No. 11-1423

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

COMMUNITIES FOR A BETTER ENVIRONMENT,
WILDEARTH GUARDIANS,

Petitioners,

SIERRA CLUB,

Intervenor-Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

Petition for Review of a Rule of the
United States Environmental Protection Agency

BRIEF FOR RESPONDENT

IGNACIA S. MORENO
Assistant Attorney General
ANDREW J. DOYLE, Attorney
Environment & Natural Resources Division
United States Department of Justice
P.O. Box 7611
Washington, D.C. 20044
(202) 514-4427 (p)
andrew.doyle@usdoj.gov

Of Counsel:

David P.W. Orlin
United States Environmental
Protection Agency
Office of General Counsel
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

July 13, 2012 (Initial Brief)

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

(A) Parties and amici: All parties are listed in Petitioners' and Petitioner-Intervenor's Corrected Opening Brief.

(B) Rulings under review: This case is a petition for review of a final EPA rule entitled "Review of National Ambient Air Quality Standards for Carbon Monoxide," 76 Fed. Reg. 54,294 (Aug. 31, 2011).

(C) Related cases: Neither this nor any other Court has reviewed the foregoing EPA rule, and there are no related cases pending in this or any other Court.

Dated: 07/13/2012

/s/ Andrew J. Doyle
ANDREW J. DOYLE, Attorney
United States Department of Justice
Environment & Natural Resources Division

Attorney for Respondent

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CODE OF FEDERAL REGULATIONS

FEDERAL REGISTER NOTICES

GLOSSARY

2000 AQCD	Air Quality Criteria for Carbon Monoxide (June 2000)[1]
(a)COHb	arterial carboxyhemoglobin
Act	Clean Air Act, 42 U.S.C. §§ 7401-7671q
Agency	United States Environmental Protection Agency
APA	Administrative Procedure Act (judicial review provisions), 5 U.S.C. §§ 701-706
Br.	Petitioners' and Petitioner-Intervenor's Corrected Opening Brief (May 14, 2012)
EPA	United States Environmental Protection Agency
CASAC	Clean Air Scientific Advisory Committee
CASAC 6/8/10 & Encl. B	Letter from Dr. Joseph D. Brain, Chair, CASAC CO Review Panel, and Dr. Jonathan M. Samet, Chair, CASAC, to EPA Administrator dated June 8, 2010, and Enclosure B entitled "CASAC's Consensus Response to EPA's Charge Questions"[2]
CASAC 5/19/10 & Encl. B	Letter from Dr. Joseph D. Brain, Chair, CASAC CO Review Panel, and Dr. Jonathan M. Samet, Chair, CASAC, to EPA Administrator dated May 19, 2010, and Enclosure B entitled "CASAC's Consensus Response to EPA's Charge Questions"[3]

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[1] Administrative record document identification: EPA-HQ-OAR-2008-0015-0052

[2] EPA-HQ-OAR-2008-0015-0029

[3] EPA-HQ-OAR-2008-0015-0034

CASAC 2/12/10 & Encl. B	Letter from Dr. Joseph D. Brain, Chair, CASAC CO Review Panel, and Dr. Jonathan M. Samet, Chair, CASAC, to EPA Administrator dated February 12, 2010, and Enclosure B entitled "CASAC's Consensus Response to EPA's Charge Questions"[4]
CASAC 1/20/10 & Encl. B	Letter from Dr. Joseph D. Brain, Chair, CASAC CO Review Panel, and Dr. Jonathan M. Samet, Chair, CASAC, to EPA Administrator dated January 20, 2010, and Enclosure B entitled "CASAC's Consensus Response to EPA's Charge Questions"[5]
CASAC 6/24/09 & Encl. B	Letter from Dr. Joseph D. Brain, Chair, CASAC CO Review Panel, and Dr. Jonathan M. Samet, Chair, CASAC, to EPA Administrator dated June 24, 2009, and Enclosure B entitled "Responses to EPA's Charge Questions"[6]
CO	carbon monoxide
COHb	carboxyhemoglobin
CAD	coronary artery disease or coronary heart disease
CVD	cardiovascular disease
Donnay Comments	comments submitted by Albert Donnay to EPA on April 12, 2011 following publication of the Proposal[7]

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[4] EPA-HQ-OAR-2008-0015-0035

[5] EPA-HQ-ORD-2007-0925-0019

[6] EPA-HQ-ORD-2007-0925-0010

[7] EPA-HQ-OAR-2008-0015-0179

eCO	exhaled carbon monoxide
ISA	Integrated Science Assessment for Carbon Monoxide (Jan. 2010)[8/]
JA	Joint (or Deferred) Appendix
Petitioners	Petitioners, Communities for a Better Environment and WildEarth Guardians, and Petitioner-Intervenor, Sierra Club
Plan	Plan for Review of the National Ambient Air Quality Standards for Carbon Monoxide (Aug. 2008)[9/]
PA	Policy Assessment for the Review of the Carbon Monoxide National Ambient Air Quality Standards (Oct. 2010)[10/]
ppm	parts per million
Proposal	Proposed Rule, Review of National Ambient Air Quality Standards for Carbon Monoxide, 76 Fed. Reg. 8,158 (Feb. 11, 2011)[11/]
QREA	Quantitative Risk and Exposure Assessment for Carbon Monoxide - Amended (July 2010)[12/]

[8/] EPA-HQ-ORD-2007-0925-0017

[9/] EPA-HQ-OAR-2008-0015-0028

[10/] EPA-HQ-OAR-2008-0015-0025

[11/] EPA-HQ-OAR-2008-0015-0122

[12/] EPA-HQ-OAR-2008-0015-0033

Recyclers	Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613 (D.C. Cir. 2010)
NAAQS	national ambient air quality standards
Nichols Decl.	Declaration of Jeremy Nichols in Support of WildEarth Guardians' Claim of Standing (Apr. 13, 2012), Addendum D to Petitioners' and Petitioner-Intervenor's Corrected Opening Brief (May 14, 2012)
RTC	Responses to Significant Comments on the 2011 Proposed Rule on the National Ambient Air Quality Standards for Carbon Monoxide[13/]
Rule	Final Rule, Review of National Ambient Air Quality Standards for Carbon Monoxide, 76 Fed. Reg. 54,294 (Aug. 31, 2011)[14/]
standards	national ambient air quality standards
(v)COHb	venous carboxyhemoglobin

[13/] EPA-HQ-OAR-2008-0015-0204

[14/] EPA-HQ-OAR-2008-0015-0187

STATEMENT OF JURISDICTION

The Court has jurisdiction to review the petition pursuant to Section 307(b) of the Clean Air Act ("Act"), 42 U.S.C. § 7607(b), except as it regards the United States Environmental Protection Agency's ("EPA" or "Agency") decision not to establish a secondary air quality standard for the pollutant carbon monoxide ("CO"). As to that claim, Petitioners, Communities for a Better Environment and WildEarth Guardians, and Petitioner-Intervenor, Sierra Club (collectively "Petitioners"), lack standing. See infra pp. 63-65.

STATUTES AND REGULATIONS

Our addendum sets forth 42 U.S.C. §§ 7408, 7409, 7602, 7607, and 40 C.F.R. § 50.8.

STATEMENT OF ISSUES

Petitioners seek review of an EPA rule concerning the national ambient air quality standards ("NAAQS" or "standards") for carbon monoxide. 76 Fed. Reg. 54,294 (Aug. 31, 2011) ("Rule") [Joint Appendix ("JA") xxx-xx]. In challenging EPA's decision to retain the primary (public health-based) standards, and not to establish a secondary (public welfare-based) standard, Petitioners raise the following issues:

1. Whether EPA's Integrated Science Assessment "accurately reflect[ed] the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health . . . which may be expected from the presence of [carbon monoxide] in the ambient air," pursuant to Section 108(a) of the Act, 42 U.S.C. § 7408(a)(2), and whether EPA reasonably considered that scientific evidence in deciding to retain the primary standards.

2. Whether EPA reasonably determined that the primary standards continue to be "requisite to protect the public health," including the health of susceptible or at risk populations, with "an adequate margin of safety," pursuant to Section 109(b) of the Act, 42 U.S.C. § 7409(b)(1).

3. Whether EPA complied with the Act in considering the views of the Clean Air Scientific Advisory Committee ("CASAC") concerning the protectiveness of the primary standards.

4. Whether EPA reasonably found an insufficient basis to establish a secondary standard (assuming that Petitioners have standing to assert that claim).

STATEMENT OF THE CASE

I. INTRODUCTION

Before the Court is a highly technical Agency decision that represents the culmination of a four-year process. After careful consideration of an array of

scientific evidence, the views of CASAC, and public comment, the EPA Administrator determined that the primary standards for carbon monoxide continue to protect public health, and that no secondary standard is requisite to protect the public welfare. As set forth in this brief, the Administrator's judgment is reasonably explained and supported by substantial evidence. While Petitioners and their consultant interpret or weigh some of the evidence differently and prefer more stringent standards, the record does not compel that result.

II. STATUTORY AND REGULATORY BACKGROUND

The Act establishes a comprehensive, federal-state scheme to protect public health and welfare from ubiquitous air pollutants. EPA establishes standards, 42 U.S.C. §§ 7408, 7409, and States are primarily responsible for ensuring their attainment and maintenance. Id. §§ 7410, 7502, 7514-7514a.

Pursuant to Section 108(a), EPA develops "air quality criteria," which must "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 [outdoor] air[.]" 42 U.S.C. § 7408(a)(2). Based on those criteria, EPA establishes "primary" and "secondary" NAAQS to protect against a pollutant's effects on public health and welfare. Id. § 7409(b).

Pursuant to Section 109(b), "primary" standards must be set at levels that, "in the judgment of the Administrator, . . . allowing an adequate margin of safety, are requisite to protect the public health." 42 U.S.C. § 7409(b)(1). "[R]equisite to protect" means "not lower or higher than necessary [] to protect the public health with an adequate margin of safety." Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 475-76 (2001); Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 617 (D.C. Cir. 2010) ("Recyclers"). In considering a margin of safety, EPA considers a number of factors such as the nature and severity of health effects, the types of health evidence, the kind and degree of uncertainty, and the size and nature of susceptible or at risk populations. Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1161 (D.C. Cir. 1980).

"Secondary" standards must, "in the judgment of the Administrator," be "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." 42 U.S.C. § 7409(b)(2). Effects on welfare include effects on soils, water, crops, vegetation, wildlife, and climate. 42 U.S.C. § 7602(h).

"Once a NAAQS has been promulgated, the Administrator must review the standard (and the criteria on which it is based) 'at five-year intervals' and make 'such revisions . . . as may be appropriate.'" Whitman, 531 U.S. at 462-63

(quoting 42 U.S.C. § 7409(d)(1)). The review process involves CASAC, "an independent scientific review committee . . . task[ed] . . . with periodically reviewing the NAAQS and advising EPA of any need for new standards or for revisions to existing standards." Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 358 (D.C. Cir. 2002) (citing 42 U.S.C. § 7409(d)(2)(A)-(B)). EPA must consider CASAC's views. As the Court has explained:

> When EPA proposes to issue new or revise existing NAAQS, it must "set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by [CASAC]." [42 U.S.C.] § 7607(d)(3). If the proposed rule "differs in any important respect from any of [CASAC's] recommendations," the Agency must provide "an explanation of the reasons for such differences." Id.

Am. Trucking Ass'ns, 283 F. 3d at 358.

The assessment of EPA's scientists is relevant as well. "[T]he staff's analysis," the Court has stated, "is something we consider when determining whether EPA has adequately addressed the relevant considerations and reasonably reached its conclusions." American Farm Bureau Fed'n v. EPA, 559 F.3d 512, 521 (D.C. Cir. 2009).

III. CARBON MONOXIDE BACKGROUND

Carbon monoxide is a colorless, odorless gas that forms when a carbon-based fuel – such as gasoline, propane, charcoal, or oil – burns. Rule 54,297/3 [JA xxx]. Cars, trucks, and other road sources account for about half of all CO emissions in the United States and up to 75 percent of the CO emissions in metropolitan areas. Id. at 54,298/1 [JA xxx]; 76 Fed. Reg. 8,158, 8,162/1 (Feb. 11, 2011) ("Proposal") [JA xxx]. Highest ambient concentrations in urban areas occur on or near heavily traveled roadways and "decline somewhat steeply with distance." Rule 54,298/1 [JA xxx].

Since 1990, CO emissions have decreased by approximately 45 percent. "[N]early all of this national-scale reduction [has come] from reductions in on-road vehicle emissions." Proposal 8,162/1 (citation omitted) [JA xxx]. As of 2009, all areas of the United States meet the primary standards for carbon monoxide. Proposal 8,162/2 [JA xxx].

The primary standards for CO are nine parts per million ("ppm") with an eight-hour averaging time and 35 ppm with a one-hour averaging time, neither to be exceeded more than once per year. 40 C.F.R. § 50.8. After EPA first promulgated the standards in 1971, it completed two reviews in 1985 and 1994. 36 Fed. Reg. 8,186 (Apr. 30, 1971); 50 Fed. Reg. 37,484, 37,485-86 (Sept. 13, 1985);

59 Fed. Reg. 38,906, 38,908 (Aug. 1, 1994) [JA xxx, xxx]. Additionally, in 2000, EPA compiled relevant scientific information on health effects in an Air Quality Criteria Document ("2000 AQCD") for carbon monoxide. Rule 54,296/1 [JA xxx]; 2000 AQCD [excerpts at JA xxx-xx].

In 1971, EPA established secondary standards for carbon monoxide that were identical to the primary standards. In 1985, EPA revoked the secondary standards due to a lack of evidence of effects on public welfare at ambient concentrations. 50 Fed. Reg. at 37,494.

IV. CARBON MONOXIDE NAAQS REVIEW PROCESS

The present NAAQS review process began in 2007 with a call for information. 72 Fed. Reg. 52,369 (Sept. 13, 2007) [JA xxx]. EPA sought "new information . . . concerning toxicological studies of effects of controlled exposure to CO on laboratory animals, humans and in vitro systems as well as epidemiologic (observational) studies of health effects associated with ambient exposures of human populations to CO." Id. at 52,370/2 [JA xxx]. EPA also sought "recent information in other areas of CO research such as . . . effects on public welfare or the environment." Id.

In 2008, an expert workshop was held "to highlight significant new and emerging CO research." 73 Fed. Reg. 2,490, 2,490-91 (Jan. 15, 2008) [JA xxx-

xx]. EPA also invited "recommendations . . . regarding the design and scope of the review for the primary (health-based) CO standard to ensure that it addresses key policy-relevant issues and considers the new science." Id. at 2,491 [JA xxx]. Later that year, EPA prepared a Plan, after public review and comment, which identified key policy-relevant questions. Plan 1-2 [JA xxx]; Rule 54,296/2 [JA xxx]; 73 Fed. Reg. 12,998 (Mar. 11, 2008) [JA xxx].

From 2008 to 2010, EPA developed an Integrated Science Assessment ("ISA"), "a concise evaluation and synthesis of the most policy-relevant science[.]" ISA 1-1 [J.A. xxx]. The ISA updated and revised the evaluation of the scientific evidence available for the 2000 AQCD regarding ambient CO's effect on public health and welfare. Id. EPA submitted two drafts for review and comment by CASAC. 74 Fed. Reg. 10,734 (Mar. 12, 2009) [JA xxx]; 74 Fed. Reg. 48,536 (Sept. 23, 2009) [JA xxx]. CASAC also held public meetings. 74 Fed. Reg. 15,265 (Apr. 3, 2009) [JA xxx]; 74 Fed. Reg. 54,042 (Oct. 13, 2009) [JA xxx].

As EPA neared completion of the ISA, it began developing a Quantitative Risk and Exposure Assessment ("QREA"). Rule 54,296/2 [JA xxx]. The QREA used modeling and air quality data from areas with historically high levels of CO to assess the occurrence of exposures of potential public health concern under the current standards and possible alternative standards. Rule 54,301/2-3 [JA xxx].

Two drafts of this document were prepared and discussed at public meetings to obtain input from CASAC. Rule 54,296/2 [JA xxx]; CASAC 1/20/10 [JA xxx-xx], 6/24/09 [JA xxx-xx].

In 2010, EPA issued a Policy Assessment ("PA") prepared by its scientists. The purpose of the PA was "to help 'bridge the gap' between the relevant scientific information and assessments and the judgments required of the EPA Administrator in determining whether, and if so, how it is appropriate to revise the NAAQS for CO." PA 1-1 [JA xxx]. A draft of the PA was made available for public comment and review by CASAC. 75 Fed. Reg. 9,206 (Mar. 1, 2010) [JA xxx]; CASAC 6/8/10 [JA xxx-xx].

In February 2011, EPA published a Proposal to retain the primary standards and not to establish a secondary standard. Proposal 8,158 [JA xxx]. In response, interested persons, including States, Industries, Petitioners, and Mr. Donnay, submitted comments. E.g., EPA-HQ-OAR-2008-0015-0179 ("Donnay Comments") [JA xxx-xx]. In addition, Mr. Donnay and others testified at a hearing. Rule 54,296/3 [JA xxx].

V. JUDGMENT OF THE EPA ADMINISTRATOR

The carbon monoxide NAAQS review process concluded in August 2011, when EPA published the Rule. The decision to retain the primary standards

involved "an integration of information on health effects associated with exposure to ambient CO; expert judgment on the adversity of such effects on individuals," as well as "air quality and related analyses, quantitative exposure and risk assessments when possible, and qualitative assessment of impacts that could not be quantified." Rule 54,303/2 [JA xxx]. In addition, EPA gave "consideration to the full breadth of CASAC's advice[,]" Rule 54,308/1 [JA xxx], and "carefully considered" comments and testimony from the public. Rule 54,296/3, 54,306/3 [JA xxx, xxx]. Based on all of that, the Administrator made a public health policy judgment that the primary standards are requisite to protect public health with an adequate margin of safety. Rule 54,303/2-3, 54,306/3 [JA xxx, xxx].

Each relevant part of the decision is addressed below, including a summary of the Administrator's judgment not to establish a secondary standard.

A. ASSESSMENT OF HEALTH EFFECTS EVIDENCE

EPA started with the evidence and considerations from its prior review. Proposal 8,174/2 [JA xxx]; Plan 3-1 to 3-2 (framing the threshold question as whether currently available evidence "supports or calls into question the scientific conclusions reached in the last review regarding health effects related to exposure to CO in the ambient air") [JA xxx]. In concluding the review of the NAAQS in 1994, for example, EPA recognized that "cardiovascular effects . . . [were] the

health effects of greatest concern . . . associated with CO exposures at levels observed in the ambient air." 59 Fed. Reg. at 38,913/1 [JA xxx]. EPA explained that cardiovascular effects were "directly related to a reduced oxygen . . . content of the blood caused by combination of CO with hemoglobin . . . to form COHb and resulting in tissue hypoxia," a condition associated with inadequate oxygen. 59 Fed. Reg. at 38,909/1-2 [JA xxx].

EPA's Integrated Science Assessment, as explained supra p. 8, integrated the evidence available from the 1994 and 2000 reviews with new scientific information available as of May 2009. ISA 1-4 [JA xxx]. The ISA contained an assessment of a range of studies: controlled human exposure, animal toxicological, and epidemiological. ISA 1-14 [JA xxx]. Controlled human exposure (or clinical) studies "evaluate the effects of exposures to a variety of pollutants in a highly controlled laboratory setting" and "allow investigators to expose subjects to known concentrations of air pollutants under carefully regulated environmental conditions and activity levels." ISA 1-10 [JA xxx]. Animal toxicological studies assess biological responses in nonhuman species to controlled air pollutant exposures. ISA 1-12 [JA xxx].

Epidemiological studies – a focus of Petitioners' brief – generally involve statistical analyses of levels of pollutants in ambient air as measured at available

monitoring stations and mortality or morbidity events such as emergency room visits or hospital admissions. They can provide "important information on the association between health effects and exposure of human populations to ambient air pollution." ISA 1-10 [JA xxx]. However, because epidemiological studies do not take place in a laboratory and their inputs are uncontrolled, scientists look to other evidence "to assess biologic plausibility and mechanistic evidence for the epidemiologic findings." Plan 4-11 [JA xxx]. As EPA noted, "[t]he epidemiological evidence ha[d] expanded considerably since the last review," Rule 54,300/3 [JA xxx].

Reviewing the entire body of evidence, EPA found that "the clearest evidence . . . available" links ambient carbon monoxide with cardiovascular effects, particularly related to reduced oxygen delivery to the heart. Rule 54,298/3 [JA xxx].[1] EPA explained that the "consisten[cy] and coheren[ce]" of the "epidemiological and human clinical studies, along with biological plausibility" showed this. Rule 54,299/1 (quoting ISA 2-6 [JA xxx]) [JA xxx]. The evidence supported a "likely" causal relationship between relevant short-term exposures to CO and cardiovascular health effects. Id. Although a likely causal relationship is the second strongest finding the ISA can make, "important uncertainties remain."

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[1] See also Rule 54,299/1, 54,301/1 [JA xxx, xxx]; ISA 5-40 to 5-41 [JA xxx-xx].

ISA 1-14 [JA xxx].

In addition, EPA examined the evidence as it concerned the extent to which ambient carbon monoxide exposures are associated with non-cardiovascular health outcomes, including central nervous system effects, birth outcomes, developmental effects, respiratory morbidity, and mortality. Rule 54,299/1 [JA xxx]. That evidence, however, was only "suggestive" of a causal relationship with ambient CO exposures. ISA 5-80, 5-100, 5-109 [JA xxx, xxx, xxx]. A suggestive causal relationship is weaker than a likely causal relationship. "[C]hance, bias and confounding cannot be ruled out." ISA 1-14 [JA xxx].

EPA also drew conclusions about susceptible or at-risk populations. EPA found that "the current evidence continues to support the identification of people with cardiovascular disease ["CVD"] as susceptible to CO-induced health effects . . . and those having CAD [coronary artery disease] as the population with the best-characterized susceptibility." Rule 54,299/2 [JA xxx].[2/] As EPA explained, CO exposure can lead to "[i]ncreasing levels of COHb in the blood stream with subsequent decrease in oxygen availability for organs and tissues [that] are of concern in people who have compromised compensatory mechanisms (e.g., lack of

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[2/] CAD is a condition associated with narrowed heart arteries. Rule 54,299 n.9 [JA xxx].

capacity to increase blood flow in response to hypoxia), such as those with pre-existing heart disease." Rule 54,298/2 [JA xxx].[3/] EPA also identified a number of potentially susceptible populations but concluded that the evidence did not establish that they were any more susceptible than people with CAD. Rule 54,306/3 [JA xxx]. EPA found that the evidence indicates that people with CAD are the most susceptible population. Rule 54,298/2, 54,299 n.8 [JA xxx, xxx].

Additionally, EPA found that "COHb level in blood . . . is supported by the evidence as the most useful indicator of CO exposure that is related to CO health effects of major concern[.]" Rule 54,298/3 [JA xxx]. EPA explained that "[t]he best characterized health effect associated with CO levels of concern is decreased oxygen availability to critical tissues and organs, specifically the heart, induced by increased COHb in the blood." Id. [JA xxx]; ISA 2-5 to 2–6, 2-13 to 2-14[JA xxx-xx, xxx-xx]. EPA noted that "COHb level in blood continues to be well recognized as an important internal dose metric and the one most commonly used in evaluating CO exposure and the potential for health effects." Proposal 8,162/3 [JA xxx]; Rule 54,298/3 (same) [JA xxx].

[3/] As noted supra p. 11, inhaled CO enters the bloodstream through the lungs and binds to hemoglobin to form carboxyhemoglobin ("COHb"). COHb reduces the oxygen-carrying capacity of the blood and the availability of oxygen to organs and tissues. ISA 2-4 [JA xxx].

B. ANALYSES OF EXPOSURE AND RISK

EPA evaluated risk to susceptible populations through analyses of estimated population exposure and resultant COHb levels. Rule 54,301/1-54,303/1, 54,308/1-2 [JA xxx-xx, xxx]. Those analyses provided estimates of the percentages of simulated susceptible populations expected to experience daily maximum COHb levels at or above a range of benchmark levels under varying air quality scenarios (e.g., just meeting the current or alternative standards), as well as characterizations of the kind and degree of uncertainties inherent in such estimates. Rule 54,301/1-2 [JA xxx]. EPA based the benchmark COHb levels on the quantitative COHb dose-response data for people with coronary artery disease from controlled human exposure studies. ISA 2-5, 2-12 [JA xxx, xxx]; Rule 54,302/1 [JA xxx].

The susceptible populations simulated in the quantitative assessment were adults with CAD, both diagnosed and undiagnosed, and also a larger population of adults suffering from any heart disease (such as arrhythmia and congestive heart failure). Rule 54,302/1 [JA xxx]. EPA scientists did not develop quantitative dose estimates for other potentially susceptible populations because evidence characterizing the nature of health effects of CO was too limited. Id.

The exposure and risk analyses indicated that under air quality conditions just meeting the existing standard, 99.7 and 99.9 percent of the susceptible populations in the respective study areas would not experience daily maximum COHb levels at or above three percent COHb. Rule 54,308/2 [JA xxx]; Proposal 8,179-80 (table 1) [JA xxx-xx]. In addition, COHb levels would be below two percent for 99.9 percent of all "person-days." Proposal 8,179/2, 8,184/2 [JA xxx, xxx].[4/]

C. CONSIDERATION OF CASAC'S VIEWS

CASAC provided "an array of advice" to EPA throughout the NAAQS review process. Proposal 8,161/3, 8,183/2 [JA xxx, xxx]. CASAC relayed its views through letters and enclosures. Rule 54,304 [JA xxx]; CASAC 6/8/10 & Encl. B [JA xxx-xx], 5/19/10 & Encl. B [JA xxx-xx], 2/12/10 & Encl. B [JA xxx-xx], 1/20/10 & Encl. B [JA xxx-xx], 6/24/09 & Encl. B [JA xxx-xx, xxx-xx].[5/]

CASAC advised EPA that the Integrated Science Assessment was comprehensive. For example, CASAC reviewed the first draft ISA and concluded

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[4/] "The person-days metric is a common cumulative measure of population exposure/dose that simultaneously takes into account both numbers of people affected and numbers of times affected." PA 2-48 [JA xxx].

[5/] Each letter had an enclosure ("B") that reflected consensus views. A different enclosure ("C") contained individual members' opinions.

that it "pull[ed] together critical evidence from the past decades while emphasizing new evidence and associated insights[.]" CASAC 6/24/09 at 1 [JA xxx]. Similarly, after reviewing the second draft, CASAC endorsed both the process and the adequacy of the ISA, observing, for example, that it "integrate[d] relevant evidence from the past decades while emphasizing newer evidence and a deeper understanding of mechanisms by which CO affects health[.]" CASAC 1/20/10 at 1 [JA xxx].

CASAC also provided advice concerning "various limitations and uncertainties associated with the evidence, particularly from the epidemiological studies[.]" Proposal 8,183/2 [JA xxx]. For example, CASAC noted the potential problem of confounding, stating: "'Distinguishing the effects of CO per se from the consequences of CO as a marker of pollution or vehicular traffic is a challenge, which [the ISA] needs to confront as thoroughly as possible.'" Rule 54,304/2 (quoting CASAC 6/24/09 at 2 [JA xxx]) [JA xxx]. CASAC also expressed concern about the epidemiological evidence's "representation of population exposure to ambient CO." Proposal 8,183/2 [JA xxx].

CASAC provided advice concerning other evidence. For example, it stated that "[t]he conclusion that the current evidence supports a primary focus on those with cardiovascular disease is justifiably based on observations from clinical

studies." CASAC 6/8/10, Encl. B at 11 [JA xxx].

Also, as EPA summarized, "CASAC agreed with the conclusion that the current evidence provides support for retaining the current suite of standards[.]" Rule 54,304/2 (citing CASAC 6/8/10 & Encl. B [JA xxx-xx]) [JA xxx]. EPA noted CASAC's additional "state[ments] that '[i]f the epidemiological evidence is given additional weight, the conclusion could be drawn that health effects are occurring at levels below the current standard, which would support the tightening of the current standard.'" Proposal 8,183/2 (quoting CASAC 6/8/10, Encl. B at 12 [JA xxx]) [JA xxx]. CASAC advised EPA that "revisions that result in lowering the standard should be considered." Proposal 8,183/2 (quoting CASAC 6/8/10, Encl. B at 11 [JA xxx]) [JA xxx].

EPA revised the Policy Assessment and considered alternative primary standards in light of CASAC's (last) letter of June 8, 2010. Proposal 8,182/1-8,183/2 [JA xxx-xx]; PA 2-60 to 2-76 [JA xxx-xx].

D. RESPONSE TO PUBLIC COMMENT

In considering comments from the public, EPA noted that "[a]ll of the state and local environmental agencies or governments that provided comments on the standards concurred with EPA's proposed conclusions as did the three industry commenters." Rule 54,304/3 [JA xxx]. Additionally, EPA considered and

responded to comments from objectors, including Petitioners and their consultant, Mr. Donnay, both in the Rule, 54,296/3-54,297/2, 54,304/1-54,306/3, 54,309/3-54,310/2 [JA xxx-xx, xxx-xx, xxx-xx], as well as in a Response to Comments ("RTC") document [JA xxx-xx].

E. ADMINISTRATOR'S PUBLIC HEALTH POLICY JUDGMENT

In judging whether more stringent standards were necessary to protect the public health with an adequate margin of safety, the Administrator considered the scientific evidence, in light of the QREA, and concluded that the standards protect against health effects of concern, with a margin of safety, by protecting against occurrence of COHb levels in the range of three to four percent and against multiple occurrences of COHb levels of approximately two percent. Rule 54,307/2-3 [JA xxx].

As noted supra p. 15, the benchmark COHb levels that EPA used to analyze risk and exposure were from controlled human exposure studies. In other respects as well, the Administrator assigned "primary consideration" to those studies because they demonstrated cardiovascular effects in response to increased COHb resulting from short-term CO exposures. Rule 54,307/1 [JA xxx]. Those studies, which had also been extensively evaluated during the 1994 review and 2000 AQCD, involved people suffering from coronary artery disease who experienced

exercised-induced angina (chest pain) more quickly when exposed to CO. Rule 54,300/1 [JA xxx].

The Administrator carefully considered but generally assigned less weight to the epidemiological evidence given its "multiple complicating features." Rule 54,307/3 [JA xxx]. The Administrator pointed out that "very few . . . studies were conducted in areas that met the current standards throughout the period of study." Id. As the Rule explained, "studies involving air quality conditions in which the current standards were met . . . are the most informative[.]" Rule 54,305/1[JA xxx].

A significant complicating feature regarded "confounding." Rule 54,307/3 [JA xxx]. Confounding means confusion of effects. ISA 1-10 [JA xxx]. Confounding in the context of pollution from cars means that because they emit more than just CO, there are many co-pollutants that cannot be ruled out as the true source of the health outcome in question.

In addition, the Administrator weighed "uncertainties related to representation of ambient CO exposures given the steep concentration gradient near roadways, as well as the prevalence of measurements below the [method detection limit] across the database." Rule 54,307/3 [JA xxx]. That is, because carbon monoxide is highly variable across time and space, it is difficult to examine

data from a particular CO monitoring station and have confidence about how the data correlate to a person's exposure during the day. RTC 34 ("[U]ncertainty of concern . . . is related to . . . what, if any, specific ambient concentrations of CO may have elicited the observed health outcomes.") [JA xxx].

Similarly, the Administrator considered that the epidemiological studies used a different exposure and dose metric (air concentration) than that used in the controlled human exposure studies (COHb). The limited nature of the monitoring data and the inability to link the results of epidemiological studies with the results of controlled human exposure studies (and the rest of the evidence) created additional uncertainty in interpreting the former, i.e., in assessing whether the observed outcomes were caused by ambient CO concentrations. Rule 54,307/3-54,308/1 [JA xxx-xx].

In light of all of the evidence, the exposure and risk assessment indicated that the standards provide a high degree of protection for people with CAD, the most susceptible population. Rule 54,308/2-3 [JA xxx]. Weighing the strengths and limitations of the epidemiological evidence, and recognizing its role in corroborating a likely causal relationship between CO and cardiovascular health effects, "the Administrator conclude[d] that consideration of epidemiological studies [did] not lead her to identify a need for any greater protection." Id.

In rendering a final judgment, the Administrator noted the Agency's "task to establish standards that are neither more nor less stringent than necessary" to meet the requirements of Section 109(b)(1) of the Act, 42 U.S.C. § 7409(b)(1), and "conclude[d] that the current suite of primary CO standards is requisite to protect public health with an adequate margin of safety from effects of ambient CO." Rule 54,295/2, 54,308/3 [JA xxx, xxx].

F. ADMINISTRATOR'S JUDGMENT REGARDING A SECONDARY STANDARD

The Administrator also judged that "no secondary standards should be set at this time because . . . having no standard is requisite to protect public welfare from any known or anticipated adverse effects from ambient CO exposures." Rule 54,310/2-3 [JA xxx]. In arriving at that judgment, she examined "the assessment and integrative synthesis of the scientific evidence presented in the ISA, building on the evidence described in the 2000 AQCD, as well as staff consideration of this evidence in the Policy Assessment and CASAC advice, and with consideration of the views of public commenters on the need for a secondary standard." Rule 54,310/2 [JA xxx].

As EPA explained, no part of the record provided "adequate information . . . to conclude that a secondary standard in the United States is requisite to protect

public welfare." Rule 54,310/1 [JA xxx]. The Integrated Science Assessment, for example, concluded that "CO has climate-related effects, that the direct effects of CO are weak, that there are significant uncertainties concerning the indirect climate effects of CO, and that these effects appear to be highly variable and dependent on localized conditions." Id.[6] Similarly, the Policy Assessment noted that "the spatial and temporal variation in emissions and concentrations of CO and the localized chemical interdependencies that cause the indirect climate effects of CO make it highly problematic to evaluate the indirect effects of CO on climate." Id.

Accordingly, while EPA embraced the notion that "the NAAQS are often established on the frontiers of scientific knowledge," based on the record the Agency lacked information to "anticipate how any secondary standard that would limit ambient CO concentrations in the United States would in turn affect climate and thus any associated welfare effects." Rule 54,310/1 [JA xxx]. Without such information, the Administrator judged that not setting a secondary standard was requisite to protect public welfare.

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[6] EPA also examined non-climate welfare effects. Rule 54,310/2 [JA xxx]. They are not at issue.

STANDARD OF REVIEW

The standard of review is set forth in Section 307(d) of the Act, which provides, in pertinent part, that challenged portions of the Rule may not be set aside unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 7607(d)(9)(A).[7]

The "arbitrary or capricious" standard presumes the validity of agency action. Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 520-21 (D.C. Cir. 1983). 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).

Moreover, as this Court recently reiterated, "we give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise." Coalition for Responsible Regulation, Inc. v. EPA, No. 09-1322, slip op. at 28 (D.C. Cir. June 26, 2012) (citation omitted).

Thus, so long as EPA "engage[d] in reasoned decision-making," Am. Trucking Ass'ns, 283 F.3d at 379 (quoting American Lung Ass'n v. EPA, 134 F.3d

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[7] Petitioners argue that the Administrative Procedure Act ("APA") provides the standard of review. Br. 30. This case is governed by Section 307(d), not the APA. See 42 U.S.C. § 7607(d)(1)(A); infra pp. 30-31.

388, 392 (D.C. Cir. 1998)), and met "minimal standards of rationality," Ethyl Corp. v. EPA, 541 F.2d 1, 36 (D.C. Cir. 1976), its decision must be upheld. Accord Br. 38 (EPA must make a "reasoned choice"), 41 ("[T]he agency must provide a rational explanation[.]").

SUMMARY OF ARGUMENT

The EPA Administrator reasonably exercised her judgment to maintain the primary (public health-based) standards for carbon monoxide. The administrative record – particularly the Rule, Proposal, Integrated Science Assessment, Policy Assessment, and Response to Comments – shows that EPA considered the relevant factors and articulated a rational connection between the facts found and the judgments made. Moreover, the record establishes that EPA engaged in reasoned decision-making, especially in light of high level of deference due EPA's technical expertise.

As an initial matter, the Declaration of Albert Donnay cannot support the petition for review. That post-decisional declaration, prepared solely for litigation, is excluded from the record for judicial review under 42 U.S.C. § 7607(d)(7)(A).

EPA complied with Section 108(a) of the Act, in that its Integrated Science Assessment "accurately reflect[ed] the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health . . . which

may be expected from the presence of [carbon monoxide] in the ambient air[.]" 42 U.S.C. § 7408(a)(2). EPA considered all scientific studies that were available as of mid-2009 and which EPA reasonably found to be useful to the questions at hand. CASAC concurred that the ISA was comprehensive and up-to-date and endorsed it.

EPA reasonably explained the consideration it gave to specific, well-established evidence in the record, including controlled human exposure studies that were also considered in previous CO reviews. As EPA cogently explained, that evidence continued to establish key aspects of carbon monoxide toxicity and was relevant to addressing whether the primary standards provide adequate protection. The record – including EPA's Response to Comments, which Petitioners fail to acknowledge in their brief – refutes Petitioners' contention that EPA acted arbitrarily in assessing evidence and finding facts.

EPA reasonably explained the consideration it gave to epidemiological evidence. EPA evaluated the entire integrated body of evidence and explained how the epidemiological evidence contributed to its overall findings concerning the link between ambient CO and cardiovascular health effects. But EPA also identified a number of significant uncertainties and limitations associated with the epidemiological studies and reasonably determined that no revision to the primary standards was warranted. EPA's explanation was reasonable, not arbitrary as

Petitioners contend.

EPA considered, and reasonably addressed, a list of epidemiological studies presented by Mr. Donnay in comments on the Proposal. EPA reasonably found that those studies would not materially change the ISA's conclusions concerning the body of evidence it assessed. With regard to Mr. Donnay's lists of "CO poisoning" and "review" studies, EPA cogently explained why they would add nothing useful to the record.

EPA reasonably focused on the protection needed for susceptible or at-risk populations and thus complied with Section 109(b), which requires standards to be requisite to protect public health with an adequate margin of safety. 42 U.S.C. § 7409(b)(1). Based on the evidence, EPA identified a number of populations that are, or could potentially be, susceptible to ambient carbon monoxide. Of those, EPA reasonably identified the population which the evidence showed to be most susceptible – people with cardiovascular disease and more specifically those with coronary artery disease – and ensured that the standards adequately protect that population. EPA reasonably found a lack of evidence indicating that other potentially at-risk populations are more susceptible than people with CAD.

In addition, EPA reasonably found that the primary standards protect not only people with CAD but also the broader category of people with CVD.

Petitioners incorrectly assert that EPA ignored the broader category when it assessed the protectiveness of the standard. For example, EPA included at-risk populations of adults with any heart disease in its quantitative risk assessment.

EPA reasonably considered the extent to which controlled human exposure, toxicological, and epidemiological studies suggest a causal relationship between ambient CO and non-cardiovascular health outcomes (e.g., respiratory, reproductive, and neurological). As EPA reasonably found, the evidence for those outcomes carried too much uncertainty to warrant a revision in the primary standards. EPA provided reasoned responses to contrary comments.

EPA gave careful consideration to CASAC's views. EPA acknowledged CASAC's preference for a lower standard and recommendation that EPA fully consider the epidemiological evidence. After receiving this advice, the record shows that EPA did, in fact, give robust consideration to the epidemiological evidence and did, in fact, consider a lower standard.

CASAC agreed that the record supported either retaining or revising the primary standards. That view was relayed in the context of CASAC's consensus response to a charge question presented to it by EPA. It was not a comment in passing, as Petitioners assert.

EPA's decision was consistent with CASAC's views. But even if CASAC's views were interpreted otherwise, the Administrator reasonably explained the basis for her judgment – including her evaluation of the epidemiological evidence and its strengths and weaknesses – and any differences with CASAC.

Petitioners lack standing to challenge EPA's decision not to establish a secondary standard for CO, which regards climate change. Only one of Petitioners' standing declarations purports to articulate a particularized injury, and it may be too general to be cognizable under the Court's precedent. In any event, Petitioners have not established traceability; that is, they have produced no evidence to show that their purported injury is caused by EPA's decision.

Regardless of standing, EPA reasonably explained its judgment that the public welfare is adequately protected without a secondary standard. The Integrated Science Assessment and Policy Assessment show that, even though at a global scale a link exists between the presence of carbon monoxide in the ambient air and warming, the impact of CO is indirect, weak, and highly variable from place-to-place. The record also shows that carbon monoxide remains in the air for a very short period of time and that its effect on climate depends on the presence of other pollutants. EPA lacked facts to determine whether regulating ambient CO concentrations would affect climate and therefore the public welfare. Thus,

consistent with CASAC's views, the Administrator reasonably found an insufficient basis to set a secondary standard.

ARGUMENT

The EPA Administrator rendered a reasoned and well-explained judgment to retain the primary standards and not to establish a secondary standard for carbon monoxide. Petitioners' claims lack merit.

I. THE DECLARATION OF ALBERT DONNAY IS INADMISSIBLE

Petitioners' attempt to introduce the declaration of their consultant, Albert Donnay, into the record for judicial review is improper and should be rejected. Mr. Donnay executed his declaration long after EPA's decision for the sole purpose of supporting Petitioners' claims. Br. 33-34 & n.5. In fact, Petitioners' brief repeatedly quotes and cites Mr. Donnay's declaration. Br. 11-12, 14-19, 21, 33-40, 42, 45, 53. Unquestionably, the declaration is not part of the administrative record.

Section 307(d) provides: "The record for judicial review shall consist exclusively of the material referred to" in a number of subsections. 42 U.S.C. § 7607(d)(7)(A) (emphasis added). None of those subsections encompasses a post-decisional declaration prepared on behalf of a petitioner in support of litigation. In a petition for review proceeding involving the ozone standards, for example, this Court concluded that a post-decisional exhibit attached to an opening brief was

"not part of the record and [could not] undercut the Administrator's conclusions on review." American Petroleum Inst. v. Costle, 665 F.2d 1176, 1186 n.3 (D.C. Cir. 1981) (citing, inter alia, 42 U.S.C. § 7607(d)(7)(A)).

Petitioners erroneously rely on Esch v. Yeutter, 876 F.2d 976, 991-92 (D.C. Cir. 1989), where the Court noted exceptions to the general rule confining review to the administrative record. Esch is inapposite because it involved review under the APA, not Section 307(d).[8]

Accordingly, the Court should disregard Mr. Donnay's declaration and Petitioners' arguments that rely on it.

II. EPA'S INTEGRATED SCIENCE ASSESSMENT REFLECTED THE LATEST USEFUL SCIENTIFIC KNOWLEDGE, AND EPA'S CONSIDERATION OF THAT EVIDENCE WAS REASONABLE

Petitioners attack the age and sufficiency of the scientific evidence before EPA. Section 108(a) requires that air quality criteria "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health . . . which may be expected from the presence of such pollutant in the ambient air[.]" 42 U.S.C. § 7408(a)(2). In preparing the Integrated

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[8] Even if Section 307(d) provided exceptions like those noted in Esch, there would be no equitable reason to admit the declaration. Mr. Donnay had numerous opportunities to, and did, submit comments and testimony during the administrative process. See supra pp. 8-9.

Science Assessment, EPA met this standard. Further, in deciding to retain the primary standards, EPA reasonably considered the evidence before it.

A. THE INTEGRATED SCIENCE ASSESSMENT ACCURATELY REFLECTED THE LATEST USEFUL SCIENTIFIC KNOWLEDGE

The scientific information before EPA was comprehensive and up-to-date. Petitioners' claim to the contrary is baseless.

From the beginning of the NAAQS review process, EPA sought out the most recent scientific information. 72 Fed. Reg. at 52,370 (soliciting "new information," including "epidemiologic . . . studies of health effects associated with ambient exposures of human populations to CO") [JA xxx]; 73 Fed. Reg. at 2,491 (conducting a workshop "to highlight significant new and emerging CO research") [JA xxx]; Plan 3-2 (outlining the first policy-relevant question: whether "new information altered scientific support" for the standards) [JA xxx]. That focus on new information continued throughout development of the Integrated Science Assessment. As EPA explained, "scientists and collaborators conducted comprehensive literature searches in multiple health . . . science disciplines to identify original peer-reviewed research published since the last CO NAAQS

review." RTC 12 [JA xxx].[9] "These searches focused on articles published between 1999 and May 2009, the cutoff date for articles to be included in the ISA." Id. See also ISA 1-4 ("Literature searches were conducted routinely to identify studies published since the last review . . . .") [JA xxx]. "Additional articles were identified by the public and CASAC during external review of two drafts of the ISA and other review documents." RTC 12 [JA xxx].

In short, EPA identified and weighed studies relevant to assessing whether concentrations of CO in the ambient air cause adverse effects on public health. Its preparation of a robust assessment of new scientific information relevant to that question met the requirements of Section 108(a). An independent body of experts agreed. Following CASAC's review of the second draft ISA, it stated: "The document integrates relevant evidence from the past decades while emphasizing newer evidence and a deeper understanding of mechanisms by which CO affects health[.]" CASAC 1/20/10 at 1 [JA xxx]. CASAC also endorsed "the process used by the EPA" and concluded that "the Draft CO ISA will be adequate for rulemaking with the incorporation of changes in response to the Panel's major comments and recommendations." CASAC 1/20/10 at 2-3 [JA xxx-xx]. EPA

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[9] The ISA integrated new studies into the existing evidence base as compiled by EPA in the 2000 AQCD. Supra pp. 8, 11.

incorporated the recommended changes, see ISA 1-6 [JA xxx]; EPA-HQ-ORD-2007-0925-0020 [JA xxx-xxx], further ensuring the sufficiency of the ISA and record.

Petitioners assert that "EPA . . . failed to consider relevant studies" and "provided no reasoned explanation why[.]" Br. 32-33. The assertion is baseless.

Petitioners' argument begins with a proposition that the ISA cited less than 10 percent of the more than "8,000 peer reviewed articles published since 2000." Br. 33 n.4. That is a meaningless statistic. The ISA is intended to be "a concise evaluation and synthesis of the most policy-relevant science for reviewing the national ambient air quality standards[.]" ISA 1-1 [JA xxx]. Through experience, EPA and CASAC have found that cataloguing study after study simply for the sake of inclusiveness makes an air quality criteria document unwieldy and less effective at achieving its intended purpose. RTC 12 [JA xxx].[10/]

Moreover, the mere existence of a new study has nothing to do with its relevance. Under Section 108(a), an ISA need only reflect "useful" scientific information. 42 U.S.C. § 7408(a)(2). While the age of the scientific evidence may be a consideration, it does not trump its relevance. RTC 25 ("EPA strongly

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[10/] EPA now uses ISAs in lieu of Air Quality Control Documents for this very reason. Id.

disagrees with [Mr. Donnay's] assertion that older studies should, as a matter of course, be given less weight in evaluating the health effects of exposures to the criteria air pollutants, particularly in cases where these studies remain the definitive works available in scientific literature.") [JA xxx]; Plan 4-1 ("[R]esults of new studies will be integrated with previous findings. Important older studies will be more specifically discussed if they remain definitive or are open to reinterpretation in light of newer data.") [JA xxx]; CASAC 6/29/09 at 1 (first draft ISA "pull[ed] together critical evidence from the past decades while emphasizing new evidence and associated insights") [JA xxx].

Petitioners' repeated charge that EPA did not explain its reasoning is baseless. Petitioners fail to even acknowledge EPA's Response to Comments, much less the explanations EPA provided in that record document.

Petitioners' remaining sufficiency-of-the-record arguments lack merit as well. EPA did not "ignore[]" a list of 46 epidemiological studies that Mr. Donnay submitted in response to the Proposal. Contra Br. 33-34 (citing, inter alia, Donnay Comments 9-15 [JA xxx-xx]). Even though Mr. Donnay could have brought at least some of those studies to EPA's attention during the ISA development, see supra pp. 8-9, the Agency still considered and addressed them. See Rule 54,296/3 [JA xxx]; RTC 13 ("Studies listed by commenters that fall within the scope of the

ISA . . ., including recent studies published after the cutoff date for inclusion, have been provisionally considered[.]") [JA xxx]. As EPA explained, none of the studies "materially change[d] any of the broad scientific conclusions made in the . . . ISA." RTC 9 [JA xxx].[11/]

EPA did not arbitrarily disregard Mr. Donnay's list of "CO poisoning" studies. Contra Br. 35 (citing, inter alia, Donnay Comments 16-27 [JA xxx-xx]). Those studies involved, for example, "accidental exposures to very high concentrations of nonambient CO resulting in very high COHb levels[.]" RTC 9 [JA xxx]. In the ISA, EPA explained that "[h]ealth effects resulting from accidental exposure to very high concentrations of non-ambient CO (i.e., CO poisoning) are not directly relevant to ambient exposures, and as such, a discussion of these effects has deliberately been excluded from this document." ISA 1-7 [JA xxx]. After reviewing Mr. Donnay's comment and list, EPA further explained that "[s]uch high-level CO exposures . . . are extremely unlikely to be experienced under ambient exposure conditions[.]" RTC 9 [JA xxx].[12/] Thus, EPA reasonably

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[11/] See also Rule 54,297/1 ("[T]he 'new' information and findings do not materially change any of the broad scientific conclusions[.]") [JA xxx].

[12/] See also RTC 13 ("[T]opics such as those raised by commenters (e.g., very high concentration exposures in humans and animals) were not found to be informative[.]") [JA xxx].

concluded that CO poisoning studies lacked "useful[ness]" for judging whether to revise the NAAQS. 42 U.S.C. § 7408(a)(2).

EPA reasonably responded to Mr. Donnay's comment that the Agency should consider approximately 143 recent "review" studies. Contra Br. 36-37 (citing Donnay Comments 28-40 [JA xxx-xx]). Review studies "typically present summaries or interpretations of existing studies" "[r]ather than bring forward new information in the form of original research or new analyses[.]" RTC 9 n.3 [JA xxx]. EPA's preference is to prepare the ISA by reviewing original research underlying the review article, rather than summaries of the original research. Ordinarily, then, there is no reason to believe that a review study would present substantively new and useful information. Thus, "[r]eview articles are generally not included in the ISA," id., and neither Petitioners' assertion nor Mr. Donnay's comment establishes that the record before EPA was deficient.

Accordingly, EPA's Integrated Science Assessment met the requirements of Section 108(a), and the Agency adequately responded to information brought to its attention after completion of the ISA.

B. EPA'S CONSIDERATION OF CONTROLLED HUMAN EXPOSURE STUDIES USING COHb AS A BIOMARKER WAS REASONABLE

EPA reasonably explained the consideration it gave to older evidence in the record, including controlled human exposure studies using COHb as a biomarker. Those studies comprised part of the longstanding body of evidence that EPA found to be highly relevant to the present review (as it had been in prior reviews). It demonstrated the key role played by hypoxia, the identification of people with cardiovascular disease as at risk from short-term ambient CO exposures, and the use of COHb for evaluating CO exposure and the potential for health effects. Rule 54,307/1-2 [JA xxx]; supra pp. 12-14, 19-20. Although Petitioners offer a number of scattershot arguments that EPA placed arbitrary weight on that evidence, the record shows otherwise.

Petitioners incorrectly suggest that "six studies" – i.e., a large multi-laboratory study referred to as the Allred Study (resulting in three publications) as well as five other controlled human exposure studies using COHb as a biomarker, Proposal 8,164/1-2 [JA xxx] – were the sole basis for EPA's finding that COHb is the most useful biomarker for evaluating health effects resulting from exposure to ambient carbon monoxide. Br. 38. The record shows that EPA considered the entire body of evidence – including but not limited to controlled human exposure

studies – in deciding to continue to use COHb. E.g., Rule 54,307/1-2 ("[T]he Administrator places weight on the long-standing evidence base that has established key aspects of CO toxicity . . . . These aspects include . . . the use of COHb as the bioindicator and dose metric for evaluating CO exposure and the potential for health effects.") [JA xxx]. Although EPA gave "primary consideration" to the Allred Study regarding the specific levels of COHb of concern to public health, Rule 54,307/1 [JA xxx]; supra pp. 19-20, it comprised only a portion of the record supporting the use of COHb as a biomarker. PA 2-17 to 2-18 [JA xxx].

The record refutes Petitioners' assertion that "there is no indication . . . that EPA considered evidence that COHb is an ineffective or even counterproductive indicator of CO exposure." Br. 38. In the Policy Assessment, for example, EPA scientists addressed the following question: "does the current evidence provide support for a focus on alternative dose indicators to characterize potential for health effects?" PA 2-17 [JA xxx]. They explained that the evidence "continues to support levels of COHb as the most useful indicator of CO exposure that is related to the health effects of CO of major concern." Id.

Moreover, EPA responded to Mr. Donnay's comments and testimony on this topic with even greater specificity in a document ignored by Petitioners, EPA's

Response to Comments. While acknowledging "limitations in terms of interpretation of the immediate dose following CO inhalation," EPA explained that "COHb measured in venous blood remains the most extensively validated biomarker of CO exposure and effects[.]" RTC 24 [JA xxx]. In addition, EPA noted that "COHb . . . is the metric used in published health outcome studies." RTC 24 [JA xxx]. In another section of the RTC, EPA further explained that "the necessary validation of COHb as a biomarker has been conducted, including the development of multiple quantitative models describing its generation in response to CO exposure." RTC 28 [JA xxx]. As EPA observed, "COHb has been used as a marker of CO dose for many years[.]" RTC 29 [JA xxx].[13/]

EPA considered and reasonably addressed Mr. Donnay's comment that "the clinical studies relied upon by EPA improperly conflate or confuse two different forms of COHb[.]" Br. 39 (citing Donnay Comments 2-4 [JA xxx-xx]). See also Br. 38 (asserting that controlled human exposure studies "used imprecise (v)COHb measurement methods"). EPA acknowledged the disparity between venous carboxyhemoglobin ("(v)COHb") and arterial carboxyhemoglobin

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[13/] Contrary to Petitioners' suggestion (Br. 39), the 2000 Air Quality Criteria Document did not reach a contrary conclusion. It stated that "[t]he blood COHb level . . . represents a useful physiological marker to predict the potential health effects of CO exposure." 2000 AQCD 7-1 [JA xxx].

("(a)COHb"); that is, "in response to changes in CO exposure conditions . . . there is a period where arterial and venous COHb levels are not equivalent." RTC 24 [JA xxx]. More importantly, EPA explained the immateriality of that disparity: "[S]uch periods are quite short and, based on the relationship between magnitude of exposure and size of disparity, any such disparity is expected to be small under exposure conditions associated with ambient CO." RTC 24 [JA xxx].

Likewise, EPA reasonably considered exhaled carbon monoxide ("eCO") as an alternative biomarker to COHb. Contra Br. 40 (citing Donnay Comment 8 [JA xxx]). EPA explained that eCO is not as reliable as COHb because factors other than ambient CO exposure – for example, respiratory infection and inflammatory diseases – influence it. See RTC 28 [JA xxx]. Further, "[t]o date, evidence is lacking to fully characterize the response of eCO concentrations to inhaled CO concentrations[.]" Id. EPA considered the list of eCO studies provided by Mr. Donnay and judged that the scientific evidence did not support using eCO as an indicator of ambient CO exposure or to assess its effects. Id. at 28-29 [JA xxx-xx]. Thus, contrary to Petitioners' assertion, EPA did not "ignore[]" Mr. Donnay's list of studies or eCO. Br. 40.

C. EPA'S CONSIDERATION OF EPIDEMIOLOGICAL EVIDENCE WAS REASONABLE

In making the public health judgment to retain the primary standards, EPA reasonably explained its consideration of the epidemiological evidence. It did not "simply dismiss this information with short phrases and cursory explanation," as Petitioners contend. Br. 43.

The record shows that more epidemiological evidence was available for the present NAAQS review than in prior reviews, Rule 54,308/2 [JA xxx], and that EPA considered it along with studies from other disciplines. As the Integrated Science Assessment provides, EPA's assessment of adverse health effects from ambient CO was "based upon the integration of evidence from across disciplines," i.e., "multiple and various types of studies[.]" ISA 1-14 [JA xxx].

EPA described in detail how epidemiological studies with cardiovascular outcomes generally corroborated findings gleaned from controlled human exposure studies. Rule 54,308/2 [JA xxx]; ISA 5-48 ("Given the consistent and coherent evidence from epidemiologic and human clinical studies . . . it is concluded that a causal relationship is likely to exist between relevant short-term exposures to CO and cardiovascular morbidity.") [JA xxx]. Also, in describing the integration of evidence across disciplines, EPA noted associations with non-cardiovascular

outcomes "suggest[ed]" by the epidemiological and other types of studies. E.g., ISA 5-100 ("[E]pidemiological studies . . . and animal toxicological studies . . . together provide evidence that is suggestive of a causal relationship between relevant short-term exposures to CO and respiratory morbidity.") [JA xxx]. A suggestive causal relationship, however, is weaker than a likely causal relationship. As EPA scientists explained, "chance, bias and confounding cannot be ruled out." ISA 1-14 [JA xxx].

Moreover, EPA found "multiple complicating features of the epidemiological evidence base[.]" Rule 54,307/3 [JA xxx]. They included: (i) the fact that "very few of these studies were conducted in areas that met the current standards throughout the period of study[;]" (ii) the possibility that pollutants produced by fossil fuel consumption other than carbon monoxide were responsible for the health outcomes "given the currently low ambient CO levels[;]" (iii) the expected low change in COHb levels associated with currently low ambient CO concentrations; and (iv) "uncertainties related to representation of ambient CO exposures given the steep concentration gradient near roadways[.]" Rule 54,307/3-54,308/1 [JA xxx-xx]; supra pp. 20-22. Weighing the strengths and limitations of the epidemiological evidence in the context of the full evidence base, the Administrator judged that revisions to the primary standards were not required.

Rule 54,308/2-3 [JA xxx]. That constitutes reasoned decision-making.

Petitioners contend that "EPA improperly characterized the epidemiological evidence" in two ways. Br. 41. First, they assert that the Rule omitted citations to most of the "279 epidemiological studies [referenced] in the ISA." Id. The assertion is nonsensical. The Rule and the Response to Comments repeatedly cited and incorporated pertinent portions of the ISA, in which EPA scientists had assessed all of the useful scientific evidence, including epidemiological studies.

Petitioners also point to a particular epidemiological study, referred to as the "Bell Study," and assert that it "actually makes very clear the current level of CO standard is not protective of public health." Br. 41-42. Petitioners are wrong. The Bell Study, as EPA summarized, "evaluated the associations between ambient concentrations of multiple pollutants (i.e., fine particles . . . , nitrogen dioxide, sulfur dioxide, ozone, and CO) at fixed-site ambient monitors and increases in emergency department visits and hospital admissions for specific cardiovascular health outcomes[.]" Rule 54,301/1 [JA xxx]. Instead of mischaracterizing the Bell Study, as Petitioners assert, EPA explained why it declined to revise the standards based on epidemiological evidence, including the Bell Study, due to a number of factors, including "potential confounding by co-pollutants," "uncertainty associated with quantitative interpretation of the . . . results at low ambient

concentrations," and "uncertainty and potential error associated with exposure estimates . . . that relate to the use of area-wide or central-site monitor CO concentrations[.]" Rule 54,305/2-3 [JA xxx].

For example, the Bell Study evaluated associations in areas that did not consistently meet the existing eight-hour standard for CO, i.e., one of the standards under review. PA 2-30 [JA xxx]. The highest "design value," representing the second highest eight-hour concentrations recorded at a monitoring station in a year, for the areas and years covered by the study ranged up to over 24 ppm, as compared to the standard of nine ppm. PA 2-30, 2-32 (table 2-3) [JA xxx, xxx]. That means it was of limited use in determining whether the association would still occur if the areas had lower CO concentrations that met the standard. See Rule 54,305/1 ("[S]tudies involving air quality conditions in which the current standards were met . . . are most informative[.]") [JA xxx].[14/]

Petitioners incorrectly contend that EPA "disregarded" its own scientists' assessment of the epidemiological evidence for non-cardiovascular outcomes. Br. 42-43. In the ISA, EPA scientists conducted an extensive evaluation of the

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[14/] Similarly, with respect to studies (by Ritz, Maisonet, and Conceicao) cited on pages 47 and 48 of Petitioners' brief, EPA explained that they were of limited use in assessing the adequacy of an existing standard because they "included conditions when the current CO 8-hour standard was exceeded." RTC 6 [JA xxx].

epidemiological studies along with other evidence in the record with regard to ambient carbon monoxide's association with, inter alia, central nervous system effects, birth outcomes and developmental effects following long-term exposure to carbon monoxide; and respiratory morbidity and death following short-term exposure. See ISA 2-6 to 2-10, 5-49 to 5-114 [JA xxx-xxx, xxx-xxx]. In the Rule, EPA incorporated the ISA's conclusion that the foregoing health outcomes share only a "suggestive [] causal relationships" with relevant ambient CO exposure. Rule 54,299/1 [JA xxx]. EPA reasonably explained why it declined to revise the primary standards based on those suggestive causal relationships, stating, for example, that "evidence is generally lacking on mechanism or mode of action that might lend biological plausibility to associations of effects with low ambient concentrations observed in epidemiological studies." RTC 33 [JA xxx]. In other words, while the record contained strong evidence describing how CO can cause problems for people with heart disease, it lacked evidence explaining how CO could affect people with, for example, asthma.[15/]

Accordingly, EPA offered a reasonable explanation for the weight it placed on various aspects of the scientific evidence in making the public health policy

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[15/] Likewise, EPA reasonably considered and responded to comments concerning a suggestive association between CO exposure and lung health. See RTC 4-6 [JA xxx-xx]. Contra Br. 43.

judgment that the evidence warranted retaining the primary standards.

III. EPA REASONABLY DETERMINED THAT THE PRIMARY STANDARDS CONTINUE TO PROTECT PUBLIC HEALTH WITH AN ADEQUATE MARGIN OF SAFETY

Petitioners challenge the protectiveness of the primary standards. Pursuant to Section 109(b) those standards must be, "in the judgment of the Administrator," requisite to protect public health with "an adequate margin of safety." 42 U.S.C. § 7409(b)(1). Primary standards must protect not only "average healthy individuals," but also people with "conditions rendering them particularly vulnerable to air pollution." American Lung Ass'n, 134 F.3d at 389 (citations omitted); ISA 5-115 (defining susceptible populations) [JA xxx]. Determining what is requisite to protect public health involves a mixed judgment of science and policy. See Ethyl Corp., 541 F.2d at 24; Lead Industries, 647 F.2d at 1146.

Here, EPA assessed ambient carbon monoxide's effect on susceptible populations and found that the primary standards provide protection with an adequate margin of safety. In doing so, EPA engaged in reasoned decision-making and fulfilled its Section 109(b) responsibilities.

A. EPA REASONABLY FOUND THAT THE PRIMARY STANDARDS PROTECT SUSCEPTIBLE AND POTENTIALLY SUSCEPTIBLE POPULATIONS

Petitioners incorrectly assert that "EPA did not consider whether the current standard protects all susceptible populations." Br. 44. As the record shows, EPA considered a number of populations that are or even could potentially be vulnerable to ambient carbon monoxide, including the following populations discussed in Petitioners' brief:

- people with coronary artery disease
- people with cardiovascular disease
- older adults and elderly people
- people with diabetes
- people with anemia
- people with obstructive lung diseases
- fetuses during critical phases of development
- newborns and young infants
- children with asthma
- people who visit high-altitude locations
- people with pulmonary disease

- people who spend a substantial time on or near heavily traveled roadways

Rule 54,299/2-3, 54,306/2, 54,308/1-2 [JA xxx, xxx, xxx]; Proposal 8,167/2-3, 8,168/2 [JA xxx-xx]; RTC 4-8 [JA xxx-xxx]; PA 2-18 to 2-22 [JA xxx-xxx]; ISA 2-10 to 2-12, 5-114 to 5-124 [JA xxx-xx, xxx-xx].

Of those populations, EPA found the evidence to be "clearest" that people with coronary artery disease are the "most susceptible to an increase in CO-induced health effects." Rule 54,299/2-3 & n.8 (quoting ISA 2-12 [JA xxx]) [JA xxx]. EPA also found that "people with cardiovascular disease [are] a key population at risk from short-term ambient CO exposure." Rule 54,306/2 [JA xxx].[16]

In addition, EPA considered factors that indicate a potential for susceptibility to ambient CO exposure. "Older adults," for example, can have an "increased prevalence of cardiovascular disease . . . when compared to all age groups or lifestages." PA 2-21 [JA xxx]. Similarly, "[t]hose with other preexisting diseases that may have already limited oxygen availability or increased COHb production or levels, such as people with obstructive lung diseases, diabetes and anemia," may also be at greater risk from the hypoxic effects of CO. Proposal

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[16] CAD is a subset of cardiovascular disease. PA 2-19 [JA xxx].

8,167/2 [JA xxx]. With respect to those other groups, however, EPA did not find that they were more susceptible than people with CAD. Rule 54,306/3 ("[T]he currently available evidence does not indicate a greater susceptibility for any of the other populations or lifestages recognized as potentially at risk from exposure to ambient CO.") [JA xxx].

EPA did more than merely acknowledge potentially susceptible populations and note that the record provided "limited" information to characterize them. Contra Br. 45, 48-49. EPA explained why it concluded that a standard protecting people who have been demonstrated to be susceptible to CO would also protect people who are considered potentially susceptible for CO, where "evidence is limited or lacking with regard to the effects of CO at ambient levels, and associated exposures and COHb levels, while providing no indication of susceptibility to ambient CO greater than that of [coronary heart disease, which is also called coronary artery disease] and [heart disease] populations." Proposal 8,168/2 (emphasis added) [JA xxx].[17] EPA further explained that by protecting "people with heart disease, such as CAD, regardless of age," the primary standards

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[17] See also Rule 54,299/3-54,300/1 ("[I]nformation is lacking on specific CO exposures or COHb levels that may be associated with health effects in these other groups and the nature of the effects, as well as a way to relate the specific evidence available for the CAD population to these other populations.") [JA xxx-xx].

"provide the requisite protection, including an adequate margin of safety, to potentially susceptible populations or lifestages, including pregnant women and infants[.]" RTC 8 [JA xxx]. In EPA's judgment, providing adequate protection for people with CAD will also provide adequate protection for other susceptible populations, as well as the general public.[18]

Petitioners are incorrect that "[t]he administrative record . . . makes it clear" that the primary standards do not adequately protect potentially susceptible or at-risk populations. Br. 45. The Integrated Science Assessment, for example, "note[d] that evidence is lacking on mechanism or mode of action that might lend biological plausibility to a causal relationship between birth outcomes and developmental effects and low ambient concentrations of CO observed in epidemiological studies []." RTC 7 (citing ISA 5-80 [JA xxx]) [JA xxx]. Additionally, with respect to populations other than people with CVD and CAD, EPA could not "sufficiently rule out the role of chance, bias and confounding in the epidemiological associations observed[.]" RTC 7 (citing ISA § 5.4.3, table 1-2 [JA xxx, xxx]) [JA xxx]. Thus, as EPA reasonably found, the evidence did not

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[18] This is not a case like American Farm, where the Court remanded the standards for fine particular matter "for . . . EPA to explain why it believes [they] will provide . . . an adequate margin of safety against morbidity in children and other vulnerable subpopulations." 559 F.3d at 526. Here, EPA amply explained how the primary standards for CO protect susceptible populations.

indicate that other potentially susceptible populations were more susceptible and needed more protection than people with coronary artery disease.

Petitioners assert that they and other "[c]ommenters strongly urged EPA to more fully consider whether the current standard is adequate to protect susceptible populations." Br. 47. The assertion is inapposite. That Mr. Donnay and others disagreed with EPA's evaluation of the evidence does not establish that EPA acted arbitrarily. It is not the Court's "function to resolve disagreement among the experts or judge the merits of competing expert views." Lead Industries, 647 F.2d at 1160.

B. EPA REASONABLY FOUND THAT THE PRIMARY STANDARDS PROTECT PEOPLE WITH CARDIOVASCULAR DISEASE

EPA reasonably found that the primary standards protect people with cardiovascular disease, not just the subset of people with coronary artery disease. Although EPA found that "individuals with CAD are most susceptible," Rule 54,299 n.8 (emphasis added) [JA xxx], it also found that "people with cardiovascular disease [are] a key population at risk from short-term ambient CO exposures." Rule 54,306/2 [JA xxx]. Further, EPA's quantitative assessment of exposure and risk simulated adults with CAD and adults with any heart diseases. Rule 54,302/1 [JA xxx]. Thus, Petitioners incorrectly assert that "EPA only

considered one susceptible population in setting the standard – those with CAD." Br. 49.

Similarly baseless is Petitioners' assertion that "[o]verall, the record supports the need for a lower standard in order to protect those with CAD, and more broadly CVD." Br. 52. The question before the Court is whether the record supports EPA's judgment, not whether the record could also be construed to support a different judgment preferred by Petitioners. As the Court stated in Lead Industries, "where 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." 647 F.2d at 1158, 1160.

Moreover, Petitioners did not and cannot identify evidence in the record that shows that EPA's conclusion was arbitrary or capricious. Although Petitioners assert that the standard fails to protect certain populations, such as people with CVD who are susceptible to stroke, EPA reasonably determined that a standard that protects people with CAD also protects people with CVD. For example, EPA found only "very limited evidence" linking CO and strokes. ISA 5-40 [JA xxx]; see also ISA 2-14 ("Epidemiologic studies consistently show associations between ambient CO concentrations and cardiovascular endpoints other than stroke[.]") [JA xxx]. EPA's approach was to protect the most susceptible population while being

mindful not to set the standard lower than is requisite to protect the public health with an adequate margin of safety. Rule 54,303/2 ("The Act does not require that primary standards be set at zero-risk level, but rather at a level that avoids unacceptable risks to . . . the health of sensitive groups.") [JA xxx].

EPA considered the epidemiological studies (by Bell, Mann, and Linn) cited on pages 50 and 51 of Petitioners' brief and found that they "provide[] support to the clinical evidence for a direct effect of short-term ambient CO exposure on CVD morbidity []." Rule 54,301/1 (citing ISA 5-40 to 5-41 [JA xxx-xx]) [JA xxx]. That finding was reasonable, just as it was reasonable for the Administrator to judge the existing standards to be adequate based on the record, including controlled human exposure studies, exposure and risk estimates, and the uncertainties related to the epidemiological evidence (including the Bell, Mann, and Linn studies). See supra pp. 20-22, 43.

C. EPA REASONABLY FOUND THAT THE PRIMARY STANDARDS PROTECT PEOPLE FROM NON-CARDIOVASCULAR HEALTH EFFECTS

EPA reasonably considered evidence regarding the extent to which ambient carbon monoxide exposures are associated with non-cardiovascular health outcomes, including central nervous system effects, birth outcomes, developmental effects, respiratory morbidity, and mortality. Rule 54,299/3 [JA xxx]; Proposal

8,166/1-2 [JA xxx]; RTC 4-8, 11 [JA xxx-xxx, xxx]. Contra Br. 53 (asserting that EPA "ignore[d]" such evidence).

As Petitioners acknowledge, in the Integrated Science Assessment, EPA scientists concluded that certain non-cardiovascular health effects "are only supported by a 'suggestive' relationship." Br. 54. See also RTC 9 ("EPA has determined the separate bodies of evidence for birth outcomes and developmental effects, short-term exposure and respiratory morbidity, and short-term exposure and mortality to each be only suggestive of a causal relationship with ambient CO exposures [].") (citing ISA §§ 5.4 to 5.6 [JA xxx-xxx,]) [JA xxx]. Yet Petitioners also refer to those health outcomes as being "caused by CO exposure[.]" Br. 55 (emphasis added). Such assertions of causation lack support. After fully evaluating the relevant science, EPA did not find evidence sufficient to conclude that CO in the ambient air causes or even likely causes any non-cardiovascular health effect. To the contrary, EPA found a "much greater uncertainty" associated with a relationship between ambient CO and those health outcomes as compared to a relationship between ambient CO and cardiovascular effects. RTC 7-8 [JA xxx-xx].

Petitioners also make the unsupported charge that "EPA did not reference any evidence in the final rule demonstrating a positive correlation between CO

exposure and these other [non-cardiovascular] health effects." Br. 54. EPA's Response to Comments, issued in conjunction with the Rule, expressly addressed and explained the possibility of a link between ambient CO and non-cardiovascular health outcomes. RTC 4-8, 11 [JA xxx-xx, xxx]. With respect to respiratory morbidity, for example, EPA explained that it found "a lack of evidence on mechanism or mode of action that might lend biological plausibility to such a relationship for the low ambient concentrations of CO observed in epidemiological studies." RTC 4 [JA xxx].

None of the epidemiological studies discussed on pages 54 and 55 of Petitioners' brief compelled EPA to reach a different conclusion. For example, with respect to the assertion that "many studies . . . analyz[ed] effects of CO well below the current standard," Br. 55, EPA explained that, "when considering the publicly available information on attainment and non-attainment of the current standards in the study locations for the time periods relevant to the U.S. studies cited by the commenters, it can be documented that the current standards were met throughout the period of study in only two study areas." RTC 4 [JA xxx]. Petitioners ignore that response, as well as the RTC in its entirety. Supra p. 35. Their claims fail.

IV. EPA REASONABLY CONSIDERED AND ACTED CONSISTENT WITH THE VIEWS OF THE CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE

In pages 56-61 of Petitioners' brief, as well as in conjunction with other arguments (Br. 43, 47, 52), Petitioners take issue with EPA's consideration of CASAC's views concerning the protectiveness of the primary standards. The Act requires EPA to consider "any pertinent findings, recommendations, and comments by [CASAC]," and "if [EPA's] proposal differs in any important respect from any of these recommendations" to provide "an explanation of the reasons for such differences." 42 U.S.C. § 7607(d)(3). The record shows that EPA fully considered CASAC's views, acted consistent with them, and fulfilled the Act's requirements. Proposal 8,183/1-3 [JA xxx]; Rule 54,307/3-54,308/1 [JA xxx-xx]; RTC 56-57 [JA xxx-xx]; supra pp. 16-18.

Contrary to Petitioners' assertions (Br. 56-61), EPA correctly characterized CASAC's views. CASAC did, as EPA stated, express a "preference" for a revised standard. Compare Proposal 8,183/2 [JA xxx] with CASAC 6/8/10 at 2 [JA xxx]. CASAC also advised to "consider[]" "revisions that result in lowering the standard" based on epidemiological studies. Compare Proposal 8,183/2 [JA xxx] with CASAC 6/8/10, Encl. B at 11 [JA xxx].

In the same communication, CASAC further stated that it "agree[d]" with the conclusion of EPA scientists that "the data provide support for retaining or revising the current 8-hr standard." Compare Proposal 8,183/2 [JA xxx] with CASAC 6/8/10, Encl. B at 12 [JA xxx]. CASAC also stated that "[i]f the epidemiological evidence is given additional weight, the conclusion could be drawn that health effects are occurring at levels below the current standard, which would support the tightening of the current standard." Compare Proposal 8,183/2 [JA xxx] with CASAC 6/8/10, Encl. B at 12 [JA xxx]. Based on those statements, EPA concluded that CASAC's "preference for a lower standard was contingent on a judgment as to the weight to be placed on the epidemiological evidence." Rule 54,308/1 [JA xxx]; RTC 56-57 [JA xxx-xx].

Petitioners dismiss CASAC's agreement that the evidence provides support for either retaining or revising the primary standards as "a single . . . comment made in passing." Br. 57. However, CASAC meant what it said, that "[o]verall the Panel agrees with this conclusion," i.e., the conclusion of EPA scientists as expressed in the draft Policy Assessment that the evidence supports either retaining or revising the eight-hour primary standard. CASAC 6/8/10, Encl. B at 12 [JA xxx]. Nothing about CASAC's statement supports – much less compels – a characterization that it was a stray remark or uttered in meaningless isolation.

CASAC's agreement was made in the context of its consensus response to a charge question concerning the adequacy of the existing standards. Moreover, CASAC qualified its views regarding a tightening of the standard by the phrase "if the epidemiological evidence is given additional weight." CASAC 6/8/10, Encl. B at 12 [JA xxx]. "[I]f" was an acknowledgment that scientists, and more importantly the EPA Administrator, could reasonably differ in their assessment of the scientific evidence. Indeed, it is common for CASAC to advise EPA to consider a range of options. See, e.g., Recyclers, 604 F.3d at 616 (noting that CASAC had recommended that the standards for lead fall within a range).

EPA did not "ignore CASAC's multiple recommendations that [it] give greater weight to epidemiological studies," as Petitioners assert. Br. 58. See also Br. 43 (asserting that CASAC's June 8, 2010 letter shows that EPA arbitrarily considered the epidemiological evidence). EPA followed CASAC's advice by devoting more attention and discussion to epidemiological studies after CASAC's last letter to the Administrator. Proposal 8,182/1-8,183/2 [JA xxx-xx].

Moreover, contrary to Petitioners' cursory assertion (Br. 60-61), EPA's consideration of CASAC's views included consideration of a lower standard. RTC 57 ("EPA . . . has acted consistent with CASAC's advice in considering a lower standard.") [JA xxx]. In the Policy Assessment, for example, EPA extensively

discussed the possible scientific rationale for more stringent primary standards. See PA 2-60 to 2-76 [JA xxx-xx]. Furthermore, in the Proposal, EPA invited public comment on whether to revise the existing standards in light of CASAC's views and the rationale for lower standards identified in the PA. Proposal 8,184/3 [JA xxx].

EPA also followed the advice CASAC relayed in earlier letters to the Administrator. Contra Br. 47 (citing CASAC's letters of February 12 and May 19, 2010). CASAC, for example, advised EPA to "consider[]" "the degree of protection afforded to susceptible populations by the current NAAQS." CASAC 5/19/10 at 1 [JA xxx]. EPA did so. See supra pp. 13-16, 21-22. CASAC "recognize[d] . . . compelling evidence . . . from clinical studies demonstrating a relationship between elevated levels of carboxyhemoglobin (COHb) and a reduced time to the onset of angina." CASAC 5/19/10 at 1-2 [JA xxx-xxx]. So did EPA. See supra p. 20.

Moreover, Petitioners' claim ignores the EPA Administrator's "consideration to the full breadth of CASAC's advice," including CASAC's "range of advice regarding interpretation of the CO epidemiological studies in light of the associated uncertainties." Rule 54,308/1 [JA xxx]; supra pp. 20-22, 43. CASAC advised, for example, that "[t]he problem of co-pollutants serving as potential

confounders is particularly problematic for CO[,]" and "CO may be a surrogate for exposure to a mix of pollutants generated by fossil fuel combustion." CASAC 1/20/10 at 2 [JA xxx].

CASAC's breadth of advice further included, for example, its "agree[ment]" that the Allred Study and other controlled human exposure studies were "well-designed" and received appropriate emphasis by EPA. CASAC 1/20/10 at 2 ("[I]nformation from well-designed clinical exposure studies has received emphasis. We agree with the weight that they are given in the [second draft ISA]."") [JA xxx]. Furthermore, in its last letter of the NAAQS review process, CASAC stated that "[t]he conclusion that the current evidence supports a primary focus on those with cardiovascular disease is justifiably based on observations from clinical studies." CASAC 6/8/10, Encl. B at 11 [JA xxx]. This shows CASAC's acknowledgment that after its earlier comments (which Petitioners focus on, Br. 52), EPA had broadened its consideration of susceptible populations beyond people with CAD.

Petitioners often point to the views of "[o]ne CASAC member" and quote from meeting transcripts. E.g., Br. 47, 52. That approach misses the mark. CASAC acted here only by consensus. See Association of Am. Physicians and Surgeons, Inc. v. Clinton, 997 F.2d 898, 913 (D.C. Cir. 1993) ("[A] group is not a

[Federal Advisory Committee Act] advisory committee unless it gives 'consensus' advice."); 77 Fed. Reg. 6,796, 6,797 (Feb. 9, 2012) ("CASAC is a Federal Advisory Committee[.]"); EPA-HQ-OAR-2008-0015-0018 at 10 [JA xxx]. Further, as explained supra p. 16 & n.5, CASAC expressed its consensus views through letters, not through the remarks of individual members made at a meeting.

Accordingly, as the record shows, EPA reasonably considered and weighed the full range of CASAC's advice, including its agreement that the scientific evidence supported either retaining or revising the primary standards for carbon monoxide. Thus, EPA's decision did not "differ[] in any important respect" from CASAC's. 42 U.S.C. § 7607(d)(3). Alternatively, by explaining its evaluation of the epidemiological evidence (supra pp. 19-22, 43), EPA provided "an explanation of the reasons for [any] such differences." 42 U.S.C. § 7607(d)(3).

V. EPA REASONABLY FOUND INSUFFICIENT EVIDENCE TO ESTABLISH A SECONDARY STANDARD

Petitioners challenge the absence of a secondary standard for carbon monoxide. The Act provides that "[a]ny . . . secondary . . . standard . . . shall specify a level of air quality . . . which in the judgment of the Administrator . . . 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." 42

U.S.C. § 7409(b)(2). Public welfare includes effects on climate. Id. § 7602(h). While climate change is matter of "unusual importance," Massachusetts v. EPA, 549 U.S. 497, 506 (2007), EPA reasonably found no indication that a secondary standard for carbon monoxide would "protect the public welfare," 42 U.S.C. § 7409(b)(2), by alleviating climate change. Petitioners' claim to the contrary is jurisdictionally deficient and without merit.

A. PETITIONERS LACK STANDING

Petitioners lack standing to challenge EPA's decision not to establish a secondary standard for CO. To establish representational standing,[19] Petitioners must demonstrate, inter alia, that their "members would otherwise have standing to sue in their own right[.]" National Ass'n of Home Builders v. EPA, 667 F.3d 6, 12 (D.C. Cir. 2011) (citations and internal quotation marks omitted). A member has standing if he has a "personal injury fairly traceable to the [opposing party's] allegedly unlawful conduct and likely to be redressed by the requested relief." Allen v. Wright, 468 U.S. 737, 751 (1984) (citation omitted; alteration in original). Here, Petitioners have failed to establish at least one of those essential elements (traceability) and possibly another (injury in fact).

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[19] Petitioners offer no argument that they have organizational or procedural standing. Br. 28-30.

An injury in fact must be "(a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992) (citations and quotation marks omitted). "[P]articularized" means in a "personal and individual way." Id. at 561 n.1. The only member who comes close to alleging a particularized injury, Jeremy Nichols, avers that EPA's secondary standard decision "diminish[es] [his] ability to enjoy viewing wildlife and to enjoy [his] recreational activities." Nichols Decl. ¶ 16. He refers to various species of birds he observes and concludes that climate change is affecting their overall population. Id. ¶ 15. Under circuit precedent, those averments may be too general to be cognizable. See Center for Biological Diversity v. United States Dep't of Interior, 563 F.3d 466, 478 (D.C. Cir. 2009) ("Standing analysis does not examine whether the environment in general has suffered an injury.") (citation omitted).

Moreover, Petitioners have not established traceability, i.e., that "it is substantially probable . . . that the challenged acts of the defendant . . . will cause the particularized injury of the plaintiff." Florida Audubon Soc'y v. Bentsen, 94 F.3d 658, 663 (D.C. Cir. 1996) (citations omitted). Neither in Mr. Nichols' declaration nor elsewhere have Petitioners articulated an evidentiary link between EPA's decision and the purported injury, nor do they provide evidence that, or

explain how, a secondary standard would redress that injury. See Nichols Decl. ¶¶ 13-17.

B. PETITIONERS' CHALLENGE FAILS ON THE MERITS

Regardless of Petitioners' standing, their claim lacks merit. EPA reasonably determined, based on the record, that having no secondary standard is requisite to protect public welfare.

The Integrated Science Assessment acknowledged the indirect climate effects of CO, primarily through its effect on concentrations of other gases. ISA 3-11 [JA xxx]. It is well known that carbon monoxide plays a participatory role in the reactions of chemicals in the atmosphere, which, in turn, contribute to increased concentrations of other pollutants that directly contribute to global warming. See ISA §§ 2.2, 3.3 [JA xxx-xx, xxx-xx].[20] CO itself is not a greenhouse gas. As the ISA found, "CO is a weak direct contributor to greenhouse warming[.]" ISA 3-11 [JA xxx]. Moreover, the ISA concluded that the regional climate effects of CO are highly variable and uncertain. ISA 3-12, 3-15, 3-16 [JA xxx, xxx, xxx].

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[20] For example, "more than half of the indirect forcing effect of CO is attributable to ozone . . . formation[.]" Rule 54,309/3 [JA xxx]. A climate forcing effect means there is more radiation coming into the Earth's atmosphere than leaving it. That a secondary standard for ozone exists further establishes the reasonableness of EPA's decision. PA 3-4 [JA xxx]; RTC 41 [JA xxx].

In the Policy Assessment, EPA scientists concluded that "the available information provides no basis for estimating how localized changes in the temporal and spatial patterns of ambient CO likely to occur across the U.S. with (or without) a secondary standard would affect local, regional, or nationwide changes in climate." PA 3-4 [JA xxx]. As a result, they assessed the evidence to be "insufficient . . . to support the consideration of a secondary NAAQS based on CO effects on climate processes," or to even conduct an analysis of what a secondary standard might look like. Id.[21/]

The notion that at a global scale "a causal relationship exists between current atmospheric concentrations of CO and effects on climate," Rule 54,309/1 [JA xxx]; ISA 1-8 (distinguishing between "global scale conclusions related to climate and the strongly variable continental and regional climate forcing effects from CO") [JA xxx], does not in and of itself mandate the establishment of a secondary standard. Contra Br. 64-65. Any standard the Administrator sets must be neither more nor less stringent than necessary. Whitman, 531 U.S. at 475-76. Thus, the central question before EPA was whether sufficient information exists to indicate

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[21/] Page 64 of Petitioners' brief stresses a sentence from the PA ("CO is classified as a short-lived climate forcing agent . . . .") while omitting a critical one that follows ("However, it is highly problematic to evaluate the indirect effects of CO on climate . . . ."). PA 3-3 (citing ISA) [JA xxx].

whether a secondary standard could mitigate adverse public welfare effects associated with climate change. In EPA's considered judgment, "in light of both the significant uncertainties, and the evidence of the direct effects being weak and the indirect effects being highly variable and dependent on local conditions, particularly in light of CO's short lifetime, it is not possible to anticipate how any secondary standard that would limit ambient CO concentrations in the United States would in turn affect climate." Rule 54,310/1 [JA xxx]. Accordingly, the Administrator reasonably judged that there was no basis to determine that a secondary standard limiting ambient concentrations of CO was needed or would protect the public welfare.

Petitioners incorrectly argue that EPA "improperly allowed a lack of certainty to influence its decision." Br. 63 (citations omitted). Inadequate evidence, not a lack of certainty, drove EPA's decision. Rule 54,310/1 [JA xxx]. As EPA explained, information to evaluate the utility or design of a secondary standard was simply "not available." Rule 54,310/2 [JA xxx]. Neither Petitioners nor any other commenter produced any gap-filling data. Rule 54,310/1 ("[N]owhere does the comment provide evidence that EPA's conclusion regarding adequacy of the available information is in error.") [JA xxx].

CASAC supported EPA's determination. Contra Br. 64. "CASAC noted without objection or disagreement the [EPA] staff's conclusions that there is insufficient information to support consideration of a secondary standard at this time[.]" Rule 54,309/3 (citing CASAC 6/8/10, Encl. B at 14 [JA xxx]) [JA xxx]. The views of "[o]ne CASAC member," which Petitioners cite, have no controlling force. Br. 64. See supra pp. 61-62. In any event, the same member acknowledged that "[t]he current ambient concentration-based standards are not appropriate for large-scale global atmospheric concentration concerns aimed at protecting welfare," and that "the state of the science not yet adequate to establish a specific CO emissions cap[.]" CASAC 1/20/10, Encl. C at 27 [JA xxx].

Accordingly, even if Petitioners have standing, the Administrator reasonably judged that no provision of law and nothing in the record warranted the establishment of a secondary standard for carbon monoxide.

CONCLUSION

The petition for review should be denied in part and dismissed in part.

Respectfully submitted,

Dated: July 13, 2012 (Initial Brief)

IGNACIA S. MORENO
Assistant Attorney General

___/s/ Andrew J. Doyle
ANDREW J. DOYLE, Attorney
Environment & Natural Resources Division
United States Department of Justice
P.O. Box 7611
Washington, D.C. 20044
(202) 514-4427 (p)
andrew.doyle@usdoj.gov

OF COUNSEL:

David P.W. Orlin
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Attorneys for Respondent

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,971 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and D.C. Cir. Rule 32(a)(1).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in proportionally spaced typeface using Word Perfect X3 in 14-point Times New Roman font.

Dated: 07/13/2012

___/s/ Andrew J. Doyle___
ANDREW J. DOYLE, Attorney
United States Department of Justice
Environment & Natural Resources Division

Attorney for Respondent

CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2012, the foregoing (Initial) Brief for Respondent was served electronically through the Court's CM/ECF system on all registered counsel.

In addition, pursuant to Fed. R. App. P. 31(b) and D.C. Cir. Rule 31, I hereby certify that on July 13, 2012, I caused two copies of the brief foregoing brief to be served via first class U.S. mail, postage prepaid, on the following counsel of record for Petitioners, Communities for a Better Environment and WildEarth Guardians, and Petitioner-Intervenor, Sierra Club:

Michael Ray Harris
Environmental Law Clinic
University of Denver
Sturm College of Law
2255 East Evans Avenue
Denver, CO 80208
Telephone: 303-871-7870
Email: mharris@law.du.edu

Dated: 07/13/2012

/s/ Andrew J. Doyle
ANDREW J. DOYLE, Attorney
United States Department of Justice
Environment & Natural Resources Division

Attorney for Respondent

Statutory and Regulatory Addendum

Clean Air Act Provisions

Regulation

Any funds previously diverted or reprogrammed from section 105 Clean Air Act [section 7405 of this title] grants for $PM_{2.5}$ monitors must be restored to State or local air programs in fiscal year 1999.

"(b) EPA and the States, consistent with their respective authorities under the Clean Air Act [Act July 14, 1955, ch. 360, 69 Stat. 322, which is classified generally to section 7401 et seq. of this title], shall ensure that the national network (designated in subsection (a)) which consists of the $PM_{2.5}$ monitors necessary to implement the national ambient air quality standards is established by December 31, 1999.

"(c)(1) The Governors shall be required to submit designations referred to in section 107(d)(1) of the Clean Air Act [subsec. (d)(1) of this section] for each area following promulgation of the July 1997 $PM_{2.5}$ national ambient air quality standard within 1 year after receipt of 3 years of air quality monitoring data performed in accordance with any applicable Federal reference methods for the relevant areas. Only data from the monitoring network designated in subsection (a) and other Federal reference method $PM_{2.5}$ monitors shall be considered for such designations. Nothing in the previous sentence shall be construed as affecting the Governor's authority to designate an area initially as nonattainment, and the Administrator's authority to promulgate the designation of an area as nonattainment, under section 107(d)(1) of the Clean Air Act [subsec. (d)(1) of this section], based on its contribution to ambient air quality in a nearby nonattainment area.

"(2) For any area designated as nonattainment for the July 1997 $PM_{2.5}$ national ambient air quality standard in accordance with the schedule set forth in this section, notwithstanding the time limit prescribed in paragraph (2) of section 169B(e) of the Clean Air Act [section 7492(e)(2) of this title], the Administrator shall require State implementation plan revisions referred to in such paragraph (2) to be submitted at the same time as State implementation plan revisions referred to in section 172 of the Clean Air Act [section 7502 of this title] implementing the revised national ambient air quality standard for fine particulate matter are required to be submitted. For any area designated as attainment or unclassifiable for such standard, the Administrator shall require the State implementation plan revisions referred to in such paragraph (2) to be submitted 1 year after the area has been so designated. The preceding provisions of this paragraph shall not preclude the implementation of the agreements and recommendations set forth in the Grand Canyon Visibility Transport Commission Report dated June 1996.

"(d) The Administrator shall promulgate the designations referred to in section 107(d)(1) of the Clean Air Act [subsec. (d)(1) of this section] for each area following promulgation of the July 1997 $PM_{2.5}$ national ambient air quality standard by the earlier of 1 year after the initial designations required under subsection (c)(1) are required to be submitted or December 31, 2005.

"(e) **Field study.**—Not later than 2 years after the date of enactment of the SAFETEA–LU [Aug. 10, 2005], the Administrator shall—

"(1) conduct a field study of the ability of the $PM_{2.5}$ Federal Reference Method to differentiate those particles that are larger than 2.5 micrometers in diameter;

"(2) develop a Federal reference method to measure directly particles that are larger than 2.5 micrometers in diameter without reliance on subtracting from coarse particle measurements those particles that are equal to or smaller than 2.5 micrometers in diameter;

"(3) develop a method of measuring the composition of coarse particles; and

"(4) Submit a report on the study and responsibilities of the administrator under paragraphs (1) through (3) to—

"(A) the Committee on Energy and Commerce of the House of Representatives; and

"(B) the Committee on Environment and Public Works of the Senate.

"**Sec. 6103. Ozone designation requirements.**

"(a) The Governors shall be required to submit the designations referred to in section 107(d)(1) of the Clean Air Act [subsec. (d)(1) of this section] within 2 years following the promulgation of the July 1997 ozone national ambient air quality standards.

"(b) The Administrator shall promulgate final designations no later than 1 year after the designations required under subsection (a) are required to be submitted.

"**Sec. 6104. Additional provisions.**

"Nothing in sections 6101 through 6103 [set out above in this note] shall be construed by the Administrator of Environmental Protection Agency or any court, State, or person to affect any pending litigation or to be a ratification of the ozone or $PM_{2.5}$ standards."

Modification or Rescission of Rules, Regulations, Orders, Determinations, Contracts, Certifications, Authorizations, Delegations, and Other Actions

All rules, regulations, orders, determinations, contracts, certifications, authorizations, delegations, or other actions duly issued, made, or taken by or pursuant to Act July 14, 1955, the Clean Air Act, as in effect immediately prior to the date of enactment of Pub.L. 95–95 [Aug. 7, 1977] to continue in full force and effect until modified or rescinded in accordance with Act July 14, 1955, as amended by Pub.L. 95–95 [this chapter], see section 406(b) of Pub.L. 95–95, set out as an Effective and Applicability Provisions of 1977 Acts note under section 7401 of this title.

§ 7408. Air quality criteria and control techniques

[CAA § 108]

(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

(d) 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.

(July 14, 1955, c. 360, Title I, § 108, as added Dec. 31, 1970, Pub.L. 91–604, § 4(a), 84 Stat. 1678, and 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.)

HISTORICAL AND STATUTORY NOTES

Codifications

Section was formerly classified to section 1857c–3 of this title.

Reference in subsec. (e) in the original to "enactment of the Clean Air Act Amendments of 1989" has been codified as "November 15, 1990" as manifesting Congressional intent in the date of the enactment of Pub.L. 101–549, Nov. 15, 1990, 104 Stat. 2399, popularly known as the Clean Air Act Amendments of 1990.

Effective and Applicability Provisions

1990 Acts. Amendment by Pub.L. 101–549 effective Nov. 15, 1990, except as otherwise provided, see section 711(b) of Pub.L. 101–549, set out as a note under section 7401 of this title.

1977 Acts. Amendment by Pub.L. 95–95 effective Aug. 7, 1977, except as otherwise expressly provided, see section 406(d) of Pub.L. 95–95, set out as a note under section 7401 of this title.

Savings Provisions

Suits, actions or proceedings commenced under this chapter as in effect prior to Nov. 15, 1990, not to abate by reason of the taking effect of amendments by Pub.L. 101–549, except as otherwise provided for, see section 711(a) of Pub.L. 101–549, set out as a note under section 7401 of this title.

Prior Provisions

A prior section 108 of Act July 14, 1955, was renumbered section 115 by Pub.L. 91–604 and is set out as section 7415 of this title.

Modification or Rescission of Rules, Regulations, Orders, Determinations, Contracts, Certifications, Authorizations, Delegations, and Other Actions

All rules, regulations, orders, determinations, contracts, certifications, authorizations, delegations, or other actions duly issued, made, or taken by or pursuant to Act July 14, 1955, the Clean Air Act, as in effect immediately prior to the date of enactment of Pub.L. 95–95 [Aug. 7, 1977] to continue in full force and effect until modified or rescinded in accordance with Act July 14, 1955, as amended by Pub.L. 95–95 [this chapter], see section 406(b) of Pub.L. 95–95, set out as an Effective and Applicability Provisions of 1977 Acts note under section 7401 of this title.

§ 7409. National primary and secondary ambient air quality standards

[CAA § 109]

(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 Adminis-

trator 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.

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

HISTORICAL AND STATUTORY NOTES

Codifications

Section was formerly classified to section 1857c–4 of this title.

Effective and Applicability Provisions

1977 Acts. Amendment by Pub.L. 95–95 effective Aug. 7, 1977, except as otherwise expressly provided, see section 406(d) of Pub.L. 95–95, set out as a note under section 7401 of this title.

Prior Provisions

A prior section 109 of Act July 14, 1955, was renumbered section 116 by Pub.L. 91–604 and is set out as section 7416 of this title.

Modification or Rescission of Rules, Regulations, Orders, Determinations, Contracts, Certifications, Authorizations, Delegations, and Other Actions

All rules, regulations, orders, determinations, contracts, certifications, authorizations, delegations, or other actions duly issued, made, or taken by or pursuant to Act July 14, 1955, the Clean Air Act, as in effect immediately prior to the date of enactment of Pub.L. 95–95 [Aug. 7, 1977] to continue in full force and effect until modified or rescinded in accordance with Act July 14, 1955, as amended by Pub.L. 95–95 [this chapter], see section 406(b) of Pub.L. 95–95, set out as an Effective and Applicability Provisions of 1977 Acts note under section 7401 of this title.

Role of Secondary Standards

Pub.L. 101–549, Title VIII, § 817, Nov. 15, 1990, 104 Stat. 2697, which provided for a report to Congress to be prepared by the National Academy of Sciences, relating to the role of national secondary ambient air quality standards in protecting welfare and the environment, and to be transmitted not later than 3 years after the date of enactment of the Clean Air Act Amendments of 1990 [Nov. 15, 1990], terminated, effective May 15, 2000, pursuant to Pub.L. 104–66, § 3003, as amended, set out as a note under 31 U.S.C.A. § 1113, and the 6th item on page 163 of House Document No. 103–7.

Termination of Advisory Committees

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the two-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such two-year period, or in the case of a committee established by the Congress, its duration is otherwise provided for by law, see section 14 of Pub.L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in Appendix 2 to Title 5, Government Organization and Employees.

§ 7410. State implementation plans for national primary and secondary ambient air quality standards

[CAA § 110]

(a) Adoption of plan by State; submission to Administrator; content of plan; revision; new sources; indirect source review program; supplemental or intermittent control systems

(1) Each State shall, after reasonable notice and public hearings, adopt and submit to the Administrator, within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof) under section 7409 of this title for any air pollutant, a plan which provides for implementation, maintenance, and enforcement of such primary standard in each air quality control region (or portion thereof) within such State. In addition, such State shall adopt and submit to the Administrator (either as a part of a plan submitted under the preceding sentence or separately) within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national ambient air quality secondary standard (or revision thereof), a plan which provides for implementation, maintenance, and enforcement of such secondary standard in each air quality control region (or portion thereof) within such State. Unless a separate public hearing is provided,

general amendment of this chapter by Pub.L. 88–206, provided for cooperative effort.

Disadvantaged Business Concerns; Use of Quotas Prohibited

Pub.L. 101–549, Title X, §§ 1001, 1002, Nov. 15, 1990, 104 Stat. 2708, provided that:

"**Sec. 1001. Disadvantaged business concerns.**

"**(a) In general.**—In providing for any research relating to the requirements of the amendments made by the Clean Air Act Amendments of 1990 [Pub.L. 101–549, Nov. 15, 1990, 104 Stat. 2399, for distribution which Act to the Code, see Tables] which uses funds of the Environmental Protection Agency, the Administrator of the Environmental Protection Agency shall, to the extent practicable, require that not less than 10 percent of total Federal funding for such research will be made available to disadvantaged business concerns.

"**(b) Definition.**—

"(1)(A) For purposes of subsection (a), the term 'disadvantaged business concern' means a concern—

"(i) which is at least 51 percent owned by one or more socially and economically disadvantaged individuals or, in the case of a publicly traded company, at least 51 percent of the stock of which is owned by one or more socially and economically disadvantaged individuals; and

"(ii) the management and daily business operations of which are controlled by such individuals.

"(B)(i) A for-profit business concern is presumed to be a disadvantaged business concern for purposes of subsection (a) if it is at least 51 percent owned by, or in the case of a concern which is a publicly traded company at least 51 percent of the stock of the company is owned by, one or more individuals who are members of the following groups:

"(I) Black Americans.

"(II) Hispanic Americans.

"(III) Native Americans.

"(IV) Asian Americans.

"(V) Women.

"(VI) Disabled Americans.

"(ii) The presumption established by clause (i) may be rebutted with respect to a particular business concern if it is reasonably established that the individual or individuals referred to in that clause with respect to that business concern are not experiencing impediments to establishing or developing such concern as a result of the individual's identification as a member of a group specified in that clause.

"(C) The following institutions are presumed to be disadvantaged business concerns for purposes of subsection (a):

"(i) Historically black colleges and universities, and colleges and universities having a student body in which 40 percent of the students are Hispanic.

"(ii) Minority institutions (as that term is defined by the Secretary of Education pursuant to the General Education Provision Act (20 U.S.C. 1221 et seq.) [section 1221 et seq. of Title 20], Education).

"(iii) Private and voluntary organizations controlled by individuals who are socially and economically disadvantaged.

"(D) A joint venture may be considered to be a disadvantaged business concern under subsection (a), notwithstanding the size of such joint venture, if—

"(i) a party to the joint venture is a disadvantaged business concern; and

"(ii) that party owns at least 51 percent of the joint venture.

A person who is not an economically disadvantaged individual or a disadvantaged business concern, as a party to a joint venture, may not be a party to more than 2 awarded contracts in a fiscal year solely by reason of this subparagraph.

"(E) Nothing in this paragraph shall prohibit any member of a racial or ethnic group that is not listed in subparagraph (B)(i) from establishing that they have been impeded in establishing or developing a business concern as a result of racial or ethnic discrimination.

"**Sec. 1002.** Use of quotas prohibited. Nothing in this title [Title X of Pub.L. 101–594, Nov. 15, 1990, 104 Stat. 2708, enacting this note] shall permit or require the use of quotas or a requirement that has the effect of a quota in determining eligibility under section 1001."

Modification or Rescission of Rules, Regulations, Orders, Determinations, Contracts, Certifications, Authorizations, Delegations, and Other Actions

All rules, regulations, orders, determinations, contracts, certifications, authorizations, delegations, or other actions duly issued, made, or taken by or pursuant to Act July 14, 1955, the Clean Air Act, as in effect immediately prior to the date of enactment of Pub.L. 95–95 [Aug. 7, 1977] to continue in full force and effect until modified or rescinded in accordance with Act July 14, 1955, as amended by Pub.L. 95–95 [this chapter], see section 406(b) of Pub.L. 95–95, set out as an Effective Date of 1977 Acts note under section 7401 of this title.

§ 7602. Definitions

[CAA § 302]

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.[1]

(*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.

(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, and 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.)

[1] So in original.

HISTORICAL AND STATUTORY NOTES

Codifications

Section was formerly classified to section 1857h of this title.

Effective and Applicability Provisions

1990 Acts. Amendment by Pub.L. 101–549 effective Nov. 15, 1990, except as otherwise provided, see section 711(b) of Pub.L. 101–549, set out as a note under section 7401 of this title.

1977 Acts. Amendment by Pub.L. 95–95 effective Aug. 7, 1977, except as otherwise expressly provided, see section 406(d) of Pub.L. 95–95, set out as a note under section 7401 of this title.

Savings Provisions

Suits, actions or proceedings commenced under this chapter as in effect prior to Nov. 15, 1990, not to abate by reason of the taking effect of amendments by Pub.L. 101–549, except as otherwise provided for, see section 711(a) of Pub.L. 101–549, set out as a note under section 7401 of this title.

Prior Provisions

Provisions similar to subsecs. (b) and (d) of this section were contained in a prior section 1857e, Act July 14, 1955, c. 360, § 6, 69 Stat. 323, prior to the general amendment of this chapter by Pub.L. 88–206.

§ 7603. Emergency powers

[CAA § 303]

Notwithstanding any other provision of this chapter, the Administrator, upon receipt of evidence that a pollution source or combination of sources (including moving sources) is presenting an imminent and substantial endangerment to public health or welfare, or the environment, may bring suit on behalf of the United States in the appropriate United States district court to immediately restrain any person causing or contributing to the alleged pollution to stop the emission of air pollutants causing or contributing to such pollution or to take such other action as may be necessary. If it is not practicable to assure prompt protection of public health or welfare or the environment by commencement of such a civil action, the Administrator may issue such orders as may be necessary to protect public health or welfare or the environment. Prior to taking any action under this section, the Administrator shall consult with appropriate State and local authorities and attempt to confirm the accuracy of the information on which the action proposed to be taken is based. Any order issued by the Administrator under this section shall be effective upon issuance and shall remain in effect for a period of not more than 60 days, unless the Administrator brings an action pursuant to the first sentence of this section before the expiration of that period. Whenever the Administrator brings such an action within the 60–day period, such order shall remain in effect for an additional 14 days or for such longer period as may be authorized by the court in which such action is brought.

(July 14, 1955, c. 360, Title III, § 303, as added Dec. 31, 1970, Pub.L. 91–604, § 12(a), 84 Stat. 1705, and amended Aug. 7,

Subsec. (e) of this section, shown as omitted, which required the President to annually report to Congress on measures taken toward implementing the purpose and intent of this section, terminated, effective May 15, 2000, pursuant to section 3003 of Pub.L. 104–66, as amended, set out as a note under 31 U.S.C.A. § 1113. See, also, the 14th item on page 20 of House Document No. 103–7.

Effective and Applicability Provisions

1990 Acts. Amendment by Pub.L. 101–549 effective Nov. 15, 1990, except as otherwise provided, see section 711(b) of Pub.L. 101–549, set out as a note under section 7401 of this title.

Savings Provisions

Suits, actions or proceedings commenced under this chapter as in effect prior to Nov. 15, 1990, not to abate by reason of the taking effect of amendments by Pub.L. 101–549, except as otherwise provided for, see section 711(a) of Pub.L. 101–549, set out as a note under section 7401 of this title.

Prior Provisions

A prior § 306 of Act July 14, 1955, c. 360, Title III, as added Nov. 21, 1967, Pub.L. 90–148, § 2, 81 Stat. 506, was renumbered section 313 by Pub.L. 91–604, and is classified to former section 7613 of this title.

Another prior section 306 of Act July 14, 1955, c. 360, Title III, formerly § 13, as added Dec. 17, 1963, Pub.L. 88–206, § 1, 77 Stat. 401, renumbered § 306, Oct. 20, 1965, Pub.L. 89–272, Title I, § 101(4), 79 Stat. 992, renumbered § 309, Nov. 21, 1967, Pub.L. 90–148, § 2, 81 Stat. 506, renumbered § 316, Dec. 31, 1970, Pub.L. 91–604, § 12(a), 84 Stat. 1705, which related to appropriations, was classified to prior section 1857*l* of this title and was repealed by section 306 of Pub.L. 95–95. See section 7626 of this title.

Federal Acquisition Regulation: Contractor Certification or Contract Clause for Acquisition of Commercial Items

Pub.L. 103–355, Title VIII, § 8301(g), Oct. 13, 1994, 108 Stat. 3397, provided that: "The Federal Acquisition Regulation may not contain a requirement for a certification by a contractor under a contract for the acquisition of commercial items, or a requirement that such a contract include a contract clause, in order to implement a prohibition or requirement of section 306 of the Clean Air Act (42 U.S.C. 7606) [this section] or a prohibition or requirement issued in the implementation of that section [this section], since there is nothing in such section 306 [this section] that requires such a certification or contract clause."

§ 7607. Administrative proceedings and judicial review

[CAA § 307]

(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[1] 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),,[2] 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, 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,[2] 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 [3] 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 [4] 7407(d), 7502(a), 7511(a) and (b), and 7512(a) and (b) of this title.

(July 14, 1955, c. 360, Title III, § 307, as added Dec. 31, 1970, Pub.L. 91–604, § 12(a), 84 Stat. 1707, and 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.)

[1] So in original. Probably should be "this".
[2] So in original.
[3] So in original. The word "to" probably should not appear.
[4] So in original. Probably should be "sections".

HISTORICAL AND STATUTORY NOTES

References in Text

Section 7521(b)(5) of this title, referred to in subsec. (b)(1), was repealed by Pub.L. 101–549, Title II, § 203(3), Nov. 15, 1990, 104 Stat. 2529.

Section 1857c–10(c)(2)(A), (B), or (C) of this title (as in effect before August 7, 1977), referred to in subsec. (b)(1), was in the original "section 119(c)(2)(A), (B), or (C) (as in effect before the date of enactment of the Clean Air Act Amendments of 1977)", meaning section 119 of Act July 14, 1955, c. 360, Title I, as added June 22, 1974, Pub.L. 93–319, § 3, 88 Stat. 248, (which was classified to section 1857c–10 of this title) as in effect prior to the enactment of Pub.L. 95–95, Aug. 7, 1977, 91 Stat. 691, effective Aug. 7, 1977. Section 112(b)(1) of Pub.L. 95–95 repealed section 119 of Act July 14, 1955, c. 360, Title I, as added by Pub.L. 93–319, and provided that all references to such section 119 in any subsequent enactment which supersedes Pub.L. 93–319 shall be construed to refer to section 113(d) of the Clean Air Act and to paragraph (5) thereof in particular which is classified to subsec. (d)(5) of section 7413 of this title. Section 7413(d) of this title was subsequently amended generally by Pub.L. 101–549, Title VII, § 701, Nov. 15, 1990, 104 Stat. 2672, and, as so amended, no longer relates to final compliance orders. Section 117(b) of Pub.L. 95–95 added a new section 119 of Act July 14, 1955, which is classified to section 7419 of this title.

Part C of subchapter I of this chapter, referred to in subsec. (d)(1)(J), was in the original "subtitle C of Title I", and was translated as reading "part C of Title I" to reflect the probable intent of Congress, because Title I does not contain subtitles.

Codifications

Section was formerly classified to section 1857h–5 of this title.

In subsec. (h), "subchapter II of chapter 5 of Title 5" was substituted for "the Administrative Procedures Act" on authority of Pub.L. 89–554, § 7(b), Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

Effective and Applicability Provisions

1990 Acts. Amendment by Pub.L. 101–549 effective Nov. 15, 1990, except as otherwise provided, see section 711(b) of Pub.L. 101–549, set out as a note under section 7401 of this title.

1977 Acts. Amendment by Pub.L. 95–95 effective Aug. 7, 1977, except as otherwise expressly provided, see section 406(d) of Pub.L. 95–95, set out as a note under section 7401 of this title.

Savings Provisions

Suits, actions or proceedings commenced under this chapter as in effect prior to Nov. 15, 1990, not to abate by reason of the taking effect of amendments by Pub.L. 101–549, except as otherwise provided for, see section 711(a) of Pub.L. 101–549, set out as a note under section 7401 of this title.

Prior Provisions

A prior section 307 of Act July 14, 1955, c. 360, Title III, as added Nov. 21, 1967, Pub.L. 90–148, § 2, 81 Stat. 506, renumbered section 314, Dec. 31, 1970, Pub.L. 91–604, § 12(a), 84 Stat. 1705, which related to labor standards, is set out as section 7614 of this title.

Another prior section 307 of act July 14, 1955, c. 360, Title III, formerly § 14, as added Dec. 17, 1963, Pub.L. 88–206, § 1, 77 Stat. 401, was renumbered section 307 by Pub.L. 89–272, renumbered section 310 by Pub.L. 90–148, and renumbered section 317 by Pub.L. 91–604, and is set out as a Short Title of 1963 Acts note under section 7401 of this title.

Modification or Rescission of Rules, Regulations, Orders, Determinations Contracts, Certifications, Authorizations, Delegations, and Other Actions

All rules, regulations, orders, determinations, contracts, certifications, authorizations, delegations, or other actions duly issued, made, or taken by or pursuant to Act July 14, 1955, the Clean Air Act, as in effect immediately prior to the date of enactment of Pub.L. 95–95 [Aug. 7, 1977] to continue in full force and effect until modified or rescinded in accordance with Act July 14, 1955, as amended by Pub.L. 95–95 [this chapter], see section 406(b) of Pub.L. 95–95, set out as an Effective Date of 1977 Acts note under section 7401 of this title.

Pending Actions and Proceedings

Suits, actions, and other proceedings lawfully commenced by or against the Administrator or any other officer or employee of the United States in his official capacity or in relation to the discharge of his official duties under Act July 14, 1955, the Clean Air Act, as in effect immediately prior to the enactment of Pub.L. 95–95 [Aug. 7, 1977], not to abate by reason of the taking effect of Pub.L. 95–95, see section 406(a) of Pub.L. 95–95, set out as an Effective Date of 1977 Acts note under section 7401 of this title.

Termination of Advisory Committees

Advisory Committees established after Jan. 5, 1973, to terminate not later than the expiration of the two-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an

officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such two-year period, or in the case of a committee established by the Congress, its duration is otherwise provided for by law, see section 14 of Pub.L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in Appendix 2 to Title 5, Government Organization and Employees.

§ 7608. Mandatory licensing

[CAA § 308]

Whenever the Attorney General determines, upon application of the Administrator—

(1) that—

(A) in the implementation of the requirements of section 7411, 7412, or 7521 of this title, a right under any United States letters patent, which is being used or intended for public or commercial use and not otherwise reasonably available, is necessary to enable any person required to comply with such limitation to so comply, and

(B) there are no reasonable alternative methods to accomplish such purpose, and

(2) that the unavailability of such right may result in a substantial lessening of competition or tendency to create a monopoly in any line of commerce in any section of the country,

the Attorney General may so certify to a district court of the United States, which may issue an order requiring the person who owns such patent to license it on such reasonable terms and conditions as the court, after hearing, may determine. Such certification may be made to the district court for the district in which the person owning the patent resides, does business, or is found.

(July 14, 1955, c. 360, Title III, § 308, as added Dec. 31, 1970, Pub.L. 91–604, § 12(a), 84 Stat. 1708.)

HISTORICAL AND STATUTORY NOTES

Codifications

Section was formerly classified to section 1857h–6 of this title.

Prior Provisions

A prior section 308 of Act July 14, 1955, c. 360, Title III, formerly § 12, as added Dec. 17, 1963, Pub.L. 88–206, § 1, 77 Stat. 401, renumbered § 305, Oct. 20, 1965, Pub.L. 89–272, Title I, § 101(4), 79 Stat. 992, renumbered § 308, Nov. 21, 1967, Pub.L. 90–148, § 2, 81 Stat. 506, renumbered § 315, Dec. 31, 1970, Pub.L. 91–604, § 12(a), 84 Stat. 1705, which related to separability of provisions, is set out as section 7615 of this title.

Modification or Rescission of Rules, Regulations, Orders, Determinations, Contracts, Certifications, Authorizations, Delegations, and Other Actions

All rules, regulations, orders, determinations, contracts, certifications, authorizations, delegations, or other actions duly issued, made, or taken by or pursuant to Act July 14, 1955, the Clean Air Act, as in effect immediately prior to the date of enactment of Pub.L. 95–95 [Aug. 7, 1977] to continue in full force and effect until modified or rescinded in accordance with Act July 14, 1955, as amended by Pub.L. 95–95 [this chapter], see section 406(b) of Pub.L. 95–95, set out as an Effective Date of 1977 Acts note under section 7401 of this title.

§ 7609. Policy review

[CAA § 309]

(a) Environmental impact

The Administrator shall review and comment in writing on the environmental impact of any matter relating to duties and responsibilities granted pursuant to this chapter or other provisions of the authority of the Administrator, contained in any (1) legislation proposed by any Federal department or agency, (2) newly authorized Federal projects for construction and any major Federal agency action (other than a project for construction) to which section 4332(2)(C) of this title applies, and (3) proposed regulations published by any department or agency of the Federal Government. Such written comment shall be made public at the conclusion of any such review.

(b) Unsatisfactory legislation, action, or regulation

In the event the Administrator determines that any such legislation, action, or regulation is unsatisfactory from the standpoint of public health or welfare or environmental quality, he shall publish his determination and the matter shall be referred to the Council on Environmental Quality.

(July 14, 1955, c. 360, Title III, § 309, as added Dec. 31, 1970, Pub.L. 91–604, § 12(a), 84 Stat. 1709.)

HISTORICAL AND STATUTORY NOTES

Codifications

Section was formerly classified to section 1857h–7 of this title.

Prior Provisions

A prior section 309 of Act July 14, 1955, c. 360, Title III, formerly § 13, as added Dec. 17, 1963, Pub.L. 88–206, § 1, 77 Stat. 401, renumbered § 306, Oct. 20, 1965, Pub.L. 89–272, Title I, § 101(4), 79 Stat. 992, renumbered § 309, Nov. 21, 1967, Pub.L. 90–148, § 2, 81 Stat. 506, renumbered § 316, Dec. 31, 1970, Pub.L. 91–604, § 12(a), 84 Stat. 1705, which related to appropriations, was classified to section 1857l of this title and was repealed by section 306 of Pub.L. 95–95. Similar appropriation provisions are now classified to section 7626 of this title.

Modification or Rescission of Rules, Regulations, Orders, Determinations, Contracts, Certifications, Authorizations, Delegations, and Other Actions

All rules, regulations, orders, determinations, contracts, certifications, authorizations, delegations, or other actions duly issued, made, or taken by or pursuant to Act July 14, 1955, the Clean Air Act, as in effect immediately prior to the date of enactment of Pub.L. 95–95 [Aug. 7, 1977] to continue in full force and effect until modified or rescinded in accor-

based upon hourly data that are at least 75 percent complete in each calendar quarter. A 3-hour block average shall be considered valid only if all three hourly averages for the 3-hour period are available. If only one or two hourly averages are available, but the 3-hour average would exceed the level of the standard when zeros are substituted for the missing values, subject to the rounding rule of paragraph (a) of this section, then this shall be considered a valid 3-hour average. In all cases, the 3-hour block average shall be computed as the sum of the hourly averages divided by 3.

[61 FR 25580, May 22, 1996]

§ 50.6 National primary and secondary ambient air quality standards for PM_{10}.

(a) The level of the national primary and secondary 24-hour ambient air quality standards for particulate matter is 150 micrograms per cubic meter ($\mu g/m^3$), 24-hour average concentration. The standards are attained when the expected number of days per calendar year with a 24-hour average concentration above 150 $\mu g/m^3$, as determined in accordance with appendix K to this part, is equal to or less than one.

(b) [Reserved]

(c) For the purpose of determining attainment of the primary and secondary standards, particulate matter shall be measured in the ambient air as PM_{10} (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers) by:

(1) A reference method based on appendix J and designated in accordance with part 53 of this chapter, or

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

[52 FR 24663, July 1, 1987, as amended at 62 FR 38711, July 18, 1997; 65 FR 80779, Dec. 22, 2000; 71 FR 61224, Oct. 17, 2006]

§ 50.7 National primary and secondary ambient air quality standards for $PM_{2.5}$.

(a) The national primary and secondary ambient air quality standards for particulate matter are 15.0 micrograms per cubic meter ($\mu g/m^3$) annual arithmetic mean concentration, and 65 $\mu g/m^3$ 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by either:

(1) A reference method based on appendix L 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 annual primary and secondary $PM_{2.5}$ standards are met when the annual arithmetic mean concentration, as determined in accordance with appendix N of this part, is less than or equal to 15.0 micrograms per cubic meter.

(c) The 24-hour primary and secondary $PM_{2.5}$ standards are met when the 98^{th} percentile 24-hour concentration, as determined in accordance with appendix N of this part, is less than or equal to 65 micrograms per cubic meter.

[62 FR 38711, July 18, 1997, as amended at 69 FR 45595, July 30, 2004]

§ 50.8 National primary ambient air quality standards for carbon monoxide.

(a) The national primary ambient air quality standards for carbon monoxide are:

(1) 9 parts per million (10 milligrams per cubic meter) for an 8-hour average concentration not to be exceeded more than once per year and

(2) 35 parts per million (40 milligrams per cubic meter) for a 1-hour average concentration not to be exceeded more than once per year.

(b) The levels of carbon monoxide in the ambient air shall be measured by:

(1) A reference method based on appendix C and designated in accordance with part 53 of this chapter, or

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

(c) An 8-hour average shall be considered valid if at least 75 percent of the hourly average for the 8-hour period are available. In the event that only six (or seven) hourly averages are available, the 8-hour average shall be computed on the basis of the hours available using six (or seven) as the divisor.

(d) When summarizing data for comparision with the standards, averages shall be stated to one decimal place. Comparison of the data with the levels of the standards in parts per million shall be made in terms of integers with fractional parts of 0.5 or greater rounding up.

[50 FR 37501, Sept. 13, 1985]

§ 50.9 National 1-hour primary and secondary ambient air quality standards for ozone.

(a) The level of the national 1-hour primary and secondary ambient air quality standards for ozone measured by a reference method based on appendix D to this part and designated in accordance with part 53 of this chapter, is 0.12 parts per million (235 $\mu g/m^3$). The standard is attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 parts per million (235 $\mu g/m^3$) is equal to or less than 1, as determined by appendix H to this part.

(b) The 1-hour standards set forth in this section will remain applicable to all areas notwithstanding the promulgation of 8-hour ozone standards under §50.10. The 1-hour NAAQS set forth in paragraph (a) of this section will no longer apply to an area one year after the effective date of the designation of that area for the 8-hour ozone NAAQS pursuant to section 107 of the Clean Air Act. Area designations and classifications with respect to the 1-hour standards are codified in 40 CFR part 81.

(c) EPA's authority under paragraph (b) of this section to determine that the 1-hour standard no longer applies to an area based on a determination that the area has attained the 1-hour standard is stayed until such time as EPA issues a final rule revising or reinstating such authority and considers and addresses in such rulemaking any comments concerning (1) which, if any, implementation activities for a revised ozone standard (including but not limited to designation and classification of areas) would need to occur before EPA would determine that the 1-hour ozone standard no longer applies to an area, and (2) the effect of revising the ozone NAAQS on the existing 1-hour ozone designations.

[62 FR 38894, July 18, 1997, as amended at 65 FR 45200, July 20, 2000; 68 FR 38163, June 26, 2003, 69 FR 23996, Apr. 30, 2004]

§ 50.10 National 8-hour 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, measured by a reference method based on appendix D to this part and designated in accordance with part 53 of this chapter, is 0.08 parts per million (ppm), daily maximum 8-hour average.

(b) The 8-hour primary and secondary ozone ambient air quality standards are met at an ambient air quality monitoring site when the average of the annual fourth-highest daily maximum 8-hour average ozone concentration is less than or equal to 0.08 ppm, as determined in accordance with appendix I to this part.

[62 FR 38894, July 18, 1997]

§ 50.11 National primary and secondary ambient air quality standards for oxides of nitrogen (with nitrogen dioxide as the indicator).

(a) The level of the national primary annual ambient air quality standard for oxides of nitrogen is 53 parts per billion (ppb, which is 1 part in 1,000,000,000), annual average concentration, measured in the ambient air as nitrogen dioxide.

(b) The level of the national primary 1-hour ambient air quality standard for oxides of nitrogen is 100 ppb, 1-hour average concentration, measured in the ambient air as nitrogen dioxide.

(c) The level of the national secondary ambient air quality standard for nitrogen dioxide is 0.053 parts per million (100 micrograms per cubic meter), annual arithmetic mean concentration.

(d) The levels of the standards shall be measured by:

(1) A reference method based on appendix F to this part; or

(2) By a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter.