the circumstance here. The Clean Air Act citizen suit provision, therefore, already provides State Petitioners with the only appropriate remedy to address their concerns should EPA's planned schedule for its periodic review change.

Moreover, to the extent State Petitioners seek a scheduling order governing only a remand from this Court for EPA to reconsider its 2008 NAAQS based upon the existing scientific record for that standard, such extraordinary relief is not appropriate. Their reliance on *EDF v. EPA*, 852 F.2d 1316 (D.C. Cir. 1988), to justify such an order is misplaced, since in that case, unlike here, the remedy was narrow and predetermined, *id.* at 1331 ("EPA cannot refuse to relist" the wastes at issue), and EPA had previously violated a statutory deadline, a court order, and its own schedule. *Id.* In contrast, the circumstances State Petitioners allege in this case fall far short of meeting the high standard for mandamus under *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984). Moreover, the delay Petitioners allege is based upon EPA's voluntary reconsideration of the 2008 NAAQS, and State Petitioners have expressly disavowed seeking a remedial order governing that rulemaking. State Br. 38 n.5. Accordingly, the Court should not issue a schedule for any remand it may issue;

rather, if Petitioners believe a schedule is appropriate, they may seek one for further action on the Agency's periodic review of the Ozone NAAQS in district court under the Clean Air Act citizen suit provision.

CONCLUSION

For the reasons set forth above, the petitions for review should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH WORD LIMITATION

In accordance with Federal Rule of Appellate Procedure 32(a)(7)(C), I hereby certify that the foregoing Brief of Respondent EPA contains 31,948 words, as counted by the Microsoft Word 2007 word processing system used to prepare this brief, and set in Times New Roman, 14 point type, and thus complies with the applicable word limitation and type style requirements.

Dated: August 27, 2012

/S/ Madeline Fleisher
MADELINE FLEISHER
Counsel for Respondent

CERTIFICATE OF SERVICE

I hereby certify that on August 27, 2012, I filed the foregoing Final Brief of Respondent through the Court's CM/ECF system, which system will serve that brief electronically on all registered counsel.

/S/ Madeline Fleisher
MADELINE FLEISHER

STATUTORY AND REGULATORY ADDENDUM

STATUTES

REGULATIONS

LEGISLATIVE HISTORY

Effective: November 10, 1998

United States Code Annotated Currentness
Title 42. The Public Health and Welfare
Chapter 85. Air Pollution Prevention and Control (Refs & Annos)
Subchapter I. Programs and Activities
Part A. Air Quality and Emissions Limitations (Refs & Annos)

§ 7408. Air quality criteria and control techniques

(a) Air pollutant list; publication and revision by Administrator; issuance of air quality criteria for air pollutants

(1) For the purpose of establishing national primary and secondary ambient air quality standards, the Administrator shall within 30 days after December 31, 1970, publish, and shall from time to time thereafter revise, a list which includes each air pollutant--

(A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;

(B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and

(C) for which air quality criteria had not been issued before December 31, 1970, but for which he plans to issue air quality criteria under this section.

(2) The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on--

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare.

(b) Issuance by Administrator of information on air pollution control techniques; standing consulting committees for air pollutants; establishment; membership

(1) Simultaneously with the issuance of criteria under subsection (a) of this section, the Administrator shall, after consultation with appropriate advisory committees and Federal departments and agencies, issue to the States and appropriate air pollution control agencies information on air pollution control techniques, which information shall include data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology. Such information shall include such data as are available on available technology and alternative methods of prevention and control of air pollution. Such information shall also include data on alternative fuels, processes, and operating methods which will result in elimination or significant reduction of emissions.

(2) In order to assist in the development of information on pollution control techniques, the Administrator may establish a standing consulting committee for each air pollutant included in a list published pursuant to subsection (a)(1) of this section, which shall be comprised of technically qualified individuals representative of State and local governments, industry, and the academic community. Each such committee shall submit, as appropriate, to the Administrator information related to that required by paragraph (1).

(c) Review, modification, and reissuance of criteria or information

The Administrator shall from time to time review, and, as appropriate, modify, and reissue any criteria or information on control techniques issued pursuant to this section. Not later than six months after August 7, 1977, the Administrator shall revise and reissue criteria relating to concentrations of NO_2 over such period (not more than three hours) as he deems appropriate. Such criteria shall include a discussion of nitric and nitrous acids, nitrites, nitrates, nitrosamines, and other carcinogenic and potentially carcinogenic derivatives of oxides of nitrogen.

(d) Publication in Federal Register; availability of copies for general public

The issuance of air quality criteria and information on air pollution control techniques shall be announced in the Federal Register and copies shall be made available to the general public.

(e) Transportation planning and guidelines

The Administrator shall, after consultation with the Secretary of Transportation, and after providing public notice and opportunity for comment, and with State and local officials, within nine months after November 15, 1990, and periodically thereafter as necessary to maintain a continuous transportation-air quality planning process, update the June 1978 Transportation-Air Quality Planning Guidelines and publish guidance on the development and implementation of transportation and other measures necessary to demonstrate and maintain attainment of national ambient air quality standards. Such guidelines shall include information on--

(1) methods to identify and evaluate alternative planning and control activities;

(2) methods of reviewing plans on a regular basis as conditions change or new information is presented;

(3) identification of funds and other resources necessary to implement the plan, including interagency agreements on providing such funds and resources;

(4) methods to assure participation by the public in all phases of the planning process; and

(5) such other methods as the Administrator determines necessary to carry out a continuous planning process.

(f) Information regarding processes, procedures, and methods to reduce or control pollutants in transportation; reduction of mobile source related pollutants; reduction of impact on public health

(1) The Administrator shall publish and make available to appropriate Federal, State, and local environmental and transportation agencies not later than one year after November 15, 1990, and from time to time thereafter--

(A) information prepared, as appropriate, in consultation with the Secretary of Transportation, and after providing public notice and opportunity for comment, regarding the formulation and emission reduction potential of transportation control measures related to criteria pollutants and their precursors, including, but not limited to--

(i) programs for improved public transit;

(ii) restriction of certain roads or lanes to, or construction of such roads or lanes for use by, passenger buses or high occupancy vehicles;

(iii) employer-based transportation management plans, including incentives;

(iv) trip-reduction ordinances;

(v) traffic flow improvement programs that achieve emission reductions;

(vi) fringe and transportation corridor parking facilities serving multiple occupancy vehicle programs or transit service;

(vii) programs to limit or restrict vehicle use in downtown areas or other areas of emission concentration particularly during periods of peak use;

(viii) programs for the provision of all forms of high-occupancy, shared-ride services;

(ix) programs to limit portions of road surfaces or certain sections of the metropolitan area to the use of non-motorized vehicles or pedestrian use, both as to time and place;

(x) programs for secure bicycle storage facilities and other facilities, including bicycle lanes, for the convenience and protection of bicyclists, in both public and private areas;

(xi) programs to control extended idling of vehicles;

(xii) programs to reduce motor vehicle emissions, consistent with subchapter II of this chapter, which are caused by extreme cold start conditions;

(xiii) employer-sponsored programs to permit flexible work schedules;

(xiv) programs and ordinances to facilitate non-automobile travel, provision and utilization of mass transit, and to generally reduce the need for single-occupant vehicle travel, as part of transportation planning and development efforts of a locality, including programs and ordinances applicable to new shopping centers, special events, and other centers of vehicle activity;

(xv) programs for new construction and major reconstructions of paths, tracks or areas solely for the use by pedestrian or other non-motorized means of transportation when economically feasible and in the public interest. For purposes of this clause, the Administrator shall also consult with the Secretary of the Interior; and

(xvi) program to encourage the voluntary removal from use and the marketplace of pre-1980 model year light duty vehicles and pre-1980 model light duty trucks.

(B) information on additional methods or strategies that will contribute to the reduction of mobile source related pollutants during periods in which any primary ambient air quality standard will be exceeded and during episodes for which an air pollution alert, warning, or emergency has been declared;

(C) information on other measures which may be employed to reduce the impact on public health or protect the health of sensitive or susceptible individuals or groups; and

(D) information on the extent to which any process, procedure, or method to reduce or control such air pollutant may cause an increase in the emissions or formation of any other pollutant.

(2) In publishing such information the Administrator shall also include an assessment of--

(A) the relative effectiveness of such processes, procedures, and methods;

(B) the potential effect of such processes, procedures, and methods on transportation systems and the provision of transportation services; and

(C) the environmental, energy, and economic impact of such processes, procedures, and methods.

(g) Assessment of risks to ecosystems

The Administrator may assess the risks to ecosystems from exposure to criteria air pollutants (as identified by the Administrator in the Administrator's sole discretion).

(h) RACT/BACT/LAER clearinghouse

The Administrator shall make information regarding emission control technology available to the States and to the general public through a central database. Such information shall include all control technology information received pursuant to State plan provisions requiring permits for sources, including operating permits for existing sources.

CREDIT(S)

(July 14, 1955, c. 360, Title I, § 108, as added Dec. 31, 1970, Pub.L. 91-604, § 4(a), 84 Stat. 1678; amended Aug. 7, 1977, Pub.L. 95-95, Title I, §§ 104, 105, Title IV, § 401(a), 91 Stat. 689, 790; Nov. 15, 1990, Pub.L. 101-549, Title I, §§ 108(a) to (c), (o), 111, 104 Stat. 2465, 2466, 2469, 2470; Nov. 10, 1998, Pub.L. 105-362, Title XV, § 1501(b), 112 Stat. 3294.)

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United States Code Annotated Currentness
Title 42. The Public Health and Welfare
Chapter 85. Air Pollution Prevention and Control (Refs & Annos)
Subchapter I. Programs and Activities
Part A. Air Quality and Emissions Limitations (Refs & Annos)

§ 7409. National primary and secondary ambient air quality standards

(a) Promulgation

(1) The Administrator--

(A) within 30 days after December 31, 1970, shall publish proposed regulations prescribing a national primary ambient air quality standard and a national secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued prior to such date; and

(B) after a reasonable time for interested persons to submit written comments thereon (but no later than 90 days after the initial publication of such proposed standards) shall by regulation promulgate such proposed national primary and secondary ambient air quality standards with such modifications as he deems appropriate.

(2) With respect to any air pollutant for which air quality criteria are issued after December 31, 1970, the Administrator shall publish, simultaneously with the issuance of such criteria and information, proposed national primary and secondary ambient air quality standards for any such pollutant. The procedure provided for in paragraph (1)(B) of this subsection shall apply to the promulgation of such standards.

(b) Protection of public health and welfare

(1) National primary ambient air quality standards, prescribed under subsection (a) of this section shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed under subsection (a) of this section shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

(c) National primary ambient air quality standard for nitrogen dioxide

The Administrator shall, not later than one year after August 7, 1977, promulgate a national primary ambient air quality standard for NO_2 concentrations over a period of not more than 3 hours unless, based on the criteria issued under section 7408(c) of this title, he finds that there is no significant evidence that such a standard for such a period is requisite to protect public health.

(d) Review and revision of criteria and standards; independent scientific review committee; appointment; advisory functions

(1) Not later than December 31, 1980, and at five-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 7408 of this title and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section. The Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.

(2)(A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 7408 of this title and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 7408 of this title and subsection (b) of this section.

(C) Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

CREDIT(S)

(July 14, 1955, c. 360, Title I, § 109, as added Dec. 31, 1970, Pub.L. 91-604, § 4(a), 84 Stat. 1679; amended Aug. 7, 1977, Pub.L. 95-95, Title I, § 106, 91 Stat. 691.)

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Chapter 85. Air Pollution Prevention and Control (Refs & Annos)
Subchapter III. General Provisions
§ 7602. Definitions

When used in this chapter--

(a) The term "Administrator" means the Administrator of the Environmental Protection Agency.

(b) The term "air pollution control agency" means any of the following:

(1) A single State agency designated by the Governor of that State as the official State air pollution control agency for purposes of this chapter.

(2) An agency established by two or more States and having substantial powers or duties pertaining to the prevention and control of air pollution.

(3) A city, county, or other local government health authority, or, in the case of any city, county, or other local government in which there is an agency other than the health authority charged with responsibility for enforcing ordinances or laws relating to the prevention and control of air pollution, such other agency.

(4) An agency of two or more municipalities located in the same State or in different States and having substantial powers or duties pertaining to the prevention and control of air pollution.

(5) An agency of an Indian tribe.

(c) The term "interstate air pollution control agency" means--

(1) an air pollution control agency established by two or more States, or

(2) an air pollution control agency of two or more municipalities located in different States.

(d) The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa and includes the Commonwealth of the Northern Mariana Islands.

(e) The term "person" includes an individual, corporation, partnership, association, State, municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

(f) The term "municipality" means a city, town, borough, county, parish, district, or other public body created by or pursuant to State law.

(g) The term "air pollutant" means any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive (including source material, special nuclear material, and byproduct material) substance or matter which is emitted into or otherwise enters the ambient air. Such term includes any precursors to the formation of any air pollutant, to the extent the Administrator has identified such precursor or precursors for the particular purpose for which the term "air pollutant" is used.

(h) All language referring to effects on welfare includes, but is not limited to, effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants.

(i) The term "Federal land manager" means, with respect to any lands in the United States, the Secretary of the department with authority over such lands.

(j) Except as otherwise expressly provided, the terms "major stationary source" and "major emitting facility" mean any stationary facility or source of air pollutants which directly emits, or has the potential to emit, one hundred tons per year or more of any air pollutant (including any major emitting facility or source of fugitive emissions of any such pollutant, as determined by rule by the Administrator).

(k) The terms "emission limitation" and "emission standard" mean a requirement established by the State or the Administrator which limits the quantity, rate, or concentration of emissions of air pollutants on a continuous basis, including any requirement relating to the operation or maintenance of a source to assure continuous emission reduction, and any design, equipment, work practice or operational standard promulgated under this chapter.. [FN1]

(l) The term "standard of performance" means a requirement of continuous emission reduction, including any requirement relating to the operation or maintenance of a source to assure continuous emission reduction.

(m) The term "means of emission limitation" means a system of continuous emission reduction (including the use of specific technology or fuels with specified pollution characteristics).

(n) The term "primary standard attainment date" means the date specified in the applicable implementation plan for the attainment of a national primary ambient air quality standard for any air pollutant.

(o) The term "delayed compliance order" means an order issued by the State or by the Administrator to an existing stationary source, postponing the date required under an applicable implementation plan for compliance by such source with any requirement of such plan.

(p) The term "schedule and timetable of compliance" means a schedule of required measures including an enforceable sequence of actions or operations leading to compliance with an emission limitation, other limitation, prohibition, or standard.

(q) For purposes of this chapter, the term "applicable implementation plan" means the portion (or portions) of the implementation plan, or most recent revision thereof, which has been approved under section 7410 of this title, or promulgated under section 7410(c) of this title, or promulgated or approved pursuant to regulations promulgated under section 7601(d) of this title and which implements the relevant requirements of this chapter.

(r) Indian tribe.--The term "Indian tribe" means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village, which is Federally recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(s) VOC.--The term "VOC" means volatile organic compound, as defined by the Administrator.

(t) PM-10.--The term "PM-10" means particulate matter with an aerodynamic diameter less than or equal to a nominal ten micrometers, as measured by such method as the Administrator may determine.

(u) NAAQS and CTG.--The term "NAAQS" means national ambient air quality standard. The term "CTG" means a Control Technique Guideline published by the Administrator under section 7408 of this title.

(v) NO_x.--The term "NO_x" means oxides of nitrogen.

(w) CO.--The term "CO" means carbon monoxide.

(x) Small source.--The term "small source" means a source that emits less than 100 tons of regulated pollutants per year, or any class of persons that the Administrator determines, through regulation, generally lack technical ability or knowledge regarding control of air pollution.

(y) Federal implementation plan.--The term "Federal implementation plan" means a plan (or portion thereof) promulgated by the Administrator to fill all or a portion of a gap or otherwise correct all or a portion of an

inadequacy in a State implementation plan, and which includes enforceable emission limitations or other control measures, means or techniques (including economic incentives, such as marketable permits or auctions of emissions allowances), and provides for attainment of the relevant national ambient air quality standard.

(z) Stationary source.--The term "stationary source" means generally any source of an air pollutant except those emissions resulting directly from an internal combustion engine for transportation purposes or from a nonroad engine or nonroad vehicle as defined in section 7550 of this title.

CREDIT(S)

(July 14, 1955, c. 360, Title III, § 302, formerly § 9, as added Dec. 17, 1963, Pub.L. 88-206, § 1, 77 Stat. 400, renumbered Oct. 20, 1965, Pub.L. 89-272, Title I, § 101(4), 79 Stat. 992; amended Nov. 21, 1967, Pub.L. 90-148, § 2, 81 Stat. 504; Dec. 31, 1970, Pub.L. 91-604, § 15(a)(1), (c)(1), 84 Stat. 1710, 1713; Aug. 7, 1977, Pub.L. 95-95, Title II, § 218(c), Title III, § 301, 91 Stat. 761, 769; Nov. 16, 1977, Pub.L. 95-190, § 14(a)(76), 91 Stat. 1404; Nov. 15, 1990, Pub.L. 101-549, Title I, §§ 101(d)(4), 107(a), (b), 108(j), 109(b), Title III, § 302(e), Title VII, § 709, 104 Stat. 2409, 2464, 2468, 2470, 2574, 2684.)

[FN1] So in original.

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Subchapter III. General Provisions
§ 7604. Citizen suits

(a) Authority to bring civil action; jurisdiction

Except as provided in subsection (b) of this section, any person may commence a civil action on his own behalf--

(1) against any person (including (i) the United States, and (ii) any other governmental instrumentality or agency to the extent permitted by the Eleventh Amendment to the Constitution) who is alleged to have violated (if there is evidence that the alleged violation has been repeated) or to be in violation of (A) an emission standard or limitation under this chapter or (B) an order issued by the Administrator or a State with respect to such a standard or limitation,

(2) against the Administrator where there is alleged a failure of the Administrator to perform any act or duty under this chapter which is not discretionary with the Administrator, or

(3) against any person who proposes to construct or constructs any new or modified major emitting facility without a permit required under part C of subchapter I of this chapter (relating to significant deterioration of air quality) or part D of subchapter I of this chapter (relating to nonattainment) or who is alleged to have violated (if there is evidence that the alleged violation has been repeated) or to be in violation of any condition of such permit.

The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such an emission standard or limitation, or such an order, or to order the Administrator to perform such act or duty, as the case may be, and to apply any appropriate civil penalties (except for actions under paragraph (2)). The district courts of the United States shall have jurisdiction to compel (consistent with paragraph (2) of this subsection) agency action unreasonably delayed, except that an action to compel agency action referred to in section 7607(b) of this title which is unreasonably delayed may only be filed in a United States District Court within the circuit in which such action would be reviewable under section 7607(b) of this title. In any such action for unreasonable delay, notice to the entities referred to in subsection (b)(1)(A) of this section shall be provided 180 days before commencing such action.

(b) Notice

No action may be commenced--

(1) under subsection (a)(1) of this section--

(A) prior to 60 days after the plaintiff has given notice of the violation (i) to the Administrator, (ii) to the State in which the violation occurs, and (iii) to any alleged violator of the standard, limitation, or order, or

(B) if the Administrator or State has commenced and is diligently prosecuting a civil action in a court of the United States or a State to require compliance with the standard, limitation, or order, but in any such action in a court of the United States any person may intervene as a matter of right.

(2) under subsection (a)(2) of this section prior to 60 days after the plaintiff has given notice of such action to the Administrator,

except that such action may be brought immediately after such notification in the case of an action under this section respecting a violation of section 7412(i)(3)(A) or (f)(4) of this title or an order issued by the Administrator pursuant to section 7413(a) of this title. Notice under this subsection shall be given in such manner as the Administrator shall prescribe by regulation.

(c) Venue; intervention by Administrator; service of complaint; consent judgment

(1) Any action respecting a violation by a stationary source of an emission standard or limitation or an order respecting such standard or limitation may be brought only in the judicial district in which such source is located.

(2) In any action under this section, the Administrator, if not a party, may intervene as a matter of right at any time in the proceeding. A judgment in an action under this section to which the United States is not a party shall not, however, have any binding effect upon the United States.

(3) Whenever any action is brought under this section the plaintiff shall serve a copy of the complaint on the Attorney General of the United States and on the Administrator. No consent judgment shall be entered in an action brought under this section in which the United States is not a party prior to 45 days following the receipt of a copy of the proposed consent judgment by the Attorney General and the Administrator during which time the Government may submit its comments on the proposed consent judgment to the court and parties or may intervene as a matter of right.

(d) Award of costs; security

The court, in issuing any final order in any action brought pursuant to subsection (a) of this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court de-

termines such award is appropriate. The court may, if a temporary restraining order or preliminary injunction is sought, require the filing of a bond or equivalent security in accordance with the Federal Rules of Civil Procedure.

(e) Nonrestriction of other rights

Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of any emission standard or limitation or to seek any other relief (including relief against the Administrator or a State agency). Nothing in this section or in any other law of the United States shall be construed to prohibit, exclude, or restrict any State, local, or interstate authority from--

(1) bringing any enforcement action or obtaining any judicial remedy or sanction in any State or local court, or

(2) bringing any administrative enforcement action or obtaining any administrative remedy or sanction in any State or local administrative agency, department or instrumentality,

against the United States, any department, agency, or instrumentality thereof, or any officer, agent, or employee thereof under State or local law respecting control and abatement of air pollution. For provisions requiring compliance by the United States, departments, agencies, instrumentalities, officers, agents, and employees in the same manner as nongovernmental entities, see section 7418 of this title.

(f) "Emission standard or limitation under this chapter" defined

For purposes of this section, the term "emission standard or limitation under this chapter" means--

(1) a schedule or timetable of compliance, emission limitation, standard of performance or emission standard,

(2) a control or prohibition respecting a motor vehicle fuel or fuel additive, or [FN1]

(3) any condition or requirement of a permit under part C of subchapter I of this chapter (relating to significant deterioration of air quality) or part D of subchapter I of this chapter (relating to nonattainment),, [FN2]section 7419 of this title (relating to primary nonferrous smelter orders), any condition or requirement under an applicable implementation plan relating to transportation control measures, air quality maintenance plans, vehicle inspection and maintenance programs or vapor recovery requirements, section 7545(e) and (f) of this title (relating to fuels and fuel additives), section 7491 of this title (relating to visibility protection), any condition or requirement under subchapter VI of this chapter (relating to ozone protection), or any requirement under section 7411 or 7412 of this title (without regard to whether such requirement is expressed as an emission standard or otherwise); [FN3] or

(4) any other standard, limitation, or schedule established under any permit issued pursuant to subchapter V of this chapter or under any applicable State implementation plan approved by the Administrator, any permit

term or condition, and any requirement to obtain a permit as a condition of operations. [FN4]

which is in effect under this chapter (including a requirement applicable by reason of section 7418 of this title) or under an applicable implementation plan.

(g) Penalty fund

(1) Penalties received under subsection (a) of this section shall be deposited in a special fund in the United States Treasury for licensing and other services. Amounts in such fund are authorized to be appropriated and shall remain available until expended, for use by the Administrator to finance air compliance and enforcement activities. The Administrator shall annually report to the Congress about the sums deposited into the fund, the sources thereof, and the actual and proposed uses thereof.

(2) Notwithstanding paragraph (1) the court in any action under this subsection to apply civil penalties shall have discretion to order that such civil penalties, in lieu of being deposited in the fund referred to in paragraph (1), be used in beneficial mitigation projects which are consistent with this chapter and enhance the public health or the environment. The court shall obtain the view of the Administrator in exercising such discretion and selecting any such projects. The amount of any such payment in any such action shall not exceed $100,000.

CREDIT(S)

(July 14, 1955, c. 360, Title III, § 304, as added Dec. 31, 1970, Pub.L. 91-604, § 12(a), 84 Stat. 1706; amended Aug. 7, 1977, Pub.L. 95-95, Title III, § 303(a)-(c), 91 Stat. 771, 772; Nov. 16, 1977, Pub.L. 95-190, § 14(a)(77), (78), 91 Stat. 1404; Nov. 15, 1990, Pub.L. 101-549, Title III, § 302(f), Title VII, § 707(a)-(g), 104 Stat. 2574, 2682, 2683.)

[FN1] So in original. The word “or” probably should not appear.

[FN2] So in original.

[FN3] So in original. The semicolon probably should be comma.

[FN4] So in original. The period probably should be a comma.

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Chapter 85. Air Pollution Prevention and Control (Refs & Annos)
Subchapter III. General Provisions
§ 7607. Administrative proceedings and judicial review

(a) Administrative subpenas; confidentiality; witnesses

In connection with any determination under section 7410(f) of this title, or for purposes of obtaining information under section 7521(b)(4) or 7545(c)(3) of this title, any investigation, monitoring, reporting requirement, entry, compliance inspection, or administrative enforcement proceeding under the [FN1] chapter (including but not limited to section 7413, section 7414, section 7420, section 7429, section 7477, section 7524, section 7525, section 7542, section 7603, or section 7606 of this title),, [FN2] the Administrator may issue subpenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents, and he may administer oaths. Except for emission data, upon a showing satisfactory to the Administrator by such owner or operator that such papers, books, documents, or information or particular part thereof, if made public, would divulge trade secrets or secret processes of such owner or operator, the Administrator shall consider such record, report, or information or particular portion thereof confidential in accordance with the purposes of section 1905 of Title 18, except that such paper, book, document, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out this chapter, to persons carrying out the National Academy of Sciences' study and investigation provided for in section 7521(c) of this title, or when relevant in any proceeding under this chapter. Witnesses summoned shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In case of contumacy or refusal to obey a subpena served upon any person under this subparagraph, the district court of the United States for any district in which such person is found or resides or transacts business, upon application by the United States and after notice to such person, shall have jurisdiction to issue an order requiring such person to appear and give testimony before the Administrator to appear and produce papers, books, and documents before the Administrator, or both, and any failure to obey such order of the court may be punished by such court as a contempt thereof.

(b) Judicial review

(1) A petition for review of action of the Administrator in promulgating any national primary or secondary ambient air quality standard, any emission standard or requirement under section 7412 of this title, any standard of performance or requirement under section 7411 of this title,, [FN2] any standard under section 7521 of this title (other than a standard required to be prescribed under section 7521(b)(1) of this title), any determination under section 7521(b)(5) of this title, any control or prohibition under section 7545 of this title, any standard under section 7571 of this title, any rule issued under section 7413, 7419, or under section 7420 of this title, or any other nationally applicable regulations promulgated, or final action taken, by the Administrator under this

chapter may be filed only in the United States Court of Appeals for the District of Columbia. A petition for review of the Administrator's action in approving or promulgating any implementation plan under section 7410 of this title or section 7411(d) of this title, any order under section 7411(j) of this title, under section 7412 of this title,, [FN2] under section 7419 of this title, or under section 7420 of this title, or his action under section 1857c-10(c)(2)(A), (B), or (C) of this title (as in effect before August 7, 1977) or under regulations thereunder, or revising regulations for enhanced monitoring and compliance certification programs under section 7414(a)(3) of this title, or any other final action of the Administrator under this chapter (including any denial or disapproval by the Administrator under subchapter I of this chapter) which is locally or regionally applicable may be filed only in the United States Court of Appeals for the appropriate circuit. Notwithstanding the preceding sentence a petition for review of any action referred to in such sentence may be filed only in the United States Court of Appeals for the District of Columbia if such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination. Any petition for review under this subsection shall be filed within sixty days from the date notice of such promulgation, approval, or action appears in the Federal Register, except that if such petition is based solely on grounds arising after such sixtieth day, then any petition for review under this subsection shall be filed within sixty days after such grounds arise. The filing of a petition for reconsideration by the Administrator of any otherwise final rule or action shall not affect the finality of such rule or action for purposes of judicial review nor extend the time within which a petition for judicial review of such rule or action under this section may be filed, and shall not postpone the effectiveness of such rule or action.

(2) Action of the Administrator with respect to which review could have been obtained under paragraph (1) shall not be subject to judicial review in civil or criminal proceedings for enforcement. Where a final decision by the Administrator defers performance of any nondiscretionary statutory action to a later time, any person may challenge the deferral pursuant to paragraph (1).

(c) Additional evidence

In any judicial proceeding in which review is sought of a determination under this chapter required to be made on the record after notice and opportunity for hearing, if any party applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator, in such manner and upon such terms and conditions as to [FN3] the court may deem proper. The Administrator may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original determination, with the return of such additional evidence.

(d) Rulemaking

(1) This subsection applies to--

(A) the promulgation or revision of any national ambient air quality standard under section 7409 of this title,

(B) the promulgation or revision of an implementation plan by the Administrator under section 7410(c) of this title,

(C) the promulgation or revision of any standard of performance under section 7411 of this title, or emission standard or limitation under section 7412(d) of this title, any standard under section 7412(f) of this title, or any regulation under section 7412(g)(1)(D) and (F) of this title, or any regulation under section 7412(m) or (n) of this title,

(D) the promulgation of any requirement for solid waste combustion under section 7429 of this title,

(E) the promulgation or revision of any regulation pertaining to any fuel or fuel additive under section 7545 of this title,

(F) the promulgation or revision of any aircraft emission standard under section 7571 of this title,

(G) the promulgation or revision of any regulation under subchapter IV-A of this chapter (relating to control of acid deposition),

(H) promulgation or revision of regulations pertaining to primary nonferrous smelter orders under section 7419 of this title (but not including the granting or denying of any such order),

(I) promulgation or revision of regulations under subchapter VI of this chapter (relating to stratosphere and ozone protection),

(J) promulgation or revision of regulations under part C of subchapter I of this chapter (relating to prevention of significant deterioration of air quality and protection of visibility),

(K) promulgation or revision of regulations under section 7521 of this title and test procedures for new motor vehicles or engines under section 7525 of this title, and the revision of a standard under section 7521(a)(3) of this title,

(L) promulgation or revision of regulations for noncompliance penalties under section 7420 of this title,

(M) promulgation or revision of any regulations promulgated under section 7541 of this title (relating to warranties and compliance by vehicles in actual use),

(N) action of the Administrator under section 7426 of this title (relating to interstate pollution abatement),

(O) the promulgation or revision of any regulation pertaining to consumer and commercial products under section 7511b(e) of this title,

(P) the promulgation or revision of any regulation pertaining to field citations under section 7413(d)(3) of this title,

(Q) the promulgation or revision of any regulation pertaining to urban buses or the clean-fuel vehicle, clean-fuel fleet, and clean fuel programs under part C of subchapter II of this chapter,

(R) the promulgation or revision of any regulation pertaining to nonroad engines or nonroad vehicles under section 7547 of this title,

(S) the promulgation or revision of any regulation relating to motor vehicle compliance program fees under section 7552 of this title,

(T) the promulgation or revision of any regulation under subchapter IV-A of this chapter (relating to acid deposition),

(U) the promulgation or revision of any regulation under section 7511b(f) of this title pertaining to marine vessels, and

(V) such other actions as the Administrator may determine.

The provisions of section 553 through 557 and section 706 of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies. This subsection shall not apply in the case of any rule or circumstance referred to in subparagraphs (A) or (B) of subsection 553(b) of Title 5.

(2) Not later than the date of proposal of any action to which this subsection applies, the Administrator shall establish a rulemaking docket for such action (hereinafter in this subsection referred to as a "rule"). Whenever a rule applies only within a particular State, a second (identical) docket shall be simultaneously established in the appropriate regional office of the Environmental Protection Agency.

(3) In the case of any rule to which this subsection applies, notice of proposed rulemaking shall be published in the Federal Register, as provided under section 553(b) of Title 5, shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment (hereinafter referred to as the "comment period"). The notice of proposed rulemaking shall also state the docket number, the location or locations of the docket, and the times it will be open to public inspection. The statement of basis and purpose shall include a summary of--

(A) the factual data on which the proposed rule is based;

(B) the methodology used in obtaining the data and in analyzing the data; and

(C) the major legal interpretations and policy considerations underlying the proposed rule.

The statement shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 7409(d) of this title and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences. All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule.

(4)(A) The rulemaking docket required under paragraph (2) shall be open for inspection by the public at reasonable times specified in the notice of proposed rulemaking. Any person may copy documents contained in the docket. The Administrator shall provide copying facilities which may be used at the expense of the person seeking copies, but the Administrator may waive or reduce such expenses in such instances as the public interest requires. Any person may request copies by mail if the person pays the expenses, including personnel costs to do the copying.

(B)(i) Promptly upon receipt by the agency, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period shall be placed in the docket. The transcript of public hearings, if any, on the proposed rule shall also be included in the docket promptly upon receipt from the person who transcribed such hearings. All documents which become available after the proposed rule has been published and which the Administrator determines are of central relevance to the rulemaking shall be placed in the docket as soon as possible after their availability.

(ii) The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

(5) In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (iii) a transcript shall be kept of any oral presentation; and (iv) the Administrator shall keep the record of such proceeding open for thirty days after completion of the proceeding to provide an opportunity for submission of rebuttal and supplementary information.

(6)(A) The promulgated rule shall be accompanied by (i) a statement of basis and purpose like that referred to in paragraph (3) with respect to a proposed rule and (ii) an explanation of the reasons for any major changes in the promulgated rule from the proposed rule.

(B) The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.

(C) The promulgated rule may not be based (in part or whole) on any information or data which has not been placed in the docket as of the date of such promulgation.

(7)(A) The record for judicial review shall consist exclusively of the material referred to in paragraph (3), clause (i) of paragraph (4)(B), and subparagraphs (A) and (B) of paragraph (6).

(B) Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b) of this section). Such reconsideration shall not postpone the effectiveness of the rule. The effectiveness of the rule may be stayed during such reconsideration, however, by the Administrator or the court for a period not to exceed three months.

(8) The sole forum for challenging procedural determinations made by the Administrator under this subsection shall be in the United States court of appeals for the appropriate circuit (as provided in subsection (b) of this section) at the time of the substantive review of the rule. No interlocutory appeals shall be permitted with respect to such procedural determinations. In reviewing alleged procedural errors, the court may invalidate the rule only if the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made.

(9) In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or

(D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary or capricious, (ii) the requirement of paragraph (7)(B) has been met, and (iii) the condition of the last sentence of paragraph (8) is met.

(10) Each statutory deadline for promulgation of rules to which this subsection applies which requires promulgation less than six months after date of proposal may be extended to not more than six months after date of proposal by the Administrator upon a determination that such extension is necessary to afford the public, and the agency, adequate opportunity to carry out the purposes of this subsection.

(11) The requirements of this subsection shall take effect with respect to any rule the proposal of which occurs after ninety days after August 7, 1977.

(e) Other methods of judicial review not authorized

Nothing in this chapter shall be construed to authorize judicial review of regulations or orders of the Administrator under this chapter, except as provided in this section.

(f) Costs

In any judicial proceeding under this section, the court may award costs of litigation (including reasonable attorney and expert witness fees) whenever it determines that such award is appropriate.

(g) Stay, injunction, or similar relief in proceedings relating to noncompliance penalties

In any action respecting the promulgation of regulations under section 7420 of this title or the administration or enforcement of section 7420 of this title no court shall grant any stay, injunctive, or similar relief before final judgment by such court in such action.

(h) Public participation

It is the intent of Congress that, consistent with the policy of subchapter II of chapter 5 of Title 5, the Administrator in promulgating any regulation under this chapter, including a regulation subject to a deadline, shall ensure a reasonable period for public participation of at least 30 days, except as otherwise expressly provided in section [FN4] 7407(d), 7502(a), 7511(a) and (b), and 7512(a) and (b) of this title.

CREDIT(S)

(July 14, 1955, c. 360, Title III, § 307, as added Dec. 31, 1970, Pub.L. 91-604, § 12(a), 84 Stat. 1707; amended Nov. 18, 1971, Pub.L. 92-157, Title III, § 302(a), 85 Stat. 464; June 22, 1974, Pub.L. 93-319, § 6(c), 88 Stat. 259; Aug. 7, 1977, Pub.L. 95-95, Title III, §§ 303(d), 305(a), (c), (f)-(h), 91 Stat. 772, 776, 777; Nov. 16, 1977, Pub.L. 95-190, § 14(a)(79), (80), 91 Stat. 1404; Nov. 15, 1990, Pub.L. 101-549, Title I, §§ 108(p), 110(5), Title III, § 302(g), (h), Title VII, §§ 702(c), 703, 706, 707(h), 710(b), 104 Stat. 2469, 2470, 2574, 2681-2684.)

[FN1] So in original. Probably should be “this”.

[FN2] So in original.

[FN3] So in original. The word “to” probably should not appear.

[FN4] So in original. Probably should be “sections”.

Current through P.L. 112-135 approved 6-21-12

END OF DOCUMENT

1995 Acts. Section effective Oct. 1, 1995, except as otherwise provided, see section 4 of Pub.L. 104-13, set out as a note under section 3501 of this title.

Prior Provisions

A prior section 3516, added Pub.L. 96-511, § 2(a), Dec. 11, 1980, 94 Stat. 2824, which also required the Director to promulgate necessary rules, regulations, and procedures, was omitted in the general revision of this chapter by Pub.L. 104-13.

Paperwork Reduction Act Guidelines

Pub.L. 106-554, § 1(a)(3) [Title V, § 515], Dec. 21, 2000, 114 Stat. 2763, 2763A-153, provided that:

"(a)In general.--The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 [this section] of title 44, United States Code, that provide **policy** and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code [this chapter], commonly referred to as the Paperwork Reduction Act.

"(b) Content of guidelines.--The guidelines under subsection (a) shall--

"(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

"(2) Require that each Federal agency to which the guidelines apply--

"(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

"(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

"(C) Report periodically to the director--

"(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and

"(ii) how such complaints were handled by the agency."

Delayed Application of 1995 Revision

(ii) A State that flags data collected during calendar years 2004–2006, pursuant to paragraph (c)(2)(iv) of this section, must adopt the procedures and requirements specified in paragraph (c)(3)(i) of this section and must include a demonstration to justify the exclusion of the data not later than the submittal of the Governor's recommendation letter on nonattainment areas.

(iii) A State that flags Pb data collected during calendar years 2006–2009, pursuant to paragraph (c)(2)(v) of this section shall, after notice and opportunity for public comment, submit to EPA a demonstration to justify exclusion of the data not later than October 15, 2010. A State that flags Pb data collected during calendar year 2010 shall, after notice and opportunity for public comment, submit to EPA a demonstration to justify the exclusion of the data not later than May 1, 2011. A state must submit the public comments it received along with its demonstration to EPA.

(iv) The demonstration to justify data exclusion shall provide evidence that:

(A) The event satisfies the criteria set forth in 40 CFR 50.1(j);

(B) There is a clear causal relationship between the measurement under consideration and the event that is claimed to have affected the air quality in the area;

(C) The event is associated with a measured concentration in excess of normal historical fluctuations, including background; and

(D) There would have been no exceedance or violation but for the event.

(v) With the submission of the demonstration, the State must document that the public comment process was followed.

[72 FR 13580, Mar. 22, 2007; 72 FR 28612, May 22, 2007; 73 FR 67051, Nov. 12, 2008; 74 FR 70598, Nov. 21, 2008; 74 FR 23312, May 19, 2009; 75 FR 6531, Feb. 9, 2010; 75 FR 35592, June 22, 2010]

§ 50.15 National primary and secondary ambient air quality standards for ozone.

(a) The level of the national 8-hour primary and secondary ambient air quality standards for ozone (O_3) is 0.075 parts per million (ppm), daily maximum 8-hour average, measured by a reference method based on appendix D to this part and designated in accordance with part 53 of this chapter or an equivalent method designated in accordance with part 53 of this chapter.

(b) The 8-hour primary and secondary O_3 ambient air quality standards are met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration is less than or equal to 0.075 ppm, as determined in accordance with appendix P to this part.

[73 FR 16511, Mar. 27, 2008]

§ 50.16 National primary and secondary ambient air quality standards for lead.

(a) The national primary and secondary ambient air quality standards for lead (Pb) and its compounds are 0.15 micrograms per cubic meter, arithmetic mean concentration over a 3-month period, measured in the ambient air as Pb either by:

(1) A reference method based on Appendix G of this part and designated in accordance with part 53 of this chapter or;

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The national primary and secondary ambient air quality standards for Pb are met when the maximum arithmetic 3-month mean concentration for a 3-year period, as determined in accordance with Appendix R of this part, is less than or equal to 0.15 micrograms per cubic meter.

[73 FR 67052, Nov. 12, 2008]

§ 50.17 National primary ambient air quality standards for sulfur oxides (sulfur dioxide).

(a) The level of the national primary 1-hour annual ambient air quality standard for oxides of sulfur is 75 parts per billion (ppb, which is 1 part in 1,000,000,000), measured in the ambient air as sulfur dioxide (SO_2).

(b) The 1-hour primary standard is met at an ambient air quality monitoring site when the three-year average of the annual (99th percentile) of the daily maximum 1-hour average concentrations is less than or equal to 75

95th Congress
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A LEGISLATIVE HISTORY OF THE CLEAN AIR ACT AMENDMENTS OF 1977

A CONTINUATION OF THE CLEAN AIR ACT AMENDMENTS OF 1970

TOGETHER WITH

A SECTION-BY-SECTION INDEX

PREPARED BY THE

ENVIRONMENTAL POLICY DIVISION

OF THE

CONGRESSIONAL RESEARCH SERVICE

OF THE

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CLEAN AIR ACT AMENDMENTS OF 1976

REPORT

BY THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

[To accompany H.R. 10498]

together with

ADDITIONAL, SEPARATE, OPPOSING, AND MINORITY VIEWS

MAY 15, 1976.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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standards of performance); 112 (hazardous emission standards, although nature of risk must be more serious); 202 (new motor vehicle emission standards); 211 (regulation of fuels and fuel additives); and 231 (aircraft emission standards) of the Act. Furthermore, other provisions of the proposed legislation use the same formula: subtitle B of title I (ozone and stratosphere protection) and sections 235–7 (railroad emission standards).

In upholding the majority opinion in the en banc rehearing in *Ethyl*, the Committee is moving in a direction which is consistent with most judicial interpretations of the Act. Most other courts have held that a substantial element of judgment, including making comparative assessment of risks, projections of future possibilities, establishing margins of safety and margins of error, extrapolating from limited data, etc., are necessary and permissible under the Act in order to protect public health and encourage development of new technology. See *South Terminal Corp.* v. *EPA*, 504 F.2d 646 (1st Cir. 1974); *Amoco Oil Co.* v. *EPA*, 501 F.2d 722 (D.C. Cir. 1974); *Texas* v. *EPA*, 499 F.2d 289 (5th Cir. 1974).

In order to affirm this view of the Administrator's function under the Act, the Committee included the words "in the judgment of the Administrator" or "in his judgment" in each of the foregoing sections. The Committee expressly rejected an amendment which would have deleted these words and required a finding by the Administrator instead. Thus, the Committee language is intended to emphasize the necessarily judgmental element in the task of predicting future health risks of present action and to confer upon the Administrator the requisite authority to exercise such judgment.

On the other hand, the Committee does not intend this language as a license for "crystal ball" speculation. The Administrator's judgment must, of course, remain subject to restraints of reasoned decisionmaking. See *Portland Cement Assn.* v. *Ruckelshaus*, 486 F.2d 375, 391 (D.C. Cir. 1973). In addition, of course, the Administrator's exercise of judgment will be subject to the careful and thorough procedural safeguards contained in section 305 of the bill.

In order to emphasize the precautionary or preventive purpose of the Act (and, therefore, the Administrator's duty to assess risks rather than wait for proof of actual harm), the Committee not only retained the concept of endangerment to health; the Committee also added the words "may reasonably be anticipated". In evaluating what "may reasonably be anticipated", the limitations and difficulties inherent in environmental medical research referred to above must be considered.

By its use of the words "cause or contribute to air pollution", the Committee intends to require the Administrator to consider all sources of the contaminant which contribute to air pollution and to consider all sources of exposure to the contaminant—food, water, air, etc.—in determining health risk.

Finally, the term "in the judgment of the Administrator" is intended to modify both the "cause or contribute to" phrase and the "reasonably may be anticipated" phrase.

This language was believed by the Committee to be necessary to recognize inevitable limitations or inadequacies of the data base available to the Administrator, to prevent courts from restricting his health pro- ADD29

95th Congress
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CLEAN AIR ACT AMENDMENTS OF 1977

REPORT

BY THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

[To accompany H.R. 6161]

together with

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And Including Cost Estimate of the Congressional Budget Office

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NO_2 levels were meeting the primary standard.[10] This compares with annual average nitrate levels of 5 ug/m³ or more in southern California and northern Pennsylvania, with somewhat lower levels along the Great Lakes and from place to place throughout the midwest.[11] Even those who have challenged the "sulfate" theory have agreed that the harm occurring at levels at and below the standards may be due to nitrates, nitrites, sulfites, or acid aerosols. This is the essential argument of utility contractors Greenfield, Attaway, and Tyler.

G. Health Conclusions

The foregoing deficiencies in the national primary ambient air quality standards are prevasive and not easily cured. Some have suggested that since the standards are to protect against all known or anticipated effects and since no safe thresholds can be established, the ambient standards should se set at zero or background levels. Obviously, this no-risk philosophy ignores all economic and social consequences and is impractical. This is particularly true in light of the legal requirement for mandatory attainment of the national primary standards within 3 years.

Others have suggested that unless conclusive proof of actual harm can be found based on the past occurrence of adverse effects, then the standards should remain unchanged and no pollution limits should be applicable to areas which are cleaner than the ambient standards.

This second approach ignores the commonsense reality that "an ounce of prevention is worth a pound of cure". Permitting unrestricted deterioration of air quality up to the ambient standards involves trying to cure a condition after it has developed rather than using practical and currently available means to prevent or minimize the condition in the first place. This approach of unlimited air quality deterioration is particularly short-sighted at a time when all indicators point to the likely necessity for tightening the ambient air quality standards to protect public health. This approach is not good preventive medicine. Nor is it good long-term economic policy.

The committee proposal is intended to properly balance these two approaches. Since there is a reasonable basis for anticipation of tightening of the ambient standards, a policy of maximum practicable protection of health has been developed. The committee approach to prevention of significant deterioration (together with the requirement proposed by the committee in section 111 that all new major industrial sources meet an emission standard achievable through the use of best available control technology) will help provide the necessary health protection for all Americans, including those most susceptible to the damaging effects of pollution—the young, the aged, and the infirm.

The committee believes that the process it proposes for significant deterioration, in which the individual States will be primarily responsible for determining allowable increases in air pollution, strikes the needed balance between unchecked pollution increases on the one hand and no pollution increases on the other. Under this section, the public is provided the necessary information and the process is spelled

[10] EJA, NERC, "Aggravation of Asthma by Air Pollutants, 1972–3, New York-New Jersey Metropolitan Communities."
[11] Memo, Shearer to Finklea, *op. cit.*