No. 12-760

In the Supreme Court of the United States

AMERICAN PETROLEUM INSTITUTE, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the Environmental Protection Agency reasonably concluded that a maximum concentration of nitrogen dioxide of 100 parts per billion over a 1-hour period is "requisite to protect the public health," "allowing an adequate margin of safety," within the meaning of the Clean Air Act, 42 U.S.C. 7409(b)(1).

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-23a) is reported at 684 F.3d 1342. The United States Environmental Protection Agency's final rule (Pet. App. 24a-97a, App., *infra*, 1a-60a) is published at 75 Fed. Reg. 6474.

JURISDICTION

The judgment of the court of appeals was entered on July 17, 2012. A petition for rehearing was denied on September 24, 2012 (Pet. App. 98a-101a). The petition for a writ of certiorari was filed on December 21, 2012. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Under the Clean Air Act (CAA or Act), 42 U.S.C. 7401 *et seq.*, the United States Environmental Protection Agency (EPA) has developed a list of pollutants that, *inter alia*, cause or contribute to air pollution that "may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. 7408(a)(1)(A). For each such pollutant, the EPA must promulgate "[n]ational * * * ambient air quality standards" (NAAQS) to protect public health and welfare. 42 U.S.C. 7409(b)(1). The NAAQS process begins with the development of "air quality criteria," which must reflect the latest scientific knowledge on "all identifiable effects on public health or welfare" that may result from a pollutant's presence in the ambient air. 42 U.S.C. 7408(a). As relevant here, the Act directs the EPA to establish "primary" NAAQS, which are "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." 42 U.S.C. 7409(b)(1). States then develop implementation plans to meet those standards. 42 U.S.C. 7407(a), 7410(a)(2)(A) and (C). In establishing the primary standards, the EPA may not consider the financial costs of compliance, see *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 471 (2001), although the EPA and the States do consider such costs in establishing control requirements to achieve the standards.

To ensure that NAAQS will keep pace with advances in scientific knowledge, Congress also required the EPA to review each standard at least once every five years and to revise it as appropriate. 42 U.S.C. 7409(d)(1). In conducting that review, the EPA must consider, and ex-

plain any significant departure from, the recommendations of an independent scientific review committee, known as the Clean Air Scientific Advisory Committee, which was established specifically to advise the agency on air-quality criteria and NAAQS. 42 U.S.C. 7409(d)(2)(B), 7607(d)(3); see *Whitman*, 531 U.S. at 469-470.

2. This case concerns the revised NAAQS for nitrogen dioxide (often referred to by its chemical abbreviation NO_2), which the EPA uses as an indicator for all oxides of nitrogen. Pet. App. 3a. Nitrogen oxides are byproducts of combustion, primarily in automobile and truck engines and electricity-generating plants. *Ibid.* They cause a number of adverse effects on human health, such as respiratory-related hospital admissions. *Ibid.*

a. In 1971, the EPA first established the primary standard for NO_2 at an annual average of 53 parts per billion (ppb). Pet. App. 3a. This annual standard, which is designed to limit *long-term* exposure to oxides of nitrogen, is calculated by a simple arithmetic mean of all 1-hour concentrations of NO_2 measured in a calendar year. See 40 C.F.R. 50.11(a) and (e). The EPA reviewed the standard in 1985 and 1996 and concluded under Section 7409(b)(1) that it remained "requisite to protect the public health" with "an adequate margin of safety." See Pet. App. 31a.

b. In December 2005, the EPA began the latest review of the NO_2 standard. In that review, the agency considered a substantial body of evidence that had emerged since 1996 about the adverse health effects associated with *short-term* exposures to NO_2. See Pet. App. 3a-6a. That evidence consisted in part of epidemiologic studies demonstrating positive associations be-

tween short-term NO_2 concentrations and respiratory symptoms, hospitalizations, and emergency-room visits, including in areas with average annual levels of ambient NO_2 well below the 1971 annual standard of 53 ppb. *Id.* at 4a, 47a. The EPA also considered clinical studies that had documented increases in airway hyperresponsiveness in asthmatics following short-term NO_2 exposures at levels as low as 100 ppb, which was the lowest level studied. See *id.* at 5a, 48a.

Based on its review of the entire body of scientific evidence, the EPA concluded that there was sufficient evidence to infer a likely causal relationship between short-term NO_2 exposures and adverse effects on the respiratory system. Pet. App. 4a-5a, 47a. The Clean Air Scientific Advisory Committee concurred with that conclusion. *Id.* at 7a.

To further analyze the public health risk associated with short-term exposure to NO_2, and to identify an appropriate level for a new standard, the EPA developed a Risk and Exposure Assessment (REA). See Pet. App. 6a, 32a. The REA employed air-quality data from the existing network of ambient monitors, as well as data from the clinical studies and epidemiologic studies, to model exposures to NO_2 and to make quantitative assessments of health risks associated with various scenarios. Specifically, the REA considered (i) an "as-is" scenario in which it estimated the health effects from short-term exposures to NO_2 at actual current air-quality levels, which are lower than what is permitted by the 1971 annual standard; (ii) a "just meets" scenario in which it estimated the health effects if air quality barely satisfied the 1971 standard; and (iii) other scenarios in which it estimated the health effects if air quality barely

satisfied various alternative 1-hour standards. See *id.* at 16a, 59a.

The REA's health-risk estimates were based on actual or modeled ambient concentrations at pre-2010 air-quality monitors. See Pet. App. 59a. Those monitors primarily measure NO_2 concentrations representative of a broad geographic area rather than concentrations at specific locations where the highest levels of NO_2 are likely to be found, such as roads. *Id.* at 42a-43a. But because large segments of the public live, work, or travel on or near roads, the REA also estimated exposures that would occur on or near roads. In that analysis, the REA found that, under the "as is" scenario (*i.e.*, current air-quality levels), individuals on or near roads could expect to suffer short-term exposures at 100 ppb or higher multiple times per year. *Id.* at 6a. That was the level shown to cause airway hyper-responsiveness in the clinical studies.

c. On the basis of the evidence in the record—including the epidemiologic evidence demonstrating a positive relationship between short-term exposures to NO_2 and emergency-room visits at recent air-quality levels, the clinical studies showing airway hyper-responsiveness in asthmatics from short-term exposures to NO_2 at levels as low as 100 ppb, and the REA's analysis of air-quality scenarios with and without a short-term standard—the EPA concluded that the existing NAAQS was not sufficient to protect public health from the effects of short-term exposures to NO_2. See Pet. App. 7a. The agency therefore determined that a new 1-hour standard, in addition to the 1971 annual standard, was necessary to protect the large numbers of people at risk from short-term exposures occurring in areas meeting the current annual standard. It initially proposed a

standard of between 80 and 100 ppb. See *id.* at 7a, 35a. The Clean Air Scientific Advisory Committee concurred in that view and "firmly recommend[ed] that the upper end of the range [of standard levels] not exceed 100 ppb." *Id.* at 81a (second bracket in original); App., *infra*, 54a.

After the EPA published its proposal, some commenters objected to the agency's consideration of air-quality scenarios other than the "as is" scenario—*i.e.*, the scenario in which it is assumed that air-quality levels will remain constant. See Pet. App. 85a-86a. The EPA concluded, however, that it would be inappropriate to "rely only on [current] air quality." *Id.* at 86a. Rather, it stated, "[i]n considering whether the current standard is requisite to protect public health with an adequate margin of safety," it is appropriate to estimate the "exposures and risks that would be permissible under the current standard," as well as under other potential standards. *Ibid.* The agency explained that, although it had not determined that "levels of NO_2 are likely to increase under the current standard or any of the potential alternative standards," estimates of the "exposures and health risks that would be permitted under the current and potential alternative standards * * * can inform decisions on whether the current standard, or particular potential alternative standards, provide the requisite protection of public health." *Id.* at 87a-88a.

After considering the remainder of the comments submitted, and reviewing the record evidence and recommendation of the Clean Air Scientific Advisory Committee, the EPA established a 100 ppb hourly standard for NO_2. See App., *infra*, 54a-56a. That standard is a "peak" standard, rather than an "area-wide" standard, because it must be satisfied at locations that represent

peak concentrations within an area, including on or near roads. An area with an area-wide average concentration of 100 ppb, in other words, would not meet the standard if any individual location within the area exceeded 100 ppb. In fact, because NO_2 concentrations near roads are generally higher than elsewhere, the EPA concluded that the new peak standard will limit area-wide hourly concentrations of NO_2 to approximately 50 to 75 ppb. *Id.* at 53a. That level is below the current levels in locations where key United States epidemiologic studies reported that ambient NO_2 is associated with increases in respiratory-related hospital admissions and emergency room visits. See *id.* at 51a-52a.

Accordingly, the EPA found that the new standard will "provide a significant increase in public health protection compared to that provided by the current annual standard alone and would be expected to protect against the respiratory effects that have been linked with NO_2 exposures in both controlled human exposure and epidemiologic studies." App., *infra*, 54a. The agency therefore concluded that "a standard reflecting the maximum allowable NO_2 concentration anywhere in an area set at 100 ppb is sufficient to protect public health with an adequate margin of safety, including the health of at-risk populations, from adverse respiratory effects that have been linked to short-term exposures to NO_2" and "is neither more nor less stringent than necessary for this purpose." *Id.* at 55a, 56a.

3. Petitioner challenged the rulemaking by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit. The court of appeals denied the petition. The court concluded that petitioner had not shown that the EPA's adoption of the

1-hour NAAQS for NO_2 was arbitrary, capricious, or contrary to the Clean Air Act. Pet. App. 1a-23a.

The court of appeals rejected a number of challenges raised by petitioner, see Pet. App. 8a-16a, but only one is relevant here.[1] Petitioner argued that the EPA had acted arbitrarily in evaluating the proposed standard under a "scenario in which it assumed all areas just meet the current air quality standards." *Id.* at 16a. It emphasized that the EPA had "acknowledged, contrary to this 'just meets' assumption, current air quality is significantly better than what the existing annual NAAQS for NO_2 requires." *Id.* at 16a. Petitioner argued that the EPA therefore "should have measured the likely benefits of the new NAAQS relative to a projection of air quality more accurate than its 'just meets' scenario." *Id.* at 17a. It claimed that a different scenario "would have shown that the one-hour NAAQS was not necessary 'to protect the public health' with 'an adequate margin of safety.'" *Ibid.*

The court of appeals agreed with petitioner that, "as the word 'requisite' in § 109(b)(1) of the Clean Air Act indicates, the EPA is to set a NAAQS that is 'not lower or higher than is necessary . . . to protect the public health.'" Pet. App. 17a (quoting *Whitman*, 531 U.S. at 475-476). The court further explained, however, that because the statute also "enjoins the EPA to set the standard with 'an adequate margin of safety,'" the CAA "con-

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[1] Petitioner obliquely adverts (Pet. 8) to its argument below that "the EPA, by relying upon an internal meta-analysis that was not published, 'did not follow its own requirements . . . that it rely only on peer-reviewed and published studies in reviewing NAAQS.'" Pet. App. 9a (quoting Pet. C.A. Br. 26). The court of appeals rejected that argument as resting in part on a misleading excerpt from EPA policies. *Ibid.*

templates the agency 'should set standards providing 'a reasonable degree of protection . . . against hazards which research has not yet identified.'" *Ibid.* (quoting *Coalition of Battery Recyclers Ass'n* v. *EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010)). Noting the "uncertainty inherent in predicting the future * * * when one is making a projection of air quality," the court held that "it was not unreasonable for the EPA to measure expected benefits from the new NAAQS in part upon the assumption that, if the new NAAQS were not adopted, then each area would in the future just meet the existing standard." *Id.* at 18a.

The court further explained, however, that the EPA had provided sufficient evidence that the new standard would result in a substantial improvement in the public health relative to *current* air-quality levels. Petitioner had argued that the REA had found no benefits from a 100 ppb hourly standard relative to current levels. But, as the court observed, petitioner had "disregard[ed] a critical difference between the hypothetical 100 ppb standard in the REA and the 100 ppb standard the EPA eventually adopted": The promulgated standard was not an "area-wide average," as assumed in the REA, but rather a peak standard that "requires that all [air-quality] monitors in an area be below the 100 ppb level." Pet. App. 18a. The EPA had determined that a "peak hourly concentration of 100 ppb is roughly equivalent to an area-wide hourly average concentration of between 50 and 75 ppb," the court explained, and the REA had projected that an area-wide standard of 50 ppb "would provide a substantial improvement over current air quality." *Id.* at 19a. The court accordingly held that the agency had not acted arbitrarily in promulgating the new standard. See *ibid.*

ARGUMENT

The court of appeals correctly declined to disturb the EPA's determination that a primary peak 1-hour NO_2 standard of 100 ppb is "requisite to protect the public health" with "an adequate margin of safety." 42 U.S.C. 7409(b)(1). Contrary to petitioner's contention, the decision below does not conflict with this Court's construction of the CAA in *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457 (2001). Further review is not warranted.

1. The court of appeals correctly held that the EPA had not acted arbitrarily in examining multiple alternative scenarios, including a scenario in which air-quality levels remain constant and scenarios in which they "just meet" either the current standard or the current standard plus various short-term standards, to evaluate whether the new NO_2 standard was "requisite to protect the public health" with "an adequate margin of safety."

a. The EPA had ample justification for concluding that short-term exposures to NO_2 would produce adverse health effects, and petitioner does not challenge that conclusion here. Clinical studies in the record demonstrated that short-term exposures at 100 ppb cause airway hyper-responsiveness, which can create respiratory problems, particularly in asthmatics. The agency also found that short-term exposures to concentrations of 100 ppb and higher routinely occur at or near roadways under current air-quality conditions. And epidemiologic studies indicated that adverse health effects from short-term exposures to NO_2 are occurring in cities that satisfy the current NO_2 standard.

Petitioner also does not dispute the EPA's conclusion that the actual standard the agency adopted—a 100 ppb *peak* concentration standard—is equivalent to an *area-*

wide concentration standard of 50 to 75 ppb. See Pet. App. 19a, 59a; App., *infra*, 53a. Nor does it contest in this Court that the revised standard will produce significant public health benefits relative to *current* air-quality levels (*i.e.*, the "as is" scenario). See App., *infra*, 54a (finding that new standard will "provide a significant increase in public health protection compared to that provided by the current annual standard alone"). As the court of appeals explained, the REA "projected a new NAAQS of 50 ppb area-wide would provide a substantial improvement over current air quality." Pet. App. 19a. Given those facts, all uncontested here, the EPA reasonably concluded that "a standard reflecting the maximum allowable NO_2 concentration anywhere in an area set at 100 ppb is sufficient to protect public health with an adequate margin of safety, including the health of at-risk populations, from adverse respiratory effects that have been linked to short-term exposures to NO_2" and "is neither more nor less stringent than necessary for this purpose." App., *infra*, at 55a, 56a.

b. Petitioner's sole objection is to the EPA's use of the "just meets" scenario as one of various scenarios under which it considered whether the revised standard would provide benefits to the public health. See Pet. 18. Even if the "just meets" scenario were found to be an irrelevant criterion, however, the EPA's consideration of that factor would not support reversal of the decision below. The court of appeals concluded that the revised standard was independently justified because it will produce significant health benefits relative to *current* air-quality levels. See Pet. App. 18a-19a. Petitioner does not challenge that conclusion in its petition for a writ of certiorari. See Pet. 12-14 (failing to acknowledge that aspect of court of appeals' decision). Petitioner's

attack on the EPA's consideration of the "just meets" scenario, even if it were well-founded, therefore would not support reversal of the judgment below or invalidation of the EPA's rulemaking.

In any event, petitioner identifies no valid objection to the EPA's use of the "just meets" scenario as part of a comprehensive analysis that included a range of scenarios and a wealth of scientific evidence. Contrary to petitioner's assertion, the court of appeals did not "authorize[] EPA to establish a new NAAQS based on a fictional risk." Pet. 18. Rather, the court merely held that "it was not unreasonable for the EPA to measure expected benefits from the new NAAQS *in part* upon the assumption that, if the new NAAQS were not adopted, then each area would in the future just meet the existing standard." Pet. App. 18a (emphasis added). The "just meets" scenario was only one of the air-quality scenarios modeled, and the various air-quality scenarios were only one aspect of a larger body of internally consistent evidence demonstrating that the current annual standard was not sufficient to protect public health and that a short-term peak standard of 100 ppb was required. See *id.* at 93a (explaining that the REA's exposure and risk-based analysis, including the analysis of various air-quality scenarios, "*reinforce*[*d*] the scientific evidence in supporting the conclusion that consideration should be given to revising the current standard") (emphasis added). In evaluating the adequacy of a currently applicable standard and proposed new standards, there is nothing arbitrary (or even novel) about considering events that have not yet occurred but that those standards would allow.

Petitioner's contrary argument rests on a fundamental misunderstanding of what the court of appeals held.

The court did not suggest that a demonstration of benefits under the "just meets" scenario would alone suffice to support the new standard, or that the EPA may set a NAAQS based on a "fictional risk." Pet. 18. It held only that it was not unreasonable to *consider* the benefits under that scenario in conjunction with the benefits under the "as is" scenario and other scenarios examined by the agency. Because the EPA is required under the statute to account for "[t]he uncertainty inherent in predicting the future," the agency could reasonably consider, as part of a broader analysis, the possibility that air quality would deteriorate to the limit permitted under current law. Pet. App. 18a. Consideration of that possibility represented a reasonable exercise of the agency's duty to review all relevant evidence in setting air-quality standards, particularly given that the agency's ultimate determination rested on the health benefits of the new standard in light of *current* air-quality levels.

2. Attempting to frame its essentially factbound objection to the evidence that the EPA considered as a claim of legal error, petitioner argues that the decision below conflicts with this Court's decision in *Whitman*. See Pet. 20-23. That argument reflects a misunderstanding of the analysis and holding of the court of appeals.[2]

In *Whitman*, this Court considered, *inter alia*, whether Section 7409(b)(1) effects an unconstitutional delegation of legislative power to the EPA. See 531 U.S. at 462. In holding that it does not, the Court "interpret[ed] [Section 7409(b)(1)] as requiring the EPA to set air quality standards at the level that is 'requisite'—that

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[2] This Court has recently denied a petition raising a similar argument. See *ASARCO LLC* v. *EPA*, No. 12-510, 2013 WL 215554 (Jan. 22, 2013).

is, not lower or higher than is necessary—to protect the public health with an adequate margin of safety." *Id.* at 475-476. Under that standard, the Court concluded, the "scope of discretion [Section 7409(b)(1)] allows is * * * well within the outer limits of our nondelegation precedents." *Id.* at 474.

The court of appeals correctly articulated and applied the interpretation of the CAA set forth in *Whitman*. See Pet. App. 17a-18a. While acknowledging that the D.C. Circuit "has adhered to [the interpretation articulated in *Whitman*] for over thirty years," Pet. 20, petitioner contends that the decision below suddenly broke from that body of case law by "permit[ting] [the] EPA to go far beyond what is 'necessary' to protect the public health—neutralizing the 'intelligible principle' this Court identified in [*Whitman*] and bringing the Clean Air Act's constitutionality into question anew," Pet. 19.

That is incorrect. The court of appeals did not depart from its consistent understanding of the statute, and it repeated the holding of *Whitman* verbatim. See Pet. App. 17a. Nothing in *Whitman* addresses, much less calls into question, the EPA's authority to examine a range of scenarios in predicting risk. Nor does *Whitman* cast doubt on the actual rationale under which the court of appeals upheld the new NO_2 standard: that, even as measured against current air-quality levels, a peak standard of 100 ppb will have significant health benefits. *Id.* at 19a. That holding, which petitioner does not challenge in this Court, fully satisfies the legal principles set forth in *Whitman*.

3. Petitioner also contends (Pet. 23-26) that the practical importance of the EPA's role in setting air-quality standards makes this case appropriate for further review. The agency's administration of the CAA is surely

critical to the national well-being. For the reasons discussed above, however, there is no sound basis for petitioner's contention that the court of appeals "has now effectively given [the] EPA a free hand to establish whatever NAAQS it pleases." Pet. 24. The EPA and the court below both explicitly recognized the limits that constrain establishment of a NAAQS. The court of appeals did not commit any legal error or announce any new legal rule of broad continuing importance. And the fact that the challenged EPA rulemaking will impose economic costs does not call for further review, particularly in light of this Court's holding in *Whitman* that Section 7409(b) "unambiguously bars cost considerations from the NAAQS-setting process." 531 U.S. at 471.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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FEBRUARY 2013

APPENDIX

75 Fed. Reg. 6474 provides:

* * * * *

F. Elements of a New Short-Term Standard

In considering a revised NO_2 primary NAAQS, the Administrator notes the need to protect at-risk individuals from short-term exposures to NO_2 air quality that could cause the types of respiratory morbidity effects reported in epidemiologic studies and the need to protect at-risk individuals from short-term exposure to NO_2 concentrations reported in controlled human exposure studies to increase airway responsiveness in asthmatics. The Administrator's considerations with regard to her decisions are discussed in the following sections in terms of indicator (II.F.1), averaging time (II.F.2), level (II.F.3), and form (II.F.4).

1. Indicator

a. Rationale for Proposed Decision

In past reviews, EPA has focused on NO_2 as the most appropriate indicator for ambient NO_X. In making a decision in the current review on the most appropriate indicator, the Administrator considered the conclusions of the ISA and the policy assessment chapter of the REA as well as the view expressed by CASAC. The policy assessment chapter of the REA noted that, while the presence of NO_X species other than NO_2 has been recognized, no alternative to NO_2 has been advanced as being a more appropriate surrogate. Controlled human exposure studies and animal toxicology studies assessed in the ISA provide specific evidence

for health effects following exposure to NO_2. Epidemiologic studies also typically report levels of NO_2 though the degree to which monitored NO_2 reflects actual NO_2 levels, as opposed to NO_2 plus other gaseous NO_X, can vary (REA, section 2.2.3). In addition, because emissions that lead to the formation of NO_2 generally also lead to the formation of other NO_X oxidation products, measures leading to reductions in population exposures to NO_2 can generally be expected to lead to reductions in population exposures to other gaseous NO_X. Therefore, an NO_2 standard can also be expected to provide some degree of protection against potential health effects that may be independently associated with other gaseous NO_X even though such effects are not discernable from currently available studies indexed by NO_2 alone. Given these key points, the policy assessment chapter of the REA concluded that the evidence supports retaining NO_2 as the indicator. Consistent with this conclusion, the CASAC Panel stated in its letter to the EPA Administrator that it "concurs with retention of NO_2 as the indicator" (Samet, 2008b). In light of the above considerations, the Administrator proposed to retain NO_2 as the indicator in the current review.

b. Comments on Indicator

A relatively small number of comments directly addressed the issue of the indicator for the standard (CASAC, Dow, API, AAM, and the Missouri Department of Natural Resources Air Pollution Control Program (MODNR)). All of these commenters endorsed the proposal to continue to use NO_2 as the indicator for ambient NO_X.

c. Conclusions on Indicator

Based on the available information discussed above, and consistent with the views of CASAC and other commenters, the Administrator concludes that it is appropriate to continue to use NO_2 as the indicator for a standard that is intended to address effects associated with exposure to NO_2, alone or in combination with other gaseous NO_X. In so doing, the Administrator recognizes that measures leading to reductions in population exposures to NO_2 will also reduce exposures to other nitrogen oxides.

2. Averaging Time

This section discusses considerations related to the averaging time of the NO_2 primary NAAQS. Specifically, this section summarizes the rationale for the Administrator's proposed decision regarding averaging time (II.F.2.a; *see* section II.F.2 of the proposal for more detail), discusses comments related to averaging time (II.F.2.b), and presents the Administrator's final conclusions regarding averaging time (II.F.2.c).

a. Rationale for Proposed Decision

In considering the most appropriate averaging time for the NO_2 primary NAAQS, the Administrator noted in the proposal the conclusions and judgments made in the ISA about available scientific evidence, air quality correlations discussed in the REA, conclusions of the policy assessment chapter of the REA, and CASAC recommendations (section II.F.2 in the proposal). Specifically, she noted the following:

• Experimental studies in humans and animals have reported respiratory effects following NO_2 exposures

lasting from less than 1-hour up to several hours. Epidemiologic studies have reported associations between respiratory effects and both 1 hour and 24-hour NO_2 concentrations. Therefore, the experimental evidence provides support for an averaging time of shorter duration than 24 hours (*e.g.*, 1 hour) while the epidemiologic evidence provides support for both 1-hour and 24-hour averaging times. At a minimum, this suggests that a primary concern with regard to averaging time is the level of protection provided against 1-hour NO_2 concentrations.

• Air quality correlations presented in the policy assessment chapter of the REA illustrated the relatively high degree of variability in the ratios of annual average to short-term NO_2 concentrations (REA, Table 10–2). This variability suggests that a standard based on annual average NO_2 concentrations would not likely be an effective or efficient approach to focus protection on short-term exposures.

• These air quality correlations (REA, Table 10-1) suggested that a standard based on 1-hour daily maximum NO_2 concentrations could also be effective at protecting against 24-hour NO_2 concentrations.

• The policy assessment chapter of the REA concluded that the scientific evidence, combined with the air quality correlations, support the appropriateness of a standard based on 1-hour daily maximum NO_2 concentrations to protect against health effects associated with short-term exposures.

• CASAC concurred "with having a short-term NAAQS primary standard for oxides of nitrogen and

using the onehour maximum NO_2 value" (Samet, 2008b).

Based on these considerations, the Administrator proposed to set a new standard based on 1-hour daily maximum NO_2 concentrations.

b. Comments on averaging time

As discussed above, CASAC endorsed the establishment of a new standard with a 1-hour averaging time. CASAC stated the following in their comments on the proposal (Samet, 2009):

> In reviewing the REA, CASAC supported a short-term standard for NO_2 and in reviewing the proposal, CASAC supports the proposed one-hour averaging time in EPA's proposed rule.
>
> The supporting rationale offered by CASAC in support of a new 1-hour standard was generally the same as that put forward in the final REA and the proposal. Specifically, that rationale considered the available scientific evidence, which supports a link between 1-hour NO_2 concentrations and adverse respiratory effects, and air quality information presented in the REA, which suggests that a 1-hour standard can protect against effects linked to short-term NO_2 exposures while an annual standard would not be an effective or efficient approach to protecting against these effects.

A large number of public commenters also endorsed the establishment of a new standard with a 1-hour averaging time. These included a number of State agencies and organizations (*e.g.,* NACAA, NESCAUM and agencies in CA, IL, NM, TX, VA); environmental,

medical, and public health organizations (*e.g.,* ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC); and most individual commenters. The supporting rationales offered by these commenters often acknowledged the recommendations of CASAC and the Administrator's rationale as discussed in the proposal.

Though many industry commenters recommended not revising the current annual standard (as discussed above in section II.E.2), several of these groups did conclude that if a short-term standard were to be set, a 1-hour averaging time would be appropriate (*e.g.,* Colorado Petroleum Association (CPA), Dow, NAM, Petroleum Association of Wyoming (PAW), Utah Petroleum Association (UPA)). As discussed above, industry commenters who disagreed with setting a new 1-hour standard generally based this conclusion on their interpretation of the scientific evidence and their conclusion that this evidence does not support the need to revise the current annual standard. These comments, and EPA's responses, are discussed in more detail above (section II.E) and in the Response to Comments document.

c. Conclusions on Averaging Time

In considering the most appropriate averaging time for the NO_2 primary NAAQS, the Administrator notes the available scientific evidence as assessed in the ISA, the air quality analyses presented in the REA, the conclusions of the policy assessment chapter of the REA, CASAC recommendations, and public comments received. These considerations are described below.

When considering averaging time, the Administrator notes that the evidence relating short-term (minutes to hours) NO_2 exposures to respiratory morbidity was judged in the ISA to be "sufficient to infer a likely causal relationship" (ISA, section 5.3.2.1) while the evidence relating long-term (weeks to years) NO_2 exposures to adverse health effects was judged to be either "suggestive but not sufficient to infer a causal relationship" (respiratory morbidity) or "inadequate to infer the presence or absence of a causal relationship" (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4-5.3.2.6). Thus, the Administrator concludes that these judgments most directly support an averaging time that focuses protection on short-term exposures to NO_2.

As in past reviews of the NO_2 NAAQS, the Administrator notes that it is instructive to evaluate the potential for a standard based on annual average NO_2 concentrations, as is the current standard, to provide protection against short-term NO_2 exposures. To this end, the Administrator notes that Table 10-1 in the REA reported the ratios of short-term to annual average NO_2 concentrations. Ratios of 1-hour daily maximum concentrations (98th and 99th percentile[11])

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[11] As discussed below, 98th and 99th percentile forms were evaluated in the REA. A 99th percentile form corresponds approximately to the 4th highest 1-hour concentration in a year while a 98th percentile form corresponds approximately to the 7th or 8th highest 1-hour concentration in a year. A 4th highest concentration form has been used previously in the O_3 NAAQS while a 98th percentile form has been used previously in the $PM_{2.5}$ NAAQS.

to annual average concentrations across 14 locations ranged from 2.5 to 8.7 while ratios of 24-hour average concentrations to annual average concentrations ranged from 1.6 to 3.8 (*see* Thompson, 2008 for more details). The policy assessment chapter of the REA concluded that the variability in these ratios across locations, particularly those for 1-hour concentrations, suggested that a standard based on annual average NO_2 concentrations would not likely be an effective or efficient approach to focus protection on short-term NO_2 exposures. For example, in an area with a relatively high ratio (*e.g.,* 8), the current annual standard (53 ppb) would be expected to allow 1-hour daily maximum NO_2 concentrations of about 400 ppb. In contrast, in an area with a relatively low ratio (*e.g.,* 3), the current standard would be expected to allow 1-hour daily maximum NO_2 concentrations of about 150 ppb. Thus, for purposes of protecting against the range of 1-hour NO_2 exposures, the REA noted that a standard based on annual average concentrations would likely require more control than necessary in some areas and less control than necessary in others, depending on the standard level selected.

In considering the level of support available for specific short-term averaging times, the Administrator notes that the policy assessment chapter of the REA considered evidence from both experimental and epidemiologic studies. Controlled human exposure studies and animal toxicological studies provide evidence that NO_2 exposures from less than 1-hour up to 3-hours can result in respiratory effects such as increased airway responsiveness and inflammation (ISA, section 5.3.2.7). Specifically, the ISA concluded that

NO_2 exposures of 100 ppb for 1-hour (or 200 ppb to 300 ppb for 30-min) can result in small but significant increases in nonspecific airway responsiveness (ISA, section 5.3.2.1). In contrast, the epidemiologic literature provides support for short-term averaging times ranging from approximately 1-hour up to 24-hours (ISA, section 5.3.2.7). A number of epidemiologic studies have detected positive associations between respiratory morbidity and 1-hour (daily maximum) and/or 24-hour NO_2 concentrations. A few epidemiologic studies have considered both 1-hour and 24-hour averaging times, allowing comparisons to be made. The ISA reported that such comparisons in studies that evaluate asthma emergency department visits failed to reveal differences between effect estimates based on a 1-hour averaging time and those based on a 24-hour averaging time (ISA, section 5.3.2.7). Therefore, the ISA concluded that it is not possible, from the available epidemiologic evidence, to discern whether effects observed are attributable to average daily (or multiday) concentrations (24-hour average) or high, peak exposures (1-hour maximum) (ISA, section 5.3.2.7).

As noted in the policy assessment chapter of the REA, given the above conclusions, the experimental evidence provides support for an averaging time of shorter duration than 24 hours (*e.g.,* 1-h) while the epidemiologic evidence provides support for both 1-hour and 24-hour averaging times. The Administrator concludes that, at a minimum, this suggests that a primary concern with regard to averaging time is the level of protection provided against 1-hour NO_2 concentrations. However, she also notes that it is im-

portant to consider the ability of a 1-hour averaging time to protect against 24-hour average NO_2 concentrations. To this end, the Administrator notes that Table 10-2 in the REA presented correlations between 1-hour daily maximum NO_2 concentrations and 24-hour average NO_2 concentrations (98th and 99th percentile) across 14 locations (*see* Thompson, 2008 for more detail). Typical ratios ranged from 1.5 to 2.0, though one ratio (Las Vegas) was 3.1. These ratios were far less variable than those discussed above for annual average concentrations, suggesting that a standard based on 1-hour daily maximum NO_2 concentrations could also be effective at protecting against 24-hour NO_2 concentrations. The REA concluded that the scientific evidence, combined with the air quality correlations described above, support the appropriateness of a standard based on 1-hour daily maximum NO_2 concentrations to protect against health effects associated with short-term exposures.

Based on these considerations, the Administrator concludes that a standard with a 1-hour averaging time can effectively limit short-term (*i.e.*, 1- to 24-hours) exposures that have been linked to adverse respiratory effects. This conclusion is based on the observations summarized above and in more detail in the proposal, particularly that: (1) The 1-hour averaging time has been directly associated with respiratory effects in both epidemiologic and experimental studies and that (2) results from air quality analyses suggest that a 1-hour standard could also effectively control 24-hour NO_2 concentrations. In addition, the Administrator notes the support provided for a 1-hour averaging time in comments from CASAC, States, environmental

groups, and medical/public health groups. The Administrator notes that arguments offered by some industry groups against setting a 1-hour NO_2 standard generally focus on commenters' conclusions regarding uncertainties in the scientific evidence. As discussed in more detail above (section II.E.2), the Administrator disagrees with the conclusions of these commenters regarding the appropriate interpretation of the scientific evidence and associated uncertainties. Given these considerations, the Administrator judges that it is appropriate to set a new NO_2 standard with a 1-hour averaging time.

3. Form

This section discusses considerations related to the form of the 1-hour NO_2 primary NAAQS. Specifically, this section summarizes the rationale for the Administrator's proposed decision regarding form (II.F.4.a; *see* section II.F.3 of the proposal for more detail), discusses comments related to form (II.F.4.b), and presents the Administrator's final conclusions regarding form (II.F.4.c).

a. Rationale For Proposed Decision

When considering alternative forms in the proposal, the Administrator noted the conclusions in the policy assessment chapter of the REA. Specifically, she noted the conclusion that the adequacy of the public health protection provided by the combination of standard level and form should be the foremost consideration. With regard to this, she noted that concentration-based forms can better reflect pollutant-associated health risks than forms based on expected exceedances. This is the case because concentration-

based forms give proportionally greater weight to years when pollutant concentrations are well above the level of the standard than to years when the concentrations are just above the standard, while an expected exceedance form would give the same weight to years with concentrations that just exceed the standard as to years when concentrations greatly exceed the standard. The Administrator also recognized the conclusion in the policy assessment chapter of the REA that it is desirable from a public health perspective to have a form that is reasonably stable and insulated from the impacts of extreme meteorological events. With regard to this, she noted that a form that calls for averaging concentrations over three years would provide greater regulatory stability than a form based on a single year of concentrations. Therefore, consistent with recent reviews of the O_3 and PM NAAQS, the proposal focused on concentration-based forms averaged over 3 years, as evaluated in the REA.

In considering specific concentration-based forms, the REA focused on 98th and 99th percentile concentrations averaged over 3 years. This focus on the upper percentiles of the distribution is appropriate given the reliance, in part, on NO_2 health evidence from experimental studies, which provide information on specific exposure concentrations that are linked to specific health effects. The REA noted that a 99th percentile form for a 1-hour daily maximum standard would correspond approximately to the 4th highest daily maximum concentration in a year (which is the form of the current O_3 NAAQS) while a 98th percentile form (which is the form of the current short-term $PM_{2.5}$ NAAQS) would correspond approximately to the 7th or

8th highest daily maximum concentration in a year (REA, Table 10-4; *see* Thompson, 2008 for methods).

Consideration in the REA of an appropriate form for a 1-hour standard was based on analyses of standard levels that reflected the allowable area-wide NO_2 concentration, not the maximum allowable concentration. Therefore, in their review of the final REA, CASAC did not have the opportunity to comment on the appropriateness of specific forms in conjunction with a standard level that reflects the maximum allowable NO_2 concentration anywhere in an area. Given this, when considering alternative forms for the 1-hour standard in the proposal, the Administrator judged that it was appropriate to consider both forms evaluated in the REA (*i.e.*, 98th and 99th percentiles). Therefore, she proposed to adopt either a 99th percentile or a 4th highest form, averaged over 3 years, and she solicited comment on both 98th percentile and 7th or 8th highest forms.

b. CASAC and Public Comments on Form

In their letter to the Administrator, CASAC discussed the issue of form within the context of the proposed approach of setting a 1-hour standard level that reflects the maximum allowable NO_2 concentration anywhere in an area. CASAC recommended that, for such a standard, EPA adopt a form based on the 3-year average of the 98th percentile of the distribution of 1-hour daily maximum NO_2 concentrations. Specifically, they stated the following in their comments on the proposal (Samet, 2009):

> The 98th percentile is preferred by CASAC for the form, given the likely instability of measurements

at the upper range and the absence of data from the proposed two-tier approach.

As indicated in their letter, CASAC concluded that the potential instability in higher percentile NO_2 concentrations near major roads argues for a 98th, rather than a 99th, percentile form. Several State organizations and agencies (*e.g.,* NESCAUM and agencies in IN, NC, SD, VA) and industry groups (*e.g.,* AAM, ACC, API, AirQuality Research and Logistics (AQRL), CPA, Dow, ExxonMobil, IPAMS, PAW, UPA) also recommended a 98th percentile form in order to provide regulatory stability. In contrast, a small number of State and local agencies (*e.g.,* in MO and TX), several environmental organizations (*e.g.,* EDF, EJ, GASP, NRDC), and medical/public health organizations (*e.g.,* ALA, ATS) recommended either a 99th percentile form or a more stringent form (*e.g.,* no exceedance) to further limit the occurrence of NO_2 concentrations that exceed the standard level in locations that attain the standard.

c. Conclusions On Form

The Administrator recognizes that there is not a clear health basis for selecting one specific form over another. She also recognizes that the analyses of different forms in the REA are most directly relevant to a standard that reflects NO_2 concentrations permitted to occur broadly across a community, rather than the maximum concentration that can occur anywhere in the area. In contrast, as discussed below (section II.F.4.c), the Administrator has judged it appropriate to set a new 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an

area. In light of this, the Administrator places particular emphasis on the comments received on form from CASAC relating to a 1-hour standard level that reflects the maximum allowable NO_2 concentration anywhere in an area. In particular, the Administrator notes that CASAC recommended a 98th percentile form averaged over 3 years for such a standard, given the potential for instability in the higher percentile concentrations around major roadways.

In considering this recommendation, the Administrator recognizes that the public health protection provided by the 1-hour NO_2 standard is based on the approach used to set the standard and the level of the standard (*see* below), in conjunction with the form of the standard. Given that the Administrator is setting a standard that reflects the maximum allowable NO_2 concentration anywhere in an area, rather than a standard that reflects the allowable area-wide NO_2 concentration, she agrees with CASAC that an appropriate consideration with regard to form is the extent to which specific statistics could be unstable at locations where maximum NO_2 concentrations are expected, such as near major roads. When considering alternative forms for the standard, the Administrator notes that an unstable form could result in areas shifting in and out of attainment, potentially disrupting ongoing air quality planning without achieving public health goals. Given the limited available information on the variability in peak NO_2 concentrations near important sources of NO_2 such as major roadways, and given the recommendation from CASAC that the potential for instability in the 99th percentile concentration is cause for supporting a 98th

percentile form, the Administrator judges it appropriate to set the form based on the 3-year average of the 98th percentile of the annual distribution of 1-hour daily maximum NO_2 concentrations.

4. Level

As discussed below and in more detail in the proposal (section II.F.4), the Administrator has considered two different approaches to setting the 1-hour NO_2 primary NAAQS. In the proposal, each of these approaches was linked with a different range of standard levels. Specifically, the Administrator proposed to set a 1-hour standard reflecting the maximum allowable NO_2 concentration anywhere in an area and to set the level of such a standard from 80 to 100 ppb. The Administrator also solicited comment on the alternative approach of setting a standard that reflects the allowable area-wide NO_2 concentration and setting the standard level from 50 to 75 ppb. This section summarizes the rationale for the Administrator's proposed approach and range of standard levels (II.F.3.a), describes the alternative approach and range of standard levels (II.F.3.b), discusses comments related to each approach and range of standard levels (II.F.3.c), and presents the Administrator's final conclusions regarding the approach and level (II.F.3.d).

a. Rationale For Proposed Decisions on Approach and Level

In assessing the most appropriate approach to setting the 1-hour standard and the most appropriate range of standard levels to propose, the Administrator considered the broad body of scientific evidence assessed in the ISA, including epidemiologic and con-

trolled human exposure studies, as well as the results of exposure/risk analyses presented in the REA. In light of the body of available evidence and analyses, as described above, the Administrator concluded in the proposal that it is necessary to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects linked with short-term (*i.e.,* 30 minutes to 24 hours) exposures to NO_2. Such health effects have been associated with exposure to the distribution of short-term ambient NO_2 concentrations across an area, including higher short-term (*i.e.,* peak) exposure concentrations, such as those that can occur on or near major roadways and near other sources of NO_2, as well as the lower short-term exposure concentrations that can occur in areas not near major roadways or other sources of NO_2. The Administrator's proposed decisions on approach and level, as discussed in detail in the proposal (section II.F.4), are outlined below.

In considering a standard-setting approach, the Administrator was mindful in the proposal that the available evidence and analyses from the ISA and REA support the public health importance of roadway-associated NO_2 exposures. The exposure assessment described in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO_2 concentrations (REA, Figures 8-17, 8-18). The ISA concluded (section 4.3.6) that NO_2 concentrations in heavy traffic or on freeways "can be twice the residential outdoor or residential/arterial road level." In considering the potential variability in the NO_2 concentration gradient, the proposal noted that available monitoring studies suggest that

NO_2 concentrations could be 30 to 100% higher than those in the same area but away from the road.[12]

The Administrator also considered that millions of people in the United States live, work, and/or attend school near important sources of NO_2 such as major roadways (ISA, section 4.4), and that ambient NO_2 concentrations in these locations vary depending on the distance from major roads (*i.e.,* the closer to a major road, the higher the NO_2 concentration) (ISA, section 2.5.4). Therefore, these populations, which likely include a disproportionate number of individuals in groups with higher prevalence of asthma and higher hospitalization rates for asthma (*e.g.* ethnic or racial minorities and individuals of low socioeconomic status) (ISA, section 4.4), are likely exposed to NO_2 concentrations that are higher than those occurring away from major roadways.

Given the above considerations, the Administrator proposed an approach to setting the 1-hour NO_2 primary NAAQS whereby the standard would reflect the maximum allowable NO_2 concentration anywhere in an area. In many locations, this concentration is likely to occur on or near a major roadway. EPA proposed to set the level of the standard such that, when availa-

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[12] In addition, the air quality analyses presented in the REA estimated that on-road NO_2 concentrations are about 80% higher on average than concentrations away from the road (REA, section 7.3.2) and that NO_2 monitors within 20 mof roads measure NO_2 concentrations that are, on average across locations, 40% higher than concentrations measured by monitors at least 100 m from the road (REA, compare Tables 7-11 and 7-13).

ble information regarding the concentration gradient around roads is considered, appropriate public health protection would be provided by limiting the higher short-term peak exposure concentrations expected to occur on and near major roadways, as well as the lower short-term exposure concentrations expected to occur away from those roadways. The Administrator concluded that this approach to setting the 1-hour NO_2 NAAQS would be expected to protect public health against exposure to the distribution of short-term NO_2 concentrations across an area and would provide a relatively high degree of confidence regarding the protection provided against peak exposures to higher NO_2 concentrations, such as those that can occur around major roadways. The remainder of this section discusses the proposed range of standard levels.

In considering the appropriate range of levels to propose for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area, the Administrator considered the broad body of scientific evidence and exposure/risk information as well as available information on the relationship between NO_2 concentrations near roads and those away from roads. Specifically, she considered the extent to which a variety of levels would be expected to protect at-risk individuals against increased airway responsiveness, respiratory symptoms, and respiratory-related emergency department visits and hospital admissions.

After considering the scientific evidence and the exposure/risk information (*see* sections II.B, II.C, and II.F.4.a.1 through II.F.4.a.3 in the proposal), as well as the available information on the NO_2 concentration

gradient around roadways (section II.A.2 above and in the proposal), the Administrator concluded that the strongest support is for a standard level at or somewhat below 100 ppb. The Administrator's rationale in reaching this proposed conclusion is provided below.

The Administrator noted that a standard level at or somewhat below 100 ppb in conjunction with the proposed approach would be expected to limit short-term NO_2 exposures to concentrations that have been reported to increase airway responsiveness in asthmatics (*i.e.*, at or above 100 ppb). While she acknowledged that exposure to NO_2 concentrations below 100 ppb could potentially increase airway responsiveness in some asthmatics, the Administrator also noted uncertainties regarding the magnitude and the clinical significance of the NO_2-induced increase in airway responsiveness, as discussed in the policy assessment chapter of the REA (section 10.3.2.1, discussed in section II.F.4.e in the proposal). Given these uncertainties, the Administrator concluded in the proposal that controlled human exposure studies provide support for limiting exposures at or somewhat below 100 ppb NO_2.

The Administrator also noted that a standard level at or somewhat below 100 ppb in conjunction with the proposed approach would be expected to maintain peak area-wide NO_2 concentrations considerably below those measured in locations where key U.S. epidemiologic studies have reported associations with more serious respiratory effects, as indicated by increased emergency department visits and hospital admissions. Specifically, the Administrator noted that 5 key U.S.

studies provide evidence for such associations in locations where the 99th percentile of the distribution of 1-hour daily maximum NO_2 concentrations measured at area-wide monitors ranged from 93 to 112 ppb (Ito *et al.,* 2007; Jaffe *et al.,* 2003; Peel *et al.,* 2005; Tolbert *et al.,* 2007; and a study by the New York State Department of Health, 2006).[13] The Administrator concluded that these studies provide support for a 1-hour standard that limits the 99th percentile of the distribution of 1-hour daily maximum area-wide NO_2 concentrations to below 90 ppb (corresponds to a 98th percentile concentration of 85 ppb), and that limiting area-wide concentrations to considerably below 90 ppb would be appropriate in order to provide an adequate margin of safety. The Administrator noted that, based on available information about the NO_2 concentration gradient around roads, a standard level at or somewhat below 100 ppb set in conjunction with the proposed approach would be expected to accomplish this. Specifically, she noted that given available information regarding NO_2 concentration gradients around roads (*see* section II.A.2), a standard level at or below 100 ppb (with either a 99th or 98th percentile form) would be expected to limit peak area-wide NO_2 concentrations to approximately 75 ppb or below.[14]

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[13] The 98th percentile concentrations in these study locations ranged from 85 to 94 ppb.

[14] For a standard of 100 ppb, area-wide concentrations would be expected to range from approximately 50 ppb (assuming near-road concentrations are 100% higher than area-wide concentrations) to 75 ppb (assuming near-road concentrations are 30% higher than area-wide concentrations).

Therefore, the Administrator concluded that a standard level at or somewhat below 100 ppb under the proposed approach would be expected to maintain peak area-wide NO_2 concentrations well below 90 ppb across locations despite the expected variation in the NO_2 concentration gradient that can exist around roadways in different locations and over time.

The Administrator also noted that a study by Delfino provides mixed evidence for effects in a location with area-wide 98th and 99th percentile 1-hour daily maximum NO_2 concentrations of 50 and 53 ppb, respectively. In that study, NO_2 effect estimates were positive, but some reported 95% confidence limits for the odds ratio (OR) that included values less than 1.00. Given the mixed results of the Delfino study, the Administrator concluded that it may not be necessary to maintain area-wide NO_2 concentrations at or below 50 ppb to provide protection against the effects reported in epidemiologic studies.

In addition to these evidence-based considerations, the Administrator noted that a standard level at or somewhat below 100 ppb under the proposed approach would be consistent with the results of the exposure and risk analyses presented in the REA. As discussed in section II.C of the proposal, the results of these analyses provide support for setting a standard that limits 1-hour area-wide NO_2 concentrations to between 50 and 100 ppb. As described above, a standard level of 100 ppb that reflects the maximum allowable NO_2 concentration would be expected to maintain area-wide NO_2 concentrations at or below approximately 75 ppb. Given all of these considera-

tions, the Administrator concluded in the proposal that a standard level at or somewhat below 100 ppb (with a 99th percentile form), in conjunction with the proposed approach, would be requisite to protect public health with an adequate margin of safety against the array of NO_2-associated health effects.

In addition to the considerations discussed above, which support setting a standard level at or somewhat below 100 ppb, the Administrator also considered the extent to which available evidence could support standard levels below 100 ppb. The Administrator concluded that the evidence could support setting the standard level below 100 ppb to the extent the following were emphasized:

- The possibility that an NO_2-induced increase in airway responsiveness could occur in asthmatics following exposures to concentrations below 100 ppb and/or the possibility that such an increase could be clinically significant.

- The mixed results reported in the study by Delfino *et al.* (2002) of an association between respiratory symptoms and the relatively low ambient NO_2 concentrations measured in the study area.

Specifically, she noted that a standard level of 80 ppb (99th percentile form), in conjunction with the proposed approach, could limit area-wide NO_2 concentrations to 50 ppb[15]and would be expected to limit expos-

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[15] This conclusion assumes that near-road NO_2 concentrations are 65% higher than area-wide concentrations, reflecting the mid-point in the range of 30 to 100%. Based on available information suggesting that near-road concentrations can be 30 to 100%

ure concentrations to below those that have been reported to increase airway responsiveness in asthmatics. For the reasons stated above, the Administrator proposed to set the level of a new 1-hour standard between 80 ppb and 100 ppb.

b. Rationale for the Alternative Approach and Range of Levels

As described above, the Administrator proposed to set a 1-hour NO_2 NAAQS reflecting the maximum allowable NO_2 concentration anywhere in an area and to set the level of such a standard from 80 to 100 ppb. However, prior to the proposal, the approach of setting a 1-hour NO_2 NAAQS that reflects the maximum allowable NO_2 concentration anywhere in an area had not been discussed by EPA in the REA or considered by CASAC. Rather, the potential alternative standards discussed in the REA, and reviewed by CASAC, reflected allowable area-wide NO_2 concentrations (*i.e.*, concentrations that occur broadly across communities).

Given this, the Administrator noted in the proposal that comments received on the approach to setting the 1-hour standard (*i.e.*, from CASAC and from members of the public) could provide important new information for consideration. Therefore, the Administrator also solicited comment on the alternative approach of setting a 1-hour NO_2 primary NAAQS that would reflect the allowable area-wide NO_2 concentration, analogous

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higher than area-wide concentrations, a standard level of 80 ppb could limit area-wide concentrations to between 40 and 60 ppb.

to the standards evaluated in the REA, and with a level set within the range of 50 to 75 ppb. In discussing this alternative approach with a standard level from 50 to 75 ppb, the Administrator noted the following in the proposal:

• Such a standard would be expected to maintain area-wide NO_2 concentrations below peak 1-hour area-wide concentrations measured in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions.

• Standard levels from the lower end of the range would be expected to limit roadway-associated exposures to NO_2 concentrations that have been reported in controlled human exposure studies to increase airway responsiveness in asthmatics. Specifically, a standard level of 50 ppb under this approach could limit near-road concentrations to between approximately 65 and 100 ppb, depending on the relationship between near-road NO_2 concentrations and area-wide concentrations.

• This alternative approach would provide relatively more confidence regarding the degree to which a specific standard level would limit area-wide NO_2 concentrations and less confidence regarding the degree to which a specific standard level would limit the peak NO_2 concentrations likely to occur near major roadways.

c. Comments on Approach and Level

In the proposal, each approach to setting the 1-hour standard, and each range of standard levels, was

linked to different requirements for the design of the NO_2 monitoring network. Specifically, in conjunction with the proposed approach (*i.e.,* standard reflects the maximum allowable NO_2 concentration anywhere in an area and the level is set within the range of 80 to 100 ppb), the Administrator proposed to establish a 2-tiered monitoring network that would include monitors sited to measure the maximum NO_2 concentrations anywhere in an area, including near major roadways, and monitors sited to measure maximum area-wide NO_2 concentrations. In conjunction with the alternative approach (*i.e.,* standard reflects the allowable area-wide NO_2 concentration and the level is set within the range of 50 to 75 ppb), the Administrator solicited comment on a monitoring network that would only include area-wide NO_2 monitors. Because of these linkages in the proposal, most commenters combined their comments on the approach to setting a 1-hour standard and on the standard level with their comments on the monitoring requirements. In this section, we discuss comments from CASAC and public commenters on the approach to setting a 1-hour standard and on the standard level. Comments on the monitoring network are also discussed in this section to the extent they indicate a preference for either the proposed or alternative approach to setting the 1-hour standard. More specific comments on monitor placement and network design are discussed below in section III.B.2 and in the Response to Comments document. EPA responses to technical comments on the scientific evidence and the exposure/response information are discussed above in section II.E.2 and in the Response to Comments document. The Ad-

ministrator's response to commenters' views on the approach to setting the 1-hour standard and on the standard level is embodied in the discussed in section II.F.4.d.

i. CASAC Comments on the Approach to Setting the Standard

A majority of CASAC and CASAC Panel members[16] favored the proposed approach of setting a 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area and linking such a standard with a 2-tiered monitoring network that would include both near-road and area-wide monitors, though CASAC did not reach consensus on this approach. Specifically, in their letter to the Administrator (Samet, 2009), CASAC stated the following:

> There was a split view on the two approaches among both CASAC and CASAC panel members with a majority of each favoring the Agency's proposed two-tiered monitoring network because they thought this approach would be more effective in limiting near-roadway exposures that may reach levels in the range at which some individuals with asthma may be adversely affected. Other members acknowledged the need for research and development of near-road monitoring data for criteria pollutants in general but favored retention of EPA's

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[16] CASAC members were also part of the CASAC Panel for the NO_2 NAAQS review (i.e., the Oxides of Nitrogen Primary National Ambient Air Quality Standards Panel). Therefore, references to the CASAC Panel include both CASAC members and Panel members.

> current area-wide monitoring for NO_2 regulatory purposes, due to the lack of epidemiological data based on near-roadway exposure measurements and issues related to implementing a near-road monitoring system for NO_2.

Thus, the recommendation of the majority of CASAC Panel members was based on their conclusion that the proposed approach would be more effective than the alternative at limiting near-roadway exposures to NO_2 concentrations that could adversely affect asthmatics. In addition, these CASAC Panel members noted important uncertainties with the alternative approach. Specifically, they stated the following (Samet, 2009):

> Panel members also supported the proposed two-tiered approach because basing regulations on area-wide monitoring alone was problematic. Such an approach would require EPA to embed uncertainties and assumptions about the relationship between area-wide and road-side monitoring into the area-wide standard.

A minority of CASAC Panel members expressed support for the alternative approach of setting a 1-hour standard that reflects the allowable area-wide NO_2 concentration. These CASAC Panel members concluded that there would be important uncertainties associated with the proposed approach. Specifically, they noted that the key U.S. NO_2 epidemiologic studies relied upon area-wide NO_2 concentrations. In their view, the use of area-wide concentrations in these studies introduces uncertainty into the selection of a standard level for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area

and that is linked with a requirement to place monitors near major roads. As a result of this uncertainty, CASAC Panel members who favored the alternative approach noted that "it would be better to set the standard on the same area-wide monitoring basis as employed in the epidemiologic studies upon which it [the standard] now relies" (Samet, 2009). These CASAC Panel members also strongly supported obtaining monitoring data near major roads, while recognizing uncertainties associated with identifying appropriate monitoring sites near roads (*see* section III.B.2 and the Response to Comments document for more discussion of CASAC's monitoring comments).

ii. Public Comments on the Approach to Setting the Standard

Consistent with the views expressed by the majority of CASAC members, a number of commenters concluded that the most appropriate approach would be to set a 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area and to couple that standard with a requirement that monitors be placed in locations where maximum concentrations are expected, including near major roads. This view was expressed by some State and local agencies (*e.g.*, in CA, IA, NY, TX, WA, WI), by a number of environmental organizations (*e.g.,* CAC, EDF, EJ, GASP, NRDC), by the ALA, and individual commenters. Several additional medical and public health organizations (ACCP, AMA, ATS, NADRC, NACPR) did not explicitly express a recommendation regarding the approach though these organizations did recommend that, in setting a 1-hour standard, particular attention

should be paid to NO_X concentrations around major roadways. In support of their recommendation to adopt the proposed approach and to focus monitoring around major roads, these commenters generally concluded that a primary consideration should be the extent to which the NO_2 NAAQS protects at-risk populations that live and/or attend school near important sources of NO_2 such as major roads. As such, these comments supported the rationale in the proposal for setting a 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area.

A number of State commenters expressed the view that area-wide monitors should be used for attainment/non-attainment determinations (*e.g.*, NACAA, NES CAUM and agencies in IL, IN, MI, MS, NC, NM, SC). One State commenter (NESCAUM) agreed with EPA concerns about near-road exposures but concluded that it is premature to establish a large near-road monitoring network at this time due to uncertainty regarding the relationship between near-road and area-wide NO_2 concentrations and the variability in that relationship. NESCAUM recommended that EPA work with States to establish a targeted monitoring program in select urban areas to gather data that would inform future modifications to the monitoring network, but that "[t]he existing area-wide monitoring network should be used to identify initial nonattainment areas." Other State commenters also concluded that the most appropriate approach would be to base nonattainment determinations only on area-wide monitors. Based on their monitoring comments, many of these commenters appeared to support setting a 1-hour standard that reflects the allowable area-wide

NO_2 concentration. State concerns with the proposed approach often included uncertainties associated with identifying and accessing appropriate monitor sites near major roads, as well as concerns related to implementation and cost to States (as discussed further in the Response to Comments document, the Administrator may not consider cost of implementation in decisions on a NAAQS).

One commenter (AAM) concluded that the focus of the proposed approach on NO_2 concentrations around major roadways is not justified because the REA and the proposal overstate the extent to which NO_2 concentrations near roads are higher than NO_2 concentrations farther away from the road. This conclusion is based on an analysis of 42 existing NO_2 monitors in 6 locations. Comparing NO_2 concentrations measured by these monitors, some of which are closer to roads and others of which are farther from roads, AAM concluded that "roadside monitors are not measuring high NO_2 concentrations."

We agree that there is uncertainty associated with estimates of roadway-associated NO_2 concentrations (*see* REA, sections 7.4.6 and 8.4.8.3 for detailed discussion of these uncertainties) and in identifying locations where maximum concentrations are expected to occur. However, we note that the Administrator's conclusions regarding the relationship between NO_2 concentrations near roads and those away from roads rely on multiple lines of scientific evidence and information. Specifically, the Administrator relied in the proposal on the following in drawing conclusions re-

garding the distribution of NO_2 concentrations across areas:

• Monitoring studies discussed in the ISA and REA that were designed to characterize the NO_2 concentration gradient around roads, which indicated that NO_2 concentrations near roads can be approximately 30 to 100% higher than concentrations away from the road in the same area.

• Air quality and exposure analyses presented in the REA which estimate that, on average across locations, NO_2 concentrations on roads could be 80% higher than those away from roads and that roadway-associated exposures account for the majority of exposures to NO_2 concentrations at or above 100 ppb.

In contrast, the existing NO_2 monitoring network, which was the basis for the analysis submitted by AAM, was not designed to characterize the spatial gradients in NO_2 concentrations surrounding roadways. Rather, concentrations of NO_2 measured by existing monitors are likely to reflect contributions from a combination of mobile and stationary sources, with one or the other dominating depending on the proximity of these sources to the monitors. Therefore, we conclude that the analysis submitted by AAM, which does not consider other relevant lines of evidence and information, does not appropriately characterize the relationship between NO_2 concentrations near roads and those away from roads. (*See* the Response to Comments document for a more detailed discussion of AAM comments.)

In addition, we note that, although the Administrator concluded in the proposal that maximum NO_2 concen-

trations in many areas are likely to occur around major roads, she also recognized that maximum concentrations can occur elsewhere in an area. For this reason, she proposed to set a 1-hour NO_2 standard that reflects the maximum allowable NO_2 concentration anywhere in an area, regardless of where that maximum concentration occurs.[17] Therefore, the proposed approach to setting the standard would be expected to limit the maximum NO_2 concentrations anywhere in an area even if in some areas, as is contended by AAM, those maximum NO_2 concentrations do not occur near roads.

iii. CASAC Comments on Standard Level

In commenting on the proposal, CASAC discussed both the proposed range of standard levels (*i.e.*, 80-100 ppb) and the alternative range of standard levels (*i.e.*, 50-75 ppb). CASAC did express the consensus conclusion that if the Agency finalizes a 1-hour standard in accordance with the proposed approach (*i.e.*, standard level reflects the maximum allowable NO_2 concentration anywhere in an area), then it is appropriate to consider the proposed range of standard levels from 80 to 100 ppb. Specifically, the CASAC letter to the

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[17] To measure maximum concentrations, the Administrator proposed monitoring provisions that would require monitors within 50 meters of major roads and to allow the Regional Administrator to require additional monitors in situations where maximum concentrations would be expected to occur in locations other than near major roads (*e.g.*, due to the influence of multiple smaller roads and/or stationary sources).

Administrator on the proposal (Samet, 2009) stated the following with regard to the proposed approach:

> [T]he level of the one-hour NO_2 standard should be within the range of 80-100 ppb and not above 100 ppb. In its letter of December 2, 2008, CASAC strongly voiced a consensus view that the upper end of the range should not exceed 100 ppb, based on evidence of risk at that concentration. The lower limit of 80 ppb was viewed as reasonable by CASAC; selection of a value lower than 80 ppb would represent a policy judgment based on uncertainty and the degree of public health protection sought, given the limited health-based evidence at concentrations below 100 ppb.

CASAC also recommended that this level be employed with a 98th percentile form, in order to promote the stability of the standard (*see* above for discussion of form).

iv. Public Comments on Standard Level

A number of State and local agencies and organizations expressed support for setting the level of the 1-hour NO_2 standard within the proposed range of 80 to 100 ppb. While some State and local agencies (*e.g.,* in CA, IA, MI, NY, TX) made this recommendation in conjunction with a recommendation to focus monitoring near major roads and other important sources of NO_2, a number of State commenters (*e.g.,* NACAA, NESCAUM and agencies in IL, NC, NM, TX, VA) recommended a standard level from 80 to 100 ppb in conjunction with a recommendation that only area-wide monitors be deployed for purposes of determining attainment with the standard. Based on these

monitoring comments, these State commenters appear to favor an approach where a standard level from 80 to 100 ppb would reflect the allowable area-wide NO_2 concentration. As discussed above (and in more detail in section III.B.2 and the Response to Comments document), State commenters often based these recommendations on uncertainties associated with designing an appropriate national near-road monitoring network.

A number of environmental organizations (*e.g.*, CAC, EDF, EJ, GASP, NRDC) and medical/public health organizations (*e.g.*, ACCP, ALA, AMA, ATS, NACPR, NAMDRC) supported setting a standard level below 80 ppb for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area. Several of these groups recommended a standard level of 50 ppb. This recommendation was typically based on the commenters' interpretation of the epidemiologic and controlled human exposure evidence, as described below.

Some of these commenters noted that the 98th percentile area-wide NO_2 concentration was below 80 ppb in the location of a single key U.S. epidemiologic study (*i.e.*, 50 ppb in study by Delfino). Given this, commenters concluded that the standard level should be set at 50 ppb. Their comments on the monitoring network generally favored a requirement to place monitors near major roads and, therefore, these commenters appeared to favor a standard level as low as 50 ppb and to recommend that such a standard level reflect the maximum allowable NO_2 concentration

anywhere in an area. In their comments, the ALA, EDF, EJ, and NRDC stated the following:

> Considering the Delfino study alone on EPA's terms, that is, focusing on the 98th percentile of the 1-hour daily maximum concentrations, EPA reports a concentration of 50 ppb where asthma symptoms were observed. Based primarily on this study, EPA concluded in the REA that it was appropriate to set the lower end of the range at 50 ppb, which corresponded to the lowest-observed effects level of airway hyperresponsiveness in asthmatics. To provide the strongest public health protection, we therefore urge the level of the standard be set at 50 ppb.

In some cases, the same commenters also appeared to recommend setting a standard level below 50 ppb because mean area-wide NO_2 concentrations reported in locations of key U.S. epidemiologic studies are below this concentration. Specifically, with regard to the key U.S. epidemiologic studies, these commenters (*e.g.,* ALA, EDF, EJ, NRDC) stated the following:

> These studies clearly identify adverse health effects such as emergency room visits and hospital admissions for respiratory causes at concentrations currently occurring in the United States. Mean concentrations for all but two of these studies are about or below 50 ppb, suggesting that the standard must be set below this level to allow for a margin of safety.

The Administrator's consideration of the Delfino study as it relates to a decision on standard level is discussed below (section II.F.4.d). Regarding the recommen-

dation to set the level below 50 ppb based on mean area-wide NO_2 concentrations in epidemiologic study locations, we note that the Administrator proposed to set a standard that reflects the maximum allowable NO_2 concentration anywhere in an area and to set the form of that standard at the upper end of the distribution of 1-hour daily maximum NO_2 concentrations.[18] As described in the proposal, such a standard, with a level from the proposed range of 80 to 100 ppb, would be expected to maintain peak area-wide NO_2 concentrations below the peak area-wide concentrations measured in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Because reducing NO_X emissions to meet a 98th percentile NO_2 standard should lower the distribution of NO_2 concentrations, including the mean, a standard that limits the 98th percentile of the distribution of 1-hour daily maximum concentrations would also be expected to limit mean concentrations. Therefore, although we acknowledge that the relationship between peak and mean NO_2 concentrations will likely vary across locations and over time, if peak area-wide NO_2 concentrations are maintained below those in key epidemiologic study locations, mean area-wide NO_2 concentrations would also be expected to be maintained below the mean area-wide concentrations in those locations (*see* ISA, figure 2.4-13 for information on the relationship between peak and mean NO_2 concentrations).

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[18] As discussed above, the Administrator has selected the 98th percentile as the form for the new 1-hour NO2 standard.

As discussed above (section, II.E.2), a number of industry groups did not support setting a new 1-hour NO_2 standard. However, several of these groups (*e.g.,* AAM, Dow, NAM, NPRA) also concluded that, if EPA does choose to set a new 1-hour standard, the level of that standard should be above 100 ppb. As a basis for this recommendation, these groups emphasized uncertainties in the scientific evidence. Specifically, as discussed in more detail above (section II.E.2), these commenters typically concluded that available epidemiologic studies do not support the conclusion that NO_2 causes reported health effects. This was based on their assertion that the presence of co-pollutants in the ambient air precludes the identification of a specific NO_2 contribution to reported effects. As a result, these commenters recommended that a 1-hour standard should be based on the controlled human exposure evidence and that, in considering that evidence, EPA should rely on the meta-analysis of NO_2 airway responsiveness studies conducted by Goodman *et al.,* (2009) rather than the meta-analysis included in the final ISA. As described above, they concluded that in relying on the ISA meta-analysis, EPA has inappropriately relied on a new unpublished meta-analysis that has not been peer-reviewed, was not reviewed by CASAC, and was not conducted in a transparent manner. EPA recognizes the uncertainties in the scientific evidence that are discussed by these industry commenters; however, we strongly disagree with their conclusions regarding the implications of these uncertainties for decisions on the NO_2 NAAQS. These comments, and EPA's responses, are discussed in detail above (section II.E.2) and in

the Response to Comments document and are summarized briefly below.

As noted in section II.E.2, we agree that the presence of co-pollutants in the ambient air complicates the interpretation of epidemiologic studies; however, our conclusions regarding causality are based on consideration of the broad body of epidemiologic studies (including those employing multipollutant models) as well as animal toxicological and controlled human exposure studies. The ISA concluded that this body of evidence "supports a direct effect of short-term NO_2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS level" (ISA, p. 5-16). In addition, the ISA (p. 5-15) concluded the following:

> [T]he strongest evidence for an association between NO_2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms and ED visits and hospital admissions. These new findings were based on numerous studies, including panel and field studies, multipollutant studies that control for the effects of other pollutants, and studies conducted in areas where the whole distribution of ambient 24-h avg NO_2 concentrations was below the current NAAQS level of 0.053 ppm (53 ppb) (annual average).

Given that epidemiologic studies provide the strongest support for an association between NO_2 and respiratory morbidity, and that a number of these studies controlled for the presence of other pollutants with multi-pollutant models (in which NO_2 effect estimates remained robust), we disagree that NO_2 epidemiologic

studies should not be used to inform a decision on the level of the 1-hour NO_2 standard.

In addition, we agree that uncertainty exists regarding the extent to which the NO_2-induced increase in airway responsiveness is adverse (REA, section 10.3.2.1); however, as discussed in detail above (section II.E.2), we disagree with the conclusion by many industry commenters that this effect is not adverse in asthmatics following exposures from 100 to 600 ppb NO_2. Specifically, we do not agree that the approach taken in the study by Goodman *et al.* (2009), which was used by many industry commenters to support their conclusions, was appropriate. The authors of the Goodman study used data from existing NO_2 studies to characterize the dose-response relationship of NO_2 and airway responsiveness and to calculate the magnitude of the NO_2 effect. Given the protocol differences in existing studies of NO_2 and airway responsiveness, we do not agree that it is appropriate to base such an analysis on these studies.

The Administrator's consideration of these uncertainties, within the context of setting a standard level, is discussed in the next section.

d. Conclusions on Approach and Standard Level

Having carefully considered the public comments on the appropriate approach and level for a 1-hour NO_2 standard, as discussed above, the Administrator believes the fundamental conclusions reached in the ISA and REA remain valid. In considering the approach, the Administrator continues to place primary emphasis on the conclusions of the ISA and the analyses of the REA, both of which focus attention on the im-

portance of roadways in contributing to peak NO_2 exposures, given that roadway-associated exposures can dominate personal exposures to NO_2. In considering the level at which the 1-hour primary NO_2 standard should be set, the Administrator continues to place primary emphasis on the body of scientific evidence assessed in the ISA, as summarized above in section II.B, while viewing the results of exposure and risk analyses, discussed above in section II.C, as providing information in support of her decision.

With regard to her decision on the approach to setting the 1-hour standard, the Administrator continues to judge it appropriate to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects linked with short-term exposures to NO_2, where such health effects have been associated with exposure to the distribution of short-term ambient NO_2 concentrations across an area. In protecting public health against exposure to the distribution of short-term NO_2 concentrations across an area, the Administrator is placing emphasis on providing a relatively high degree of confidence regarding the protection provided against exposures to peak concentrations of NO_2, such as those that can occur around major roadways. Available evidence and information suggest that roadways account for the majority of exposures to peak NO_2 concentrations and, therefore, are important contributors to NO_2-associated public health risks. In reaching this conclusion, the Administrator notes the following:

• Mobile sources account for the majority of NO_X emissions (ISA, Table 2.2-1).

• The ISA stated that NO_2 concentrations in heavy traffic or on freeways "can be twice the residential outdoor or residential/arterial road level," that "exposure in traffic can dominate personal exposure to NO_2," and that "NO_2 levels are strongly associated with distance from major roads (*i.e.,* the closer to a major road, the higher the NO_2 concentration)" (ISA, sections 2.5.4, 4.3.6).

• The exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO_2 concentrations (REA, Figures 8-17, 8-18).

• Monitoring studies suggest that NO_2 concentrations near roads can be considerably higher than those in the same area but away from roads (*e.g.,* by 30-100%, *see* section II.A.2).

• In their comments on the approach to setting the 1-hour NO_2 standard, the majority of CASAC Panel members emphasized the importance of setting a standard that limits roadway-associated exposures to NO_2 concentrations that could adversely affect asthmatics. These CASAC Panel members favored the proposed approach, including its focus on roads.

In addition, the Administrator notes that a considerable fraction of the population resides, works, or attends school near major roadways or other sources of NO_2 and that these populations are likely to have increased exposure to NO_2 (ISA, section 4.4). Based on data from the 2003 American Housing Survey, approximately 36 million individuals live within 300

feet (~90 meters) of a four-lane highway, railroad, or airport (ISA, section 4.4).[19] Furthermore, in California, 2.3% of schools with a total enrollment of more than 150,000 students were located within approximately 500 feet of high-traffic roads (ISA, section 4.4). Of this population, which likely includes a disproportionate number of individuals in groups with a higher prevalence of asthma and higher hospitalization rates for asthma (*e.g.,* ethnic or racial minorities and individuals of low socioeconomic status) (ISA, section 4.4), asthmatics and members of other susceptible groups (*e.g.,* children, elderly) will have the greatest risks of experiencing health effects related to NO_2 exposure. In the United States, approximately 10% of adults and 13% of children have been diagnosed with asthma, and 6% of adults have been diagnosed with COPD (ISA, section 4.4).

In considering the approach to setting the 1-hour standard, the Administrator also notes that concerns with the proposed approach expressed by the minority of CASAC Panel members included concern with the uncertainty in the relationship between near-road and

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[19] The most current American Housing Survey *(http://www.census.gov/hhes/www/housing/ahs/ahs.html)* is from 2007 and lists a higher fraction of housing units within the 300 foot boundary. According to Table 1A-6 from that report *(http:// www.census.gov/hhes/www/housing/ahs/ahs07/tab1a-6.pdf),* out of 128.2 million total housing units in the United States, about 20 million were reported by the surveyed occupant or landlord as being within 300 feet of a 4-or-more lane highway, railroad, or airport. That constitutes 15.6% of the total housing units in the U.S. Assuming equal distributions, with a current population of 306.3 million, that means that there would be 47.8 million people meeting the 300 foot criteria.

area-wide NO_2 concentrations, given that U.S. epidemiologic studies have been based on concentrations measured at area-wide monitors. However, as discussed by the majority of CASAC Panel members, a similar uncertainty would be involved in setting a standard with the alternative approach (Samet, 2009). The Administrator agrees with the majority of CASAC Panel members and concludes that uncertainty in the relationship between near-road and area-wide NO_2 concentrations should be considered regardless of the approach selected to set the standard. She recognizes that this uncertainty can and should be taken into consideration when considering the level of the standard.

In drawing conclusions on the approach, the Administrator has considered the extent to which each approach, in conjunction with the ranges of standard levels discussed in the proposal, would be expected to limit the distribution of NO_2 concentrations across an area and, therefore, would be expected to protect against risks associated with NO_2 exposures. Specifically, she has considered the extent to which a standard set with each approach would be expected to limit maximum NO_2 concentrations and area-wide NO_2 concentrations.

With regard to expected maximum concentrations, the Administrator notes the following:

• A standard reflecting the maximum allowable NO_2 concentration anywhere in an area would provide a relatively high degree of confidence regarding the level of protection provided against peak exposures, such as those that can occur on or near major road-

ways. A standard level from anywhere within the proposed range (*i.e.*, 80 to 100 ppb) would be expected to limit exposures to NO_2 concentrations reported to increase airway responsiveness in asthmatics.

• A standard reflecting the allowable area-wide NO_2 concentration would not provide a high degree of confidence regarding the extent to which maximum NO_2 concentrations would be limited. Maximum NO_2 concentrations would be expected to be controlled to varying degrees across locations and over time depending on the NO_2 concentration gradient around roads. Given the expected variability in gradients across locations and over time, most standard levels within the range considered in the proposal with this option (*i.e.*, 50 to 75 ppb) would not be expected to consistently limit the occurrence of NO_2 concentrations that have been reported to increase airway responsiveness in asthmatics.

With regard to expected area-wide concentrations, the Administrator notes the following:

• The extent to which a standard reflecting the maximum allowable NO_2 concentration anywhere in an area would be expected to limit area-wide NO_2 concentrations would vary across locations, *e.g.*, depending on the NO_2 concentration gradient around roads. However, in conjunction with a standard level from anywhere within the proposed range (*i.e.*, 80-100 ppb), such an approach would be expected to maintain area-wide NO_2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO_2 and respiratory-related hospital admissions and emergency

department visits (based on available information regarding the NO_2 concentration gradient around roads as discussed below).

• A standard reflecting the maximum allowable area-wide NO_2 concentration would provide a relatively high degree of certainty regarding the extent to which area-wide NO_2 concentrations are limited. In conjunction with a standard level from anywhere within the range of levels discussed in the proposal (*i.e.*, 50-75 ppb) with this alternative approach, such a standard would be expected to maintain area-wide NO_2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO_2 and respiratory-related hospital admissions and emergency department visits.

Given the above considerations, the Administrator concludes that both approaches, in conjunction with appropriate standard levels, would be expected to maintain area-wide NO_2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO_2 and respiratory-related hospital admissions and emergency department visits. In contrast, the Administrator concludes that only a standard reflecting the maximum allowable NO_2 concentration anywhere in an area, in conjunction with an appropriate standard level, would be expected to consistently limit exposures, across locations and over time, to NO_2 concentrations reported to increase airway responsiveness in asthmatics. After considering the evidence and uncertainties, and the advice of the CASAC Panel, the

Administrator judges that the most appropriate approach to setting a 1-hour standard to protect against the distribution of short-term NO_2 concentrations across an area, including the higher concentrations that can occur around roads and result in elevated exposure concentrations, is to set a standard that reflects the maximum allowable NO_2 concentration anywhere in an area.

In considering the level of a 1-hour NO_2 standard that reflects the maximum allowable NO_2 concentration anywhere in an area, the Administrator notes that there is no bright line clearly directing the choice of level. Rather, the choice of what is appropriate is a public health policy judgment entrusted to the Administrator. This judgment must include consideration of the strengths and limitations of the evidence and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments. Specifically, the Administrator notes the following:

• Controlled human exposure studies have reported that various NO_2 exposure concentrations increased airway responsiveness in mostly mild asthmatics (section II above and II.B.1.d in proposal). These studies can inform an evaluation of the risks associated with exposure to specific NO_2 concentrations, regardless of where those exposures occur in an area. Because concentrations evaluated in controlled human exposure studies are at the high end of the distribution of ambient NO_2 concentrations (ISA, section 5.3.2.1), these studies most directly inform consideration of the risks associated with exposure to peak short-term NO_2 concentrations.

• Epidemiologic studies (section II.B.1.a and b) conducted in the United States have reported associations between ambient NO_2 concentrations measured at area-wide monitors in the current network and increased respiratory symptoms, emergency department visits, and hospital admissions. Area-wide monitors in the urban areas in which these epidemiologic studies were conducted are not sited in locations where localized peak concentrations are likely to occur. Thus, they do not measure the full range of ambient NO_2 concentrations across the area. Rather, the area-wide NO_2 concentrations measured by these monitors are used as surrogates for the distribution of ambient NO_2 concentrations across the area, a distribution that includes NO_2 concentrations both higher than (*e.g.,* around major roadways) and lower than the area-wide concentrations measured in study locations. Epidemiologic studies evaluate whether area-wide NO_2 concentrations are associated with the risk of respiratory morbidity. Available information on NO_2 concentration gradients around roadways can inform estimates of the relationship between the area-wide NO_2 concentrations measured in epidemiologic study locations and the higher NO_2 concentrations likely to have occurred around roads in those locations, which can then inform the decision on the level of a standard reflecting the maximum allowable NO_2 concentration anywhere in an area.

• The risk and exposure analyses presented in the REA provide information on the potential public health implications of setting standards that limit area-wide NO_2 concentrations to specific levels. While the Administrator acknowledges the uncertain-

ties associated with these analyses which, as discussed in the REA, could result in either over- or underestimates of NO_2-associated health risks, she judges that these analyses are informative for considering the relative levels of public health protection that could be provided by different standards.

The Administrator's consideration of the controlled human exposure evidence, epidemiologic evidence, and exposure/risk information are discussed below specifically with regard to a decision on the level of a standard that reflects the maximum allowable NO_2 concentration anywhere in an area.

In considering the potential for controlled human exposure studies of NO_2 and airway responsiveness to inform a decision on standard level, the Administrator notes the following:

• NO_2-induced increases in airway responsiveness, as reported in controlled human exposure studies, are logically linked to the adverse respiratory effects that have been reported in NO_2 epidemiologic studies.

• The meta-analysis of controlled human exposure data in the ISA reported increased airway responsiveness in a large percentage of asthmatics at rest following exposures at and above 100 ppb NO_2, the lowest NO_2 concentration for which airway responsiveness data are available in humans.

• This meta-analysis does not provide any evidence of a threshold below which effects do not occur. The studies included in the meta-analysis evaluated primarily mild asthmatics while more severely affected individuals could respond to lower concentrations.

Therefore, it is possible that exposure to NO_2 concentrations below 100 ppb could increase airway responsiveness in some asthmatics.

In considering the evidence, the Administrator recognizes that the NO_2-induced increases in airway responsiveness reported for exposures to NO_2 concentrations at or above 100 ppb could be adverse for some asthmatics. However, she also notes that important uncertainties exist with regard to the extent to which NO_2-induced increases in airway responsiveness are adverse. Specifically, she notes the following with regard to these uncertainties:

- The magnitude of the NO_2-induced increase in airway responsiveness, and the extent to which it is adverse, cannot be quantified from the ISA meta-analysis (REA, section 10.3.2.1).

- The NO_2-induced increase in airway responsiveness in resting asthmatics was typically not accompanied by increased respiratory symptoms, even following exposures to NO_2 concentrations well above 100 ppb (ISA, section 3.1.3.3).

- The increase in airway responsiveness that was reported for resting asthmatics was not present in exercising asthmatics (ISA, Table 3.1-3).

Taking into consideration all of the above, the Administrator concludes that existing evidence supports the conclusion that the NO_2-induced increase in airway responsiveness at or above 100 ppb presents a risk of adverse effects for some asthmatics, especially those with more serious (*i.e.,* more than mild) asthma. The Administrator notes that the risks associated with

increased airway responsiveness cannot be fully characterized by these studies, and thus she is not able to determine whether the increased airway responsiveness experienced by asthmatics in these studies is an adverse health effect. However, based on these studies the Administrator concludes that asthmatics, particularly those suffering from more severe asthma, warrant protection from the risk of adverse effects associated with the NO_2-induced increase in airway responsiveness. Therefore, the Administrator concludes that the controlled human exposure evidence supports setting a standard level no higher than 100 ppb to reflect a cautious approach to the uncertainty regarding the adversity of the effect. However, those uncertainties lead her to also conclude that this evidence does not support setting a standard level lower than 100 ppb.

In considering the more serious health effects reported in NO_2 epidemiologic studies, as they relate to the level of a standard that reflects the maximum allowable NO_2 concentration anywhere in an area, the Administrator notes the following:

• A cluster of 5 key U.S. epidemiologic studies (Ito *et al.,* 2007; Jaffe *et al.,* 2003; Peel *et al.,* 2005; Tolbert *et al.,* 2007; and a study by the New York State Department of Health, 2006) provide evidence for associations between NO_2 and respiratory-related emergency department visits and hospital admissions in locations where 98th percentile 1-hour daily maximum NO_2 concentrations measured at area-wide monitors ranged from 85 to 94 ppb. The Administrator judges it appropriate to place substantial weight on this clus-

ter of key U.S. epidemiologic studies in selecting a standard level, as they are a group of studies that reported positive, and often statistically significant, associations between NO_2 and respiratory morbidity in multiple cities across the United States.[20]

• A single study (Delfino *et al.,* 2002) provides mixed evidence for NO_2 effects (*i.e.,* respiratory symptoms) in a location with a 98th percentile 1-hour daily maximum NO_2 concentration, as measured by an area-wide monitor, of 50 ppb. In that study, most of the reported NO_2 effect estimates were positive, but not statistically significant. Given the variability in the NO_2 effect estimates in this study, as well as the lack of studies in other locations with similarly low NO_2 concentrations, the Administrator judges it appropriate to place limited weight on this study, compared to the cluster of 5 studies as noted above.

Given these considerations, the Administrator concludes that the epidemiologic evidence provides strong support for setting a standard that limits the 98th percentile of the distribution of 1-hour daily maximum area-wide NO_2 concentrations to below 85 ppb. This judgment takes into account the determinations in the ISA, based on a much broader body of evidence, that there is a likely causal association between exposure to NO_2 and the types of respiratory morbidity effects reported in these studies. Given the considerations discussed above, the Administrator judges that it is

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[20] Some of these studies also included susceptible and vulnerable populations (*e.g.,* children in Peel *et al.* (2005); poor and minority populations in Ito *et al.,* 2007).

not necessary, based on existing evidence, to set a standard that maintains peak area-wide NO_2 concentrations to below 50 ppb.

In considering specific standard levels supported by the epidemiologic evidence, the Administrator notes that a level of 100 ppb, for a standard reflecting the maximum allowable NO_2 concentration anywhere in the area, would be expected to maintain area-wide NO_2 concentrations well below 85 ppb, which is the lowest 98th percentile concentration in the cluster of 5 studies. With regard to this, she specifically notes the following:

- If NO_2 concentrations near roads are 100% higher than concentrations away from roads, a standard level of 100 ppb would limit area-wide concentrations to approximately 50 ppb.

- If NO_2 concentrations near roads are 30% higher than concentrations away from roads, a standard level of 100 ppb would limit area-wide concentrations to approximately 75 ppb.

The Administrator has also considered the NO_2 exposure and risk information within the context of the above conclusions on standard level. Specifically, she notes that the results of exposure and risk analyses were interpreted as providing support for limiting area-wide NO_2 concentrations to no higher than 100 ppb. Specifically, these analyses estimated that a standard that limits area-wide NO_2 concentrations to approximately 100 ppb or below would be expected to result in important reductions in respiratory risks, relative to the level of risk permitted by the current annual standard alone. As discussed above, a stand-

ard reflecting the maximum allowable NO_2 concentration with a level of 100 ppb would be expected to maintain area-wide NO_2 concentrations to within a range of approximately 50 to 75 ppb. Given this, the Administrator concludes that a standard level of 100 ppb is consistent with conclusions based on the NO_2 exposure and risk information.

Finally, the Administrator notes that a standard level of 100 ppb is consistent with the consensus recommendation of CASAC.

Given the above considerations and the comments received on the proposal, the Administrator determines that the appropriate judgment, based on the entire body of evidence and information available in this review, and the related uncertainties, is a standard level of 100 ppb (for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area). She concludes that such a standard, with the averaging time and form discussed above, will provide a significant increase in public health protection compared to that provided by the current annual standard alone and would be expected to protect against the respiratory effects that have been linked with NO_2 exposures in both controlled human exposure and epidemiologic studies. Specifically, she concludes that such a standard will limit exposures at and above 100 ppb for the vast majority of people, including those in at-risk groups, and will maintain maximum area-wide NO_2 concentrations well below those in locations where key U.S. epidemiologic studies have reported that ambient NO_2 is associated with clearly adverse

respiratory health effects, as indicated by increased hospital admissions and emergency department visits.

In setting the standard level at 100 ppb rather than a lower level, the Administrator notes that a 1-hour standard with a level lower than 100 ppb would only result in significant further public health protection if, in fact, there is a continuum of serious, adverse health risks caused by exposure to NO_2 concentrations below 100 ppb and/or associated with area-wide NO_2 concentrations well-below those in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Based on the available evidence, the Administrator does not believe that such assumptions are warranted. Taking into account the uncertainties that remain in interpreting the evidence from available controlled human exposure and epidemiologic studies, the Administrator notes that the likelihood of obtaining benefits to public health with a standard set below 100 ppb decreases, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increases.

Therefore, the Administrator judges that a standard reflecting the maximum allowable NO_2 concentration anywhere in an area set at 100 ppb is sufficient to protect public health with an adequate margin of safety, including the health of at-risk populations, from adverse respiratory effects that have been linked to short-term exposures to NO_2 and for which the evidence supports a likely causal relationship with NO_2 exposures. The Administrator does not believe that a

lower standard level is needed to provide this degree of protection. These conclusions by the Administrator appropriately consider the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level or to protect the most sensitive individual, but rather at a level that reduces risk sufficiently so as to protect the public health with an adequate margin of safety.

G. Annual Standard

In the proposal, the Administrator noted that some evidence supports a link between long-term exposures to NO_2 and adverse respiratory effects and that CASAC recommended in their comments prior to the proposal that, in addition to setting a new 1-hour standard to increase public health protection, the current annual standard be retained. CASAC's recommendation was based on the scientific evidence and on their conclusion that a 1-hour standard might not provide adequate protection against exposure to long-term NO_2 concentrations (Samet, 2008b).

With regard to an annual standard, CASAC and a large number of public commenters (*e.g.,* NACAA, NESCAUM; agencies from States including CA, IN, MO, NC, NY, SC, TX, VA; Tribal organizations including Fon du Lac and the National Tribal Air Organization; environmental/medical/public health groups including ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC) agreed with the proposed decision to maintain an annual standard,

though their recommendations with regard to the level of that annual standard differed (*see* below).

As noted above, CASAC recommended "retaining the current standard based on the annual average" based on the "limited evidence related to potential long-term effects of NO_2 exposure and the lack of strong evidence of no effect" and that "the findings of the REA do not provide assurance that a short-term standard based on the one-hour maximum will necessarily protect the population from long-term exposures at levels potentially leading to adverse health effects" (Samet, 2008b). A number of State agencies and organizations also recommended maintaining the current level of the annual standard (*i.e.,* 53 ppb). This recommendation was based on the conclusion that, while some evidence supports a link between longterm NO_2 exposures and adverse respiratory effects, that evidence is not sufficient to support a standard level either higher or lower than the current level. In addition, a number of industry groups (*e.g.,* AAM, API, Dow, INGAA, UARG) recommended retaining the level of the current annual standard but, as described above, did so within the context of a recommendation that EPA should not set a new 1-hour standard.

In contrast, some environmental organizations and medical/public health organizations as well as a small number of States (*e.g.,* ALA, EDF, EJ, NRDC, and organizations in CA) recommended setting a lower level for the annual standard. These commenters generally supported their recommendation by pointing to the State of California's annual standard of 30 ppb and to studies where long-term ambient NO_2 concen-

trations have been associated with adverse respiratory effects such as impairments in lung function growth.

As discussed above (II.B.3), the evidence relating long-term NO_2 exposures to adverse health effects was judged in the ISA to be either "suggestive but not sufficient to infer a causal relationship" (respiratory morbidity) or "inadequate to infer the presence or absence of a causal relationship" (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4-5.3.2.6). In the case of respiratory morbidity, the ISA (section 5.3.2.4) concluded that "The high correlation among traffic-related pollutants made it difficult to accurately estimate the independent effects in these long-term exposure studies." Given these uncertainties associated with the role of long-term NO_2 exposures in causing the reported effects, the Administrator concluded in the proposal that, consistent with the CASAC recommendation, existing evidence is not sufficient to justify setting an annual standard with either a higher or lower level than the current standard. Commenters have not submitted any new analyses or information that would change this conclusion. Therefore, the Administrator does not agree with the commenters who recommended a lower level for the annual standard.

The Administrator judges that her conclusions in the proposal regarding the annual standard remain appropriate. Specifically, she continues to agree with the conclusion that, though some evidence does support the need to limit long-term exposures to NO_2, the existing evidence for adverse health effects following

long-term NO_2 exposures does not support either increasing or decreasing the level of the annual standard. In light of this and considering the recommendation from CASAC to retain the current level of the annual standard, the Administrator judges it appropriate to maintain the level of the annual standard at 53 ppb.

H. Summary of Final Decisions on the Primary NO_2 Standard

For the reasons discussed above, and taking into account information and assessments presented in the ISA and REA, the advice and recommendations of the CASAC, and public comments, the Administrator has decided to revise the existing primary NO_2 standard. Specifically, the Administrator has determined that the current annual standard by itself is not requisite to protect public health with an adequate margin of safety. In order to provide protection for asthmatics and other at-risk populations against an array of adverse respiratory health effects related to short-term NO_2 exposure, the Administrator is establishing a short-term NO_2 standard defined by the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum NO_2 concentrations. She is setting the level of this standard at 100 ppb, which is to reflect the maximum allowable NO_2 concentration anywhere in an area. In addition to setting a new 1-hour standard, the Administrator retains the current annual standard with a level of 53 ppb. The new 1-hour standard, in combination with the annual standard, will provide protection for susceptible groups against adverse respiratory health effects associated with short-

term exposures to NO_2 and effects potentially associated with longterm exposures to NO_2.

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