American
Fuel & Petrochemical
Manufacturers

1667 K Street, NW
Suite 700
Washington, DC
20006

202.457.0480 office
202.457.0486 fax
afpm.org

September 25, 2017

U.S. Environmental Protection Agency
Air and Radiation Docket Information Center
WJC West Building, Room 3334
1301 Constitution Avenue, N.W.
Washington, DC 20460

Submitted to the Federal eRulemaking Portal (www.regulations.gov)

Re: Review of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen, 82 Fed. Reg. 34,792 (July 26, 2017); Docket ID No. EPA-HQ-OAR-2013-0146

Dear Sir/Madame:

The American Fuel & Petrochemical Manufacturers ("AFPM") appreciates the opportunity to submit comments on the Environmental Protection Agency's ("EPA" or the "Agency") proposed rule regarding the primary national ambient air quality standard ("NAAQS") for oxides of nitrogen ("NO_2").

AFPM is a national trade association representing nearly 400 companies that encompass virtually all U.S. refining and petrochemical manufacturing capacity. Our members serve the American people responsibly and effectively, strengthen economic and national security, and directly and indirectly provide jobs for nearly 5 million people.

With respect to the proposed rule, AFPM members have continuing obligations to address requirements for several NAAQS as well as other Clean Air Act ("CAA") standards. These obligations are generally implemented through State Implementation Plans, but AFPM members may also be subject to local control measures. All of these efforts have contributed to, and will continue to produce, substantial air quality benefits. Nationally, total emissions of the six primary NAAQS have been reduced by 62 percent since 1980 despite vehicle miles traveled increasing by 95 percent over the same period.[1]

As detailed in the attached comments, AFPM supports EPA's proposed decision not to make the existing standard more stringent. The scientific studies relied upon in this review simply do not justify a more stringent standard. In the seven years since EPA completed its last review of the primary NO_2 standards, there is no additional scientific information that would support promulgation of a more stringent standard.

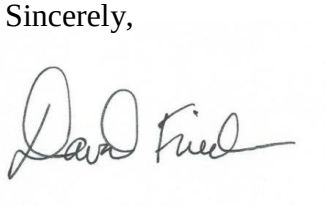
For this reason, EPA should also review whether alternative, less stringent standards may be appropriate. It is not apparent whether EPA seriously examined whether the entire body of

[1] EPA Air Trends report. Accessed at: http://www.epa.gov/airtrends/aqtrends.html#comparison.

information available to it during the current NAAQS review indicates that alternative, less stringent levels could provide the "requisite" level of protection.

Again, AFPM appreciates the opportunity to submit the views of its membership regarding important air quality standards. If you have any additional questions, please contact me at (202) 602-6604 or dfriedman@afpm.org.

Sincerely,



David Friedman
Vice President, Regulatory Affairs

COMMENTS OF THE
AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS

Review of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen

Docket ID No. EPA-HQ-OAR-2013-0146

I. While EPA Correctly Determined that the NO_2 NAAQS Should not be More Stringent, the Agency Failed to Adequately Consider Whether NO_2 NAAQS Should be Less Stringent

AFPM agrees with the Administrator that an increase in the stringency of the existing NO_2 NAAQS is not warranted, nor is any alteration of the current form, averaging period and design value for the standard desirable. As outlined in Section II, there is insufficient evidence to support a more stringent standard. This assessment is reflected in EPA's Policy Assessment ("PA") and the recommendations of the Clean Air Act Scientific Advisory Committee ("CASAC").

At the same time, the proposed rule failed to seriously examine or consider any alternative standards that would be less stringent than the current NAAQS. Although the proposed rule goes into considerable detail as to why increasing the stringency of the current standard is not justified, EPA's discussion of whether this same evidence would support less stringent standards is both conclusory and cursory.[2]

As addressed in more detail below, the CA requires more. EPA must not only decide whether more stringent standards are or are not needed, but the Agency must also undertake a fulsome examination whether the opposite is true. The Agency must examine in detail whether less stringent standards are "requisite" given the available information for this review.

A. The Clean Air Act Requires Outcome-Neutral Process

CAA §109(d)(1) requires that the EPA Administrator "complete a thorough review of the criteria . . . and national ambient air quality standards . . . and [to] make such revisions in such criteria and standards . . . as may be appropriate." Nothing within this provision dictates the outcome of this review, or provides a specific analytical framework that must be followed.[3] Instead, the statute provides for an outcome-neutral process wherein, after a thorough review, the Administrator shall promulgate "appropriate" revised standards that may be *more or less stringent* than an existing NAAQS.[4]

In conducting a periodic review of an existing NAAQS, EPA may not consider *only* whether there is or is not sufficient evidence to strengthen a NAAQS. Although previous NAAQS reviews have often resulted in final rules that lower or "tighten" existing standards,[5] on a fundamental level, EPA must examine both sides of the coin during a NAAQS review. That is, the Agency must fully consider whether the current standards are more or less stringent than necessary to provide an "adequate margin of safety."[6]

---

[2] EPA indicates that, given adverse effects from NO2 concentrations at levels above the current standards, the Administrator does not believe that less stringent standards would be appropriate given NO2 respiratory effects in people with asthma and certain information from epidemiological standards. 82 Fed. Reg. at 34,830. But this does not constitute a detailed analysis of what less stringent standards may be appropriate.

[3] The current NAAQS process is contained in Agency memorandum.

[4] CAA §109(d)(1).

[5] Since EPA makes separate decisions regarding not only the level of a NAAQS, but also its form and averaging time, NAAQS may remain at the same level but be considerably more stringent if either the form or averaging time changes.

[6] *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001).

EPA has revised NAAQS upwards in the past, perhaps most notably in 1979 when it increased the level of the ozone NAAQS from 0.08 parts per million ("ppm") as measured on an hourly basis to 0.12 ppm (not to be exceeded more than 1 hour per year).[7] This level was based on comments the Agency received that caused the Administrator to reevaluate his original assessment of ozone health effects at various ambient concentrations. Specifically, EPA indicated that "[d]uring the comment period, EPA received informed scientific opinion disputing the interpretation and application of [scientific] studies . . . EPA concluded that they do not dictate as wide a margin of safety as was established in the proposal."[8] The end result was a final rule that included an ozone NAAQS 50 percent less stringent than the former "incumbent" NAAQS (and 20 percent less stringent than the Agency originally proposed).[9]

A balanced review of scientific evidence is required by the CAA's direction to promulgate "appropriate" standards. Consistent with judicial precedent, this review must analyze all of the information before the Agency. Indeed, the D.C. Circuit has held that "[e]very time EPA reviews a NAAQS, it (presumably) does so against contemporary policy judgments and the existing corpus of scientific knowledge."[10]

Unfortunately, EPA has failed to conduct such a review with regard to the correct NO_2 NAAQS. Instead, many of the supporting documents for this review, including the staff-drafted PA, concentrate solely on whether the existing standard adequately protects public health and welfare. And although the Agency noted many limitations and uncertainties in the body of scientific evidence supporting the current level of the NAAQS, it did not follow such evidence to its logical conclusion: the possibility that the current level of the hourly NAAQS may be too stringent and therefore should be made less stringent in order to provide the "requisite" level of control.[11] EPA must consider this possibility in order to meet the requirement that it promulgate "requisite" standards.

B. EPA's Failure to Identify Alternative, Less Stringent Standards is Arbitrary and Capricious

In the NAAQS process leading to the proposed rule, EPA did not identify *any potential alternative standards* for consideration by the Administrator. Instead, EPA staff merely asserted that "available scientific evidence, in combination with the available information from quantitative analyses, supports the adequacy of the public health protection provided by the current primary NO_2 standards."[12]

In this regard, EPA staff noted that, under the current standard, there would be little potential for exposures to NO_2 of "clear public health concern in locations currently meeting the current 1-hour

[7] 44 Fed. Reg. 8,202 (Feb. 8, 1979).
[8] *Id.* at 8,217.
[9] EPA stated that "[t]here is no collection of facts or medical evidence that permits selecting an undisputed value for the standard level. EPA proposed a standard of 0.10 ppm, taking several factors into account in providing a margin of safety. . . Among those were epidemiological studies indicating effects below 0.15 ppm . . . the [EPA] Administrator has determined that a standard of 0.12 ppm is necessary and is sufficiently prudent unless further studies demonstrate reason to doubt that it adequately protects public health." *Id.*
[10] *Mississippi v. EPA*, 744 F.3d 1334, 1343 (D.C. Cir. 2013).
[11] *Whitman*, cited *supra.*
[12] Policy Assessment at ES-6.

standard."[13] But such an analysis ignores the reality that no area currently "just meets" the existing standard, but rather, *all areas* of the country have air quality substantially *under* the level of the standard. EPA's analysis of potential health effects – as it relates to ambient air quality conditions – is also inapposite to the air quality trends that have been experienced over several decades in which NO_2 concentrations have become increasing lower. Yet the Agency continues to use unrealistic exposures as part of its projection of possible health effects that then inform policy outcomes.[14]

Using this flawed analytical framework, EPA staff solely focused on whether there was a need to consider "potential alternative standards to *increase* public health protection, beyond the protection provided by the current standards."[15] And this same perspective impermissibly constrained the analysis that was provided both to the Administrator.[16]

While CAA §109 directs EPA to examine whether NAAQS are "requisite to protect the public health," EPA addressed this core statutory function in the proposed rule only in summary form. Specifically, EPA examined the issue only with reference to whether the Agency is ever required under the CAA to set a "zero-risk standard, *i.e.*, to set the level of the NAAQS at zero.[17]

But such analysis is similar to creating a "straw man" to justify a predetermined result. Despite placing voluminous evidence into the record that more protective standards are not needed, EPA did not adequately examine whether the multiple uncertainties contained in human exposure and epidemiological evidence call into question maintaining current standards. EPA did not take any further substantive steps to examine whether, based on the available scientific evidence, the level of the 1-hour NO_2 NAAQS should be less stringent than the current 100 ppb.

Without such an examination, the "Administrator's proposed conclusion" that "the current standards provide the requisite protection and that more or less stringent standards would not be requisite"[18] occurs without adequate foundation in the administrative record.

---

[13] *Id*. at 4-21. It should be noted that these locations are effectively the entire United States since currently there are no areas that are in violation of the NO_2 NAAQS.

[14] In order to examine possible exposures to NO_2 pursuant to a 100 ppb standard, EPA must "adjust upward" actual air quality (*i.e*., EPA must model that air quality is actually worse than measured by current monitoring). *Id.* at 4-19. EPA's analysis on exposures to different "benchmarks" is based on such modeled data. This is so even though "[b]ased on recent (i.e., unadjusted) ambient measurements, analyses estimate almost no potential for 1-hour exposures to NO2 concentrations at or above benchmarks, even for the lowest benchmark examined (i.e., 100 ppb)." *Id.*

[15] *Id*. (Enphasis added). It should be noted that EPA additionally reviewed whether there was evidence for adverse respiratory effects from short- or long-term exposures to NO_2 at levels below the current standards, concluding that there was not scientific support for same. But even given this observation, EPA failed to identify or consider alternative levels, forms and/or averaging periods for current standard. *Id.* at 5-12, 5-18.

[16] Having decided that no alternative standards (higher or lower) should be considered, EPA staff prepared only one draft of the PA to be submitted for review. *Id*. at 1-1, nt. 2.

[17] 82 Fed. Reg. at 34,795.

[18] *Id*. at 34,830.

II. Information Available in Current Review Does Not Support a More Stringent Standard

A. There is Limited New Information Available to EPA

The current review of the NO_2 NAAQS is required by the CAA's five-year NAAQS review cycle. CAA §109(d)(1). The specific deadline for this proposed rule as well as a notice containing the Administrator's final decision is the product of litigation and a consent decree filed in the United States District Court for the Northern District of California.[19]

While the requirement to conduct a "thorough review" of existing NAAQS at five-year intervals is statutory, it must be recognized that this required review does not often line up with the existence of additional, significant information on the health and welfare effects of a NAAQS pollutant. Instead, the five-year review requirement essentially forces EPA to review whatever evidence may be available at that point in time rather than to review standards when significant new evidence on public health or welfare effects becomes available through the scientific process.

This means that EPA may be faced, as here, with a limited amount of new scientific information when determining whether existing NAAQS are appropriate. EPA repeatedly admits as much in the proposed rule and its supporting documents:

- "Most of [controlled human exposure studies] were available in the last review . . ."[20]

- EPA lists only one new human exposure study in its Integrated Science Assessment ("ISA") related to short-term NO_2 exposure. This study shows a statistically significant fraction of individuals experience airway responsiveness during 30-minute exposures to NO_2 at 200 to 300 ppb and during 60-minute exposures at 100 ppb.[21]

- Other short term human exposure studies listed in the ISA show that to the extent effects are observed, they are small and "do not provide evidence that NO_2 has a significant adverse effect on [airway hyper-responsiveness] at concentrations up to [600 ppb]."[22]

- Regarding short-term effects as a whole, EPA staff indicates that there is a stronger relationship between exposure and effects in 2017 but that "this strengthening is based largely on more specific integration of the evidence related to asthma exacerbations rather than on the availability of new, stronger evidence. Though some evidence has become available since the last review . . . this evidence has not fundamentally altered our understanding between short-term NO_2 exposures and respiratory effects."[23]

- Similarly, much of the "key evidence" cited with respect to long-term exposure to NO_2 and respiratory effects is based on epidemiological studies that were also considered in the previous NAAQS review.[24] And EPA noted that "while the evidence for respiratory

[19] *Center for Biological Diversity v. Scott Pruitt*, Case No. 3:16-cv-03796-VC (April 28, 2017).
[20] 82 Fed. Reg. at 34,793.
[21] ISA, Table 5-39 at 5-253, referencing Brown, JS (2015).
[22] Goodman, JE; Chandalia, JK; Thakali, S; Seeley, M (2009).
[23] PA at 5-2.
[24] *See* ISA, Table 5 at 6-68.

> effects related to long-term NO_2 exposures has become stronger since the last review, there remain important uncertainties to consider in evaluating this evidence within the context of the adequacy of current standards."[25]

The limited new information that is available also suffers from several infirmities. The new meta-analysis of human exposure studies referenced in the current review has important limitations concerning respiratory effects, among them "the lack of an apparent dose-response relationship, uncertainty in the potential adversity of responses, and the general focus of available studies on people with mild asthma, rather than more severe cases of the disease."[26] In addition, EPA indicates that the evidence from controlled human exposure studies "does not consistently demonstrate these [respiratory] effects following exposures to NO_2 concentrations at or near those found in the ambient air in the U.S."[27]

Regarding epidemiological evidence reviewed, additional uncertainty lies with respect to the potential for copollutant confounding and this uncertainty has not been resolved in new studies. Traffic-related copollutants have not been examined so as to allow for EPA to discern the singular effect of NO_2 concentrations.[28] In this regard, EPA notes that a "key uncertainty" remains: whether NO_2 exposure has an independent effect from other pollutants in ambient air.[29] In other words, the Agency is uncertain whether NO_2 is actually causing the health impacts EPA considers to be of concern. Here, EPA also indicates that epidemiological correlations between asthma incidence and NO_2 exposure were based on modeled air quality, but that "studies of asthma incidence that used monitored NO_2 concentrations as exposure surrogate did not report such correlations."[30]

Therefore, while the EPA Administrator must determine the appropriate level for the NO_2 NAAQS during this review, there is little in the way of any new information or evidence on which he could justifiably conclude that the current level, form and averaging time of the NO_2 NAAQS should be made more stringent. Instead, to the extent any new information exists, such information suffers from persistent limitations and uncertainties that the EPA has not resolved.

B. The Administrator Should Reconsider Staff Recommendations in ISA and PA

In several places in the proposed rule, the Administrator references and "gives particular weight" to the staff assessments contained in the ISA and PA as well as to the advice and recommendations of CASAC.[31] The Administrator should reconsider such reliance on staff recommendations regarding the level of the proposed NAAQS. This is because while EPA staff do not believe that available information is sufficient to propose a more stringent NAAQS, they have at the same time

---

[25] PA at 5-3.
[26] 82 Fed. Reg. at 34,804.
[27] *Id.*
[28] *Id*. at 34,810. It should be noted that this same inability applies to both short-term and long-term studies. With regard to the latter, a "key uncertainty that remains when examining epidemiological evidence alone is the inability to determine whether NO2 exposure has an independent effect from that of other pollutants in the ambient mixture." *Id*. at 34,811, citing ISA at 6-21.
[29] 82 Fed. Reg. at 34,811.
[30] *Id*.
[31] *Id*. at 34,827.

concluded that the limited information available in the current review justifies increasing the certainty of their assessments. Such a result, however, is not supported given the many remaining uncertainties noted throughout the ISA, PA and proposed rule.

Specifically, under the "Framework for Causal Determinations" utilized by EPA staff in the ISA, a five-level hierarchy was used to classify the "weight of evidence" for causation.[32] Categories to assess causation used were: (a) causal relationship; (b) likely to be a causal relationship; (c) suggestive of, but not sufficient to infer, a causal relationship; (d) inadequate to infer a causal relationship; and (e) not likely to be a causal relationship. But in the current review, despite citing multiple, continuing uncertainties in the health effects that may be attributed to NO_2, EPA staff have recommended reclassifying upwards the level of certainty attached to *seven out of the eight different categories* of health effects examined. This reclassification of the weight of the evidence is reflected in the chart below:

Table ES-1 Causal determinations for relationships between nitrogen dioxide exposure and health effects from the 2008 and 2016 Integrated Science Assessment for Oxides of Nitrogen.

Exposure Duration and Health Effects Category[a]	Causal Determination[b]	
	2008 Integrated Science Assessment	2016 Integrated Science Assessment
Short-Term Nitrogen Dioxide Exposure (minutes up to 1 month)		
Respiratory effects Section 5.2, Table 5-39	Sufficient to infer a likely causal relationship	Causal relationship
Cardiovascular effects Section 5.3, Table 5-52	Inadequate to infer the presence or absence of a causal relationship	Suggestive of, but not sufficient to infer, a causal relationship
Total mortality Section 5.4, Table 5-57	Suggestive of, but not sufficient to infer, a causal relationship	Suggestive of, but not sufficient to infer, a causal relationship
Long-Term Nitrogen Dioxide Exposure (more than 1 month to years)		
Respiratory effects Section 6.2, Table 6-5	Suggestive of, but not sufficient to infer, a causal relationship	Likely to be a causal relationship
Cardiovascular effects and diabetes[c] Section 6.3, Table 6-11	Inadequate to infer the presence or absence of a causal relationship	Suggestive of, but not sufficient to infer, a causal relationship
Reproductive and developmental effects[c] Sections 6.4.2, 6.4.3, and 6.4.4, Table 6-14	Inadequate to infer the presence or absence of a causal relationship	Fertility, reproduction, and pregnancy: Inadequate to infer a causal relationship
		Birth outcomes: Suggestive of, but not sufficient to infer, a causal relationship
		Postnatal development: Inadequate to infer a causal relationship
Total mortality Section 6.5, Table 6-18	Inadequate to infer the presence or absence of a causal relationship	Suggestive of, but not sufficient to infer, a causal relationship
Cancer Section 6.6, Table 6-20	Inadequate to infer the presence or absence of a causal relationship	Suggestive of, but not sufficient to infer, a causal relationship

[a]An array of outcomes is evaluated as part of a broad health effects category: physiological measures (e.g., airway responsiveness), clinical outcomes (e.g., hospital admissions), cause-specific mortality. Total mortality includes all nonaccidental causes of mortality, and conclusions are informed by findings for the spectrum of morbidity effects (e.g., respiratory, cardiovascular) that can lead to mortality. The sections and tables referenced include a detailed discussion of the evidence that supports the causal determinations and the NO_2 concentrations with which health effects have been associated.

[b]Since the 2008 ISA for Oxides of Nitrogen, the phrasing of causal determinations has changed slightly, and the weight of evidence that describes each level in the hierarchy of the causal framework has been more explicitly characterized.

[c]In this ISA, the conclusion is based on cardiovascular effects and diabetes, which are related and share risk factors. Reproductive and developmental effects are separated into smaller subcategories of outcomes based on varied underlying biological processes and exposure patterns over different lifestages.

[32] ISA at 1ix.

Such a result is entirely out of step with the inconsistencies and uncertainties noted by the Administrator throughout his discussion of the proposed NO_2 NAAQS. These inconsistencies and uncertainties covered the full range of evidence available to the Administrator:

- Uncertainties remain regarding the degree to which estimates of long-term concentrations in studies supporting associations between asthma development in children have become stronger (*i.e.*, whether NO_2 is serving primarily as a surrogate for exposures to a broader mix of traffic-related pollutants).[33]

- Greater uncertainty exists with respect to the evidence for non-respiratory effects than the evidence of asthma-related respiratory effects.[34]

- In controlled human exposure studies, less consistent results occur at lower exposure concentrations, particularly 100 ppb, and include a lack of an apparent dose-response relationship and uncertainty in the potential adversity of responses.[35]

- Epidemiological studies conducted in the United States and Canada "do not provide support for associations with asthma-related hospital admissions or emergency department visits in locations that would have clearly met the current standards."[36]

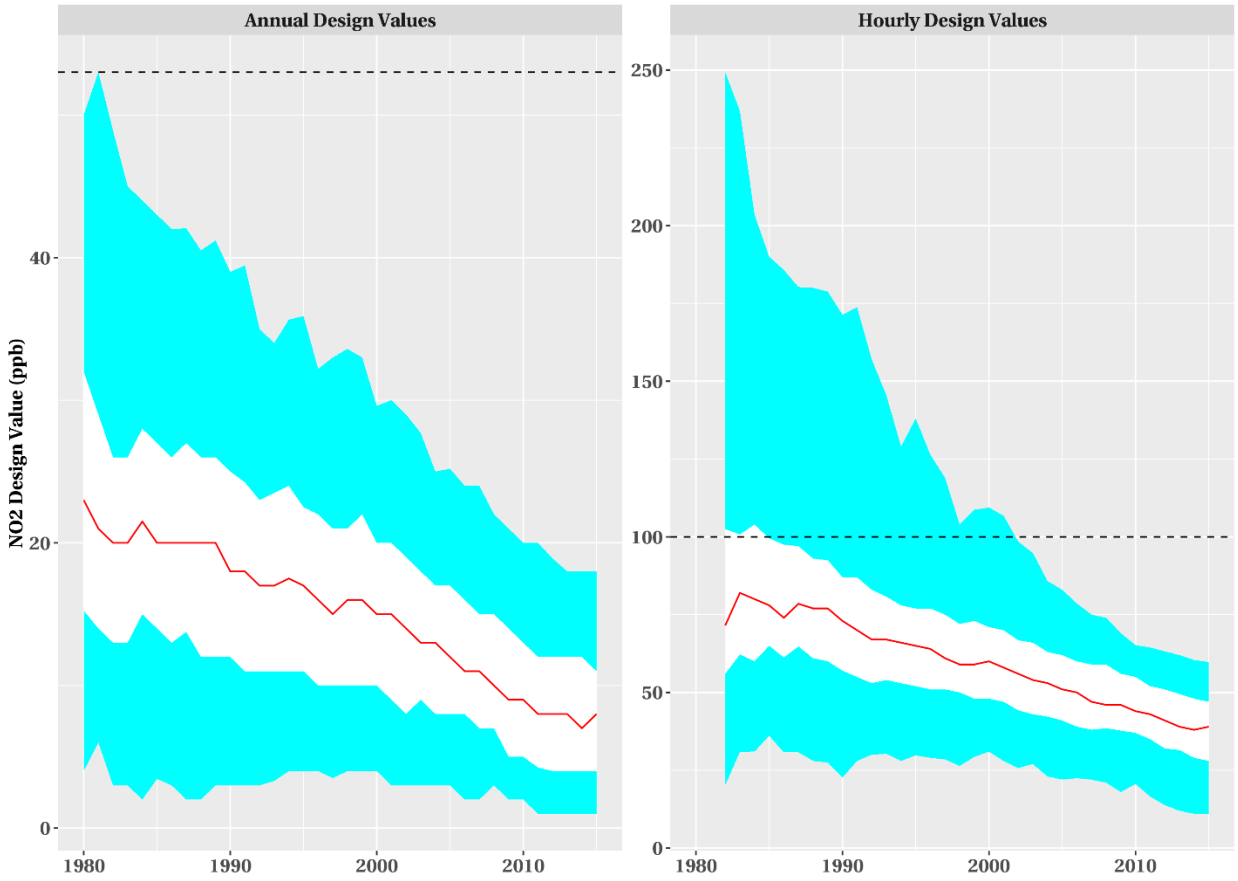
In addition, other policy rationale for not considering less-stringent standards is unpersuasive. In particular, the argument has been advanced that maintaining the current standard is somehow necessary so as to guard against health effects at levels *higher* than allowed under the current standard. Specifically, the Administrator has indicated that when he takes evidence and uncertainties together, it is appropriate to consider "the degree of protection provided against potential exposures to NO_2 concentrations at or above 100 ppb, with the most emphasis on the potential for exposures *at or above 250 ppb*.

But the realistic prospect of such exposures occurring must be seen as extremely limited, both with respect to the current standard (or, theoretically, with respect to a less stringent standard). This is due to the fact (as shown below) that EPA's own monitoring information shows NO_2 ambient levels are far below the level of both the current daily and annual NO_2 NAAQS. The Agency itself cites multiple control programs that will continue to result in decreased NO_2 emissions in coming years, including the effect of mobile source programs under Title II of the CAA, new source performance standards for stationary sources, programs to reduce interstate emissions of NOx from electric generating units and controls on hazardous air pollutants.[37]

Thus, EPA may reasonably project, based on a large body of monitored air quality, that current programs will continue to ensure that NO_2 ambient air values will continue to decrease. While this assessment is not relevant to the Administrator's decision on where to set the level of the NAAQS based on health or welfare effects, it is relevant (and contradictory) to EPA's rationale as

[33] 82 Fed. Reg. at 34,827.
[34] *Id.*, citing U.S. EPA, 2016a.
[35] *Id.* at 34,828.
[36] *Id.* at 34,829
[37] *Id.* at 34,795-6.

to why the current level of the NO2 NAAQS must be maintained in order to guard against exposures at the current 100 ppb level or levels 1.5 times higher.



Distribution of NO2 design values across the U.S. from 1980 -2015. The middle lines represent the median, the middle white band extends from the 25 to 75th percentile, and the outer, colored band extends from the 5th to the 95th percentile.

Both the monitoring information above and EPA's observation concerning the effect of current air programs call into serious question part of the rationale put forward for the proposed standard – *i.e.*, that EPA must be "concerned about exposures to NO_2 concentrations at and above 250 ppb, where the potential for NO_2-induced respiratory effects is supported by the results of the meta-analysis and by consistent results reported across individual studies."[38]

Simply put, this argument is a red herring. It is based on an evaluation that if areas *meet* the current 100 ppb standard (a level that they currently underrun by a substantial margin) there is a serious potential for exposure to 250 ppb air quality (which seems exceedingly unlikely when the median hourly design value is approximately 50 ppb). In other words, if despite over three decades of improving NO_2 air quality, ambient levels of NO_2 suddenly increase by 100 percent (from a median value of approximately 50 ppb to the level of the current 100 ppb standard) then EPA theorizes that it is necessary to maintain the level of the current NAAQS simply on this basis. This analysis defies both logic and experience.

[38] *Id*. at 34,828.

III. EPA Should Consider How Information from Roadside Monitoring Affects EPA's Policy Rationale for NO_2 NAAQS

There is limited information regarding adverse health effects occurring at the level of either the current 1-hour or annual NO_2 NAAAQS. Short-term NO_2 concentrations used in health studies involving healthy adults do not indicate respiratory systems below 4,000 ppb.[39] In addition, in five controlled human exposure studies using individuals with asthma, only one study shows a significant increase in airway responsiveness following short-term exposures to NO_2 concentrations of 100 ppb.[40]

In assessing such information, as well as other information from long-term studies and epidemiological evidence, EPA took into account (during the previous NO_2 NAAQS review) and continues to take into account (during the current review) the fact that large portions of the U.S. population live, work or attend school near roadways where the Agency has assumed that NO_2 concentrations are higher than other areas.[41] Based in part on this assumption, EPA has conducted quantitative analysis of projected health risks for NO_2 concentrations at levels of "public health concern."[42] This analysis uses different "benchmark" concentration levels of NO_2. In the current review, EPA considered benchmarks from 100 to 300 ppb.

While EPA indicates that caution is appropriate when considering the potential health impacts of 1-hour NO_2 concentrations at 100 ppb, there is a major problem with the use of such analysis given that actual, monitored concentrations of NO_2 in areas where EPA considers highest exposures to occur, *i.e.*, near roadways, are far below the assumed benchmark levels. While the available data is variable, on the whole this data indicates that individuals are not exposed to NO_2 concentration levels of 100 ppb, much less higher levels up to 300 ppb. EPA should therefore discount the use of such analysis in the current review.

A. Roadside Monitoring Indicates NO_2 Concentrations Far Below Level of Current NAAQS

In 2009, AFPM (then the National Petrochemical and Refiners Association) submitted comments regarding EPA's proposed revision to the NO_2 NAAQS.[43] AFPM argued that EPA impermissibly considered the design of a new NO_2 monitoring network to be deployed near roadways in determining the requisite level of protection necessary for NO_2. Specifically, EPA considered planned requirements for roadside monitoring with respect to projecting the effects of different levels of the NAAQS, indicating that a standard of 100 ppb could be expected to hold actual concentrations at 90 ppb across locations. EPA also considered roadway monitoring with respect to whether roadside data (available at that time) affected population-exposure estimates.[44]

---

[39] 82 Fed. Reg. at 34,806.
[40] *Id*. Other controlled exposures to individuals with asthma conducted with exercise at concentrations between 150 and 200 ppb also reported a significant increase in only one out of three studies.
[41] *Id*. at 34,816.
[42] *Id*. at 34,817.
[43] Primary National Ambient Air Quality Standard for Nitrogen Dioxide; Proposed Rule 74 Fed. Reg. 34,404 (July 15, 2009).
[44] *Id*. at 34,437.

In comments filed with the Agency, AFPM argued that the EPA Administrator must base any decision regarding the level of the NAAQS with respect to scientific information regarding the health effects of the pollutant and not with regard to planned implementation of a roadway-based monitoring system. AFPM also criticized the use of assumptions regarding the relationship between air pollution measured at microscales near highways and at existing, area-wide monitors. AFPM further cited CASAC comments warning EPA against including presumed near-roadway concentrations in the standard-setting process given the variability that might be expected with regard to roadside monitoring located in various areas under various conditions.

While EPA largely ignored AFPM's comments, more than seven years later, the results of EPA's roadway monitoring effort are now "in" and show that roadside NO_2 concentrations are indeed variable as well as well below the level of EPA's current daily and annual standards. In fact, the results of initial monitoring caused EPA to substantially reduce monitoring requirements for metropolitan areas since it became evident that the original rationale to install such monitors was in error.[45] EPA noted that:

> [N]ew data, which were not available during the 2010 NO_2 NAAQS rulemaking provide the EPA with a different and improved understanding of near-road NO_2 concentrations compared to the time when the network was originally required. In particular, these new data show that NO_2 concentrations from sites adjacent to some of the nation's highest trafficked roads in the most populated [Combined Statistical Areas] (*i.e.*, expected maximum concentrations site in the near-road environment) are not exceeding or even threatening to approach the level of the NAAQS.[46]

In a 2016 EPA analysis of roadside monitoring, the Agency stated that "[t]o date, no near-road NO_2 monitor has recorded an annual mean value that exceeds the 53 ppb NAAQS level, nor has any monitor provided a single year 98th percentile 1-hour daily maximum concentration value above the 100 ppb NAAQS level."[47] With regard to four sites that had a complete year's worth of data in 2013, EPA near-road monitoring showed annual NO_2 levels of between 9 ppb and 18 ppb (compared with the 53 ppb standard) and a highest 1-hour daily measurements of between 34.1 ppb and 49.1 ppb (compared with the 100 ppb standard).[48]

For 2014, the results are even more robust and instructive. Data from EPA's mandated system of new monitors shows that near-road monitored concentrations of NO_2 remain far below applicable standards even on the heaviest-travelled roadways in the United States:

[45] EPA finalized revisions to near-roadway monitoring in 2016. (81 Fed. Reg. 96,381 (Dec. 30, 2016)). The rule removed requirements for near-roadway monitoring for CBSAs of less than 1 million population on the basis that monitored areas are not showing NAAQS concentrations near the level of the NAAQS. 81 Fed. Reg. at 96,384.
[46] *Id.*
[47] Near Road NO_2 Network and Data Analysis, Nealson Watkins, Adam Reff, Docket No. EPA-HQ-OAR-2015-0486
[48] *Id*. at 13.

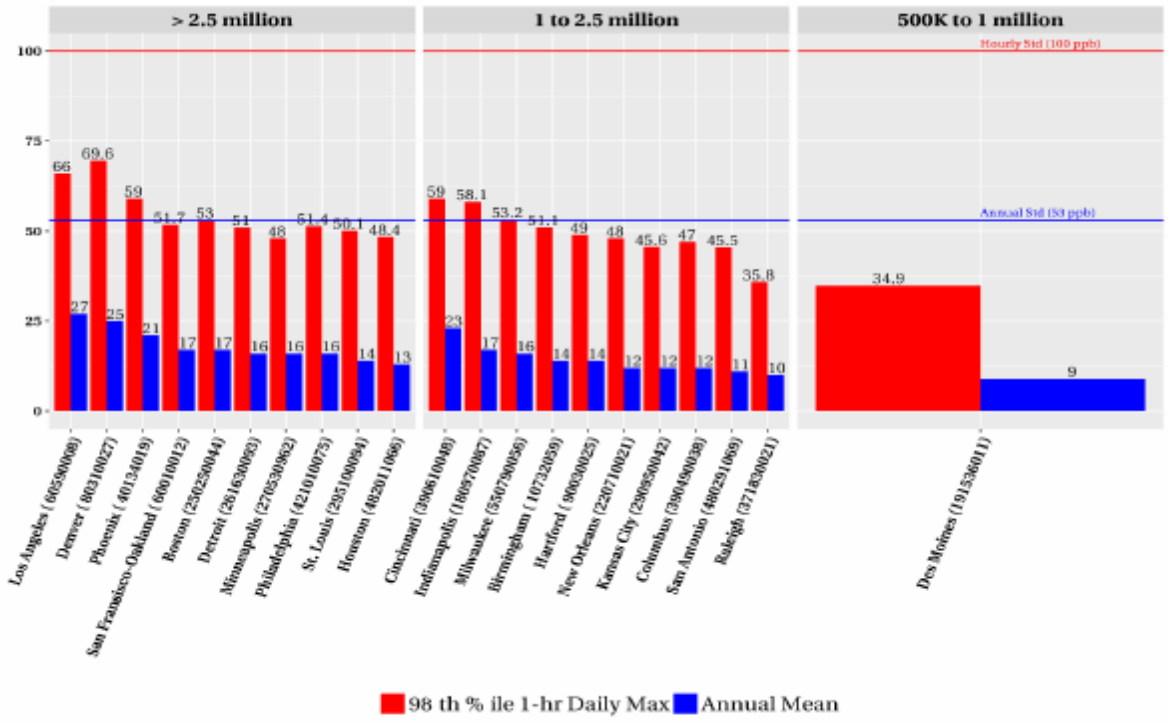


Figure 10. 2014 Near-road NO_2 concentration summary statistics (in ppb) from the sites that had at least 7200 hourly observations in AQS, binned by CBSA poupulation ranges corresponding to the three phases by which the near-road network is being installed.

B. EPA Should Further Examine Implications of Actual Roadside Monitoring Data Regarding Assumed Levels Used in EPA Benchmarks

These findings from the current network of 69 operating sites confirm and validate AFPM's 2009 comments that additional research was necessary prior to requiring the installation of new roadside monitoring across the country. Had EPA adopted this approach, it could have conserved significant Agency and state resources (as well as avoided the effort needed to propose and finalize new regulations repealing part of its original monitoring requirements).

More importantly, in the context of the current rulemaking, this experience further demonstrates that EPA should be extremely hesitant to posit ambient exposure to NO2 (and project health effects) based on assumptions concerning the relationship between a NAAQS standard and estimated or modeled air quality. EPA's original projections of the relationship between roadside monitoring and area-wide NO_2 monitoring have proved to be far off the mark for many areas. In 2010, EPA projected that NO_2 concentrations near roads "may be 30 to 100% higher than concentrations away from roads."[49] But actual monitoring data has shown varied results, including instances where area-wide monitors measured *higher* levels of NO_2 than monitors located near roadways. A limited comparison on near-road and non-near-road concentrations from 2014 shows that some major metropolitan areas experiencing higher NO_2 concentrations at area-wide monitors versus area-wide monitors cited in the same area.[50]

[49] 74 Fed. Reg. at 34,437.

[50] ISA, Table 2-10 at 2-67-2-68. For example, although all results were well below the current NAAQS, in 2014 both annual average NO_2 concentrations in some areas (*e.g.*, New York, NY; Phoenix, AZ; Kansas City, MO; Cleveland, OH; and Raleigh, NC) and 1-hour maximum 98th percentile NO_2 concentrations (e.g., Denver, CO; Los

EPA has determined no areas of the country are in nonattainment with the current NAAQS on the basis of either area-wide monitoring or near-road monitoring. [51] It has therefore not designated areas as "nonattainment" or required the submission of state implementation plans to address NO_2. But this is not a case of "no harm, no foul." EPA continues to use seriously flawed exposure benchmarks as part of the Agency's justification for setting the level of the 1-hour standard. EPA should therefore reexamine such flawed assumptions and, more importantly, avoid basing policy judgments regarding the requisite level of the NO_2 NAAQS on the basis of non-monitored air quality.

Instead, EPA should further examine the actual monitoring data it has with respect to NO_2 and consider how this new information may impact its assessment of exposures. The utility of analyzing projected health effects at 100 ppb and higher concentrations should be called into question when actual monitoring data, as supplemented by additional near-road monitoring, shows a decades-long downward trend and current levels that do not approach either the current hourly or annual NO_2 standards.

IV. Conclusion

EPA is proposing to retain the current standard "giving particular weight to the assessment of the evidence in the ISA; analysis and considerations in the Policy Assessment (PA); and the advice and recommendations of the CASAC."[52] While EPA did not propose to make the current NO_2 NAAQS more stringent, neither did the Agency seriously examine whether the NAAQS should be made less stringent. Instead, the proposed rule indicates only that "the Administrator does not believe standards less stringent than current standards would be sufficient to protect public health with an adequate margin of safety."[53]

Because EPA has not proposed a level for the NAAQS more stringent than the current NAAQS, or articulated any evidence supporting a more stringent standard, EPA may not finalize a level more stringent than that it has proposed. But based on AFPM's review of the proposed rule, ISA, PA and other documents placed into the docket, EPA should also:

- Examine whether alternative, less stringent standards are appropriate based on uncertainties in the body of scientific information available to EPA; and

- Further examine whether NO_2 concentrations that remain well below the level of current standards, as verified by current monitoring, call into question EPA's exposure analysis and its resulting impact on the Administrator's determinations in the proposed rule.

Angeles, CA; Phoenix, AZ; Boston, MA; Columbus, OH; Louisville, KY; and Buffalo, NY) experienced higher levels a non-near-road monitors than at near-road monitors. EPA's own limited analysis of this variability shows that in some cases, such as Boston, MA, area-wide and near-roadway concentrations are nearly identical.

[51] EPA classified all areas of the country as "unclassifiable/nonattainment" even though available monitored air quality at the time indicated that there were no violations of the NAAQS. 77 Fed. Reg. 9.532 (Feb 17, 2012). Since that time, EPA has not designated any area as nonattainment and maintains in the current proposed rule that no areas currently violate either of the NO_2 NAAQS.

[52] 82 Fed. Reg. at 34,793.

[53] *Id.* at 34,830.