

Table 1. Major EPA NO_x and VOC emissions control programs.

	Legislation/Regulation	Compliance Data	Affected Sources	Projected/Actual Emissions Reductions
Power Sector Sources	Title IV NO _x Reduction Program www.epa.gov/airmarkets/progsregs/arp/nox.html	1996: Phase 1 2000: Phase 2	Certain coal-fired EGUs (boilers only) subject to Title IV sulfur dioxide (SO ₂) emissions limitations	Actual 2006 nitrogen oxides (NO _x) emissions were 4.7 million tons below year 2000 NO _x emissions levels projected for all affected units had the program not been implemented
	NO _x SIP Call/NBP www.epa.gov/airmarkets/progsregs/nox/sip.html	2004–2007, depending on state	EGUs, large industrial boilers, and turbines in 20 eastern states and the District of Columbia	NO _x reductions of 880,000 ton/ozone season by 2007
	CAIR NO _x Annual and Ozone Season Trading Programs www.epa.gov/airmarkets/progsregs/cair/index.html	2009	Fossil-fuel fired EGUs in 28 eastern states and the District of Columbia (3 states: NO _x ozone season only; 3 states: NO _x annual only; 22 states and DC: both NO _x ozone season and annual)	NO _x reductions of 2 million ton/yr by 2015
Mobile Sources	Tier 2 Vehicle and Gasoline Sulfur Program www.epa.gov/otaq/regs/ld-hwy/tier-2/index.htm	2004: Gasoline sulfur content 2004–2009: Phase-in vehicle standards by model year (MY)	Gasoline sold nationwide: cars, light-duty trucks, and certain size SUVs sold outside California	NO _x reductions of 2.8 million ton/yr by 2030; also reduces volatile organic compounds (VOCs)
	Heavy Duty Highway Diesel Program www.epa.gov/otaq/highway-diesel/index.htm	2006: Diesel sulfur content 2007 (MY): Begin phase-in of new engine standards	Diesel fuel sold nationwide; heavy-duty highway diesel engines (trucks, buses, etc.) nationwide	NO _x reductions of 2.6 million ton/yr by 2030; also reduces VOCs
	Clean Air Nonroad Diesel Program www.epa.gov/nonroad-diesel/2004fr.htm	2007: Diesel sulfur content 2008 (MY): Begin phase-in of new engine standards	Nonroad diesel fuel sold nationwide; diesel engines nationwide used in most construction, agricultural, and industrial equipment	NO _x reductions of 738,000 ton/yr by 2030; also reduces VOCs
	Control of Hazardous Air Pollutants from Mobile Sources (MSAT 2) www.epa.gov/OMS/toxics.htm	2009: VOC controls on gas cans 2010 (MY): Begin phase-in of new engine standards 2011: Gasoline benzene content	Gasoline-fueled passenger vehicles nationwide; gas cans nationwide; gasoline sold nationwide	VOC reductions >1 million ton/yr by 2030
(Proposed) Locomotive and Marine Diesel Standards www.epa.gov/otaq/locomotv.htm www.epa.gov/otaq/marine.htm	2010: Remanufacture of existing engines 2014 (MY): Begin phase-in of new engine standards as early as 2008	Locomotive and marine diesel engines nationwide	(Proposed) NO _x reductions of 765,000 ton/yr by 2030; also reduces VOCs	

Source: NO_x Budget Trading Program, 2006 Program Compliance and Environmental Results, U.S. Environmental Protection Agency, www.epa.gov/airmarkets/progress/nbpo6.html.



have decreased 66% since 1998.³

This progress will continue. As Table 1 indicates, federal regulations will significantly reduce emissions that trigger ground-level ozone over the next two decades:⁴ emissions of nitrogen oxides from power plants will be cut by more than 60% by 2015; cleaner gasoline will be used in cars and trucks that must be 77–95% cleaner than those produced before 2004; and the annual emissions reductions from the use of ultra-low-sulfur diesel with cleaner technology engines will be equivalent to removing the pollution from more than 90% of today's trucks and buses by 2030.

OZONE SCIENCE IS UNCERTAIN

EPA must set NAAQS at the level that is requisite—neither more nor less stringent than necessary—to protect the public health and welfare. In 1997, EPA established both primary (based on protection of public health) and secondary (based on protection of public welfare) NAAQS for ozone at an 8-hr average level of 0.08 parts per million (ppm). At that time, the EPA administrator determined that those standards were at the level requisite to protect health and welfare. Now, the administrator has proposed to find that these standards fail to provide the requisite protection.

As explained below, however, the current scientific evidence does not demonstrate that the present standards fail to protect the public health and welfare. The current standards should therefore be retained. In fact, the science behind changing the ozone standards is uncertain and variable. While the NAAQS are to be based on the air quality criteria document, the administrator must exercise policy judgment in setting them at the level that is requisite.⁵ In exercising that judgment, he may not engage in “sheer guesswork.”⁶ And in the context of a change to an existing NAAQS, he must provide a “reasoned analysis for the change,”⁷ acknowledging any change from prior policy judgments about the requisite level of health and welfare protection,⁸ and explaining why those earlier judgments no longer govern.⁹

In assessing what standard would provide the requisite protection, the administrator receives advice from EPA's Clean Air Scientific Advisory Committee (CASAC). In this case, CASAC offered a collective recommendation as to the level of the NAAQS for ozone. However, the basis for its recommendation was not clearly articulated, limiting the usefulness of that recommendation in informing the administrator's policy judgment.

THE PRIMARY STANDARD

In reaching his policy judgment concerning the primary standard that will provide the requisite protection of public health, the administrator considers data from different types of studies: human clinical studies, epidemiological studies, and toxicological studies. He also relies on a health risk assessment prepared for EPA.

Clinical Studies

The human clinical studies conducted with controlled ozone exposures of exercising human volunteers provide useful information on changes in respiratory function.

When the current standard was set, there was clear evidence of temporary lung function changes after exposures to ozone at concentrations of 0.08 ppm and higher. Recent human clinical studies are not indicative of effects greater or different from those that had been demonstrated at that time. There are only a limited number of new human clinical studies and only one set of studies, those by Dr. William C. Adams, examined exposures below the 0.08-ppm level.

Dr. Adams' studies involved exposures at 0.060, 0.040, and 0.080 ppm. The administrator recognizes that Dr. Adams reported “no statistically significant differences for FEV₁ decrements [reductions in the volume of air that a subject can exhale in one second, a common lung function measurement] nor for most respiratory symptom responses.” The administrator notes, however, that EPA staff has conducted an unpublished reanalysis of the Adams data using a different statistical technique and indicates that for the 0.06-ppm exposure agency staff “found small group mean differences from responses to filtered air that were statistically significant.”¹⁰

Dr. Adams reviewed the unpublished reanalysis and disagrees that it demonstrates effects associated with exposure to ozone at a concentration less than that of the existing 0.08-ppm NAAQS. He stated in a comment to the EPA Docket: “EPA has misinterpreted the statistics contained in my published, peer-reviewed paper.”¹¹ Furthermore, Dr.

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Adams concludes: "... that the FEV₁ response in healthy young adults to 6.6 hr exposure to 0.06 ppm O₃ in my study (Adams, 2006a) does not demonstrate a significant mean effect by ordinarily acceptable statistical analysis."¹²

EPA appears to be relying on its unpublished, unreviewed staff analysis—one that contradicts the author's original peer-reviewed results—to help support a call for a tighter standard. Other scientists have questioned placing such great weight on this single, controversial analysis, stating, "The uncertainty that necessarily surrounds a secondary analysis and the integration of results from a single study in one laboratory with 0.06 ppm ozone exposures and results obtained in studies at higher concentrations by other investigators requires that further research be conducted to clarify the issue."¹³ We concur that the EPA analysis does not establish that a more stringent primary NAAQS than that set in 1997 is now requisite to protect public health with an adequate margin of safety.

Epidemiological Studies

Similarly, recent epidemiological studies do not establish that a more stringent primary ozone NAAQS is now requisite. These studies do not consistently report associations between ozone and health effects. Moreover, they cannot establish that ozone is the cause of any of the health effects that have been studied.¹⁴ For example, recent epidemiological studies report inconsistent findings concerning possible associations between ozone acute mortality, an effect not addressed in 1997. Major long-term epidemiological studies have not shown an association between ozone exposure and long-term mortality.

The first of these points can be illustrated by looking more closely at the 2004 Bell et al. study, which the administrator described as presenting "key findings." This study looked at data from 95 cities, in the majority of which there was no statistically significant association between ozone and premature mortality.¹⁵ Indeed, for approximately one third of these cities, the raw estimates of the association between ozone and premature mortality were actually negative (i.e., suggesting ozone reduced mortality risk), and in at least one case, statistically significantly so.¹⁶ Only when the data from all the cities were combined through a Bayesian analysis was a statistically significant positive association reported. In a review of the statistics, Dr. Paul Switzer, a professor of statistics at Stanford University, noted that, "The meaning and relevance of a statistically significant 'national' effect is unclear and its use in a two-stage model for city-specific effects obscures the issue of heterogeneity."¹⁷ Therefore, it was inappropriate for Bell et al. (or any other investigator) to prepare a national estimate from the heterogeneous data from the 95 cities. This is one illustration of why the recent epidemiological studies do not justify a conclusion that a more stringent standard is requisite to protect public health.

Toxicological Studies

Toxicological data from animal studies provides a basis for hypothesizing how ozone may cause biological changes.

Three studies from the Health Effects Institute¹⁸⁻²⁰ showed no difference in lifespan and only modest effects on mouse and rat body weight associated with ozone exposure at levels well above what is found in ambient air (up to 1 ppm ozone). Exposure to ozone at ambient levels (0.12 ppm) had little or no measurable effect on pulmonary function or impact on nasal and lung tissues of both rats and mice. There were no ozone-related increases in the incidence of neoplasms in either species. In summary, these toxicological data do not support a tightening of the standards.

EPA's Health Risk Assessment

EPA's health risk assessment is based on the unwarranted assumption of a linear concentration–response relationship between ozone and health effects in the epidemiological studies and uses incorrect ozone background information. Therefore, EPA has overestimated the risk impacts that occur at lower ozone levels; EPA's estimates of risk both at the level of the present ozone standard and at alternative possible standard levels are too uncertain to provide the basis for a conclusion that the present standard fails to provide the requisite protection of public health.²¹

With regard to EPA's assumption of a linear concentration–response relationship, a recent report by a group of scientists involved in a workshop on ozone health effects explained: "In the risk assessment, EPA takes the numerical estimate of the association from a particular epidemiological study and interprets that numerical estimate as the slope of a 'concentration–response' function for the population at large. . . . Because of the particular shape of the concentration–response relationship that EPA employs, EPA assumes that the change in population risk per unit change in ambient concentrations will be the same at much lower concentration as it was for the particular levels of pollution that were present at the time the study was conducted."²²

There is, however, ample evidence in the epidemiological literature that the relationship between ambient ozone levels and health effects is nonlinear.²³ There is also evidence that the relationship between ozone and health endpoints in the human clinical literature is nonlinear.²⁴ EPA's assumption of linearity in its risk assessment is therefore invalid and the resulting risk estimates are also invalid.²⁵

EPA's mischaracterization of uncontrollable background ozone levels also contributes to unrealistically high estimates of health benefits from a more stringent primary ozone NAAQS. When estimating the potential health risks and benefits associated with alternative NAAQS, EPA reasonably considers only health effects that it associates with ozone above an estimated uncontrollable policy relevant background (PRB) level.²⁶ Since it established the current ozone NAAQS in 1997, however, EPA has changed the way it calculates ground-level ozone background levels and by doing so has inflated the estimated benefits of a changed standard by as much as 90%.²⁷ Specifically, EPA now discounts as background all man-made ozone sources in North America—even those outside the boundaries of the United States—and has converted from a measured value to characterize ozone



background to a modeled one. This was done despite a CASAC letter indicating that EPA “did not provide a sufficient base of evidence” that this new method was the best choice.²⁸ The resulting estimates of background produced by the GEOS-CHEM model are far lower than ozone levels observed at remote monitoring sites, which receive air coming off of the ocean for prolonged periods of time. An air quality monitoring site at Trinidad Head in California, for example, regularly has hourly ozone concentrations of more than or equal to 0.05 ppm (clearly above the 0.015–0.035-ppm background ozone levels predicted by GEOS-CHEM and used by EPA in its risk assessment), during periods when the air is dominated by flow that originates outside of continental North America.²⁹

What does this mischaracterization of PRB mean for EPA’s risk estimates? EPA has undertaken a limited sensitivity analysis to examine how sensitive its risk estimates are to differing PRB estimates. The agency acknowledges that assuming PRB is a mere 0.005-ppm higher than that predicted by the GEOS-CHEM model decreases estimates of nonaccidental mortality by 50% or more.³⁰ Indeed, increasing the PRB by 0.005 ppm over that predicted by GEOS-CHEM resulted in a 62% decrease in predicted incidence of nonaccidental mortality in Los Angeles upon attainment of the present standard when 2002 ozone air quality data were used.³¹ While EPA indicates that increasing PRB by 0.005 ppm produced only a “small” change in estimates of lung function changes,³² a greater (and more realistic) change in PRB would be expected to produce a much more significant decrease in the estimated number of lung function effects attributable to ozone above background levels.³³

Certainly, the sensitivity of the risk estimates to different assumptions about PRB highlights the high degree of uncertainty in EPA’s risk estimates. The fact that the estimated health risk benefits of a more stringent NAAQS drop significantly when higher, more realistic estimates of PRB are used, points out, however, the lack of a meaningful health basis for concluding that a more stringent ozone NAAQS is warranted.

THE SECONDARY STANDARD

The EPA administrator has proposed two options for a revised secondary ozone NAAQS to provide greater protection for vegetation. One proposed option is to establish a cumulative seasonal (i.e., three-month) standard, using a W126 indicator to place greater weight on higher concentrations. A broad range of 7 to 21 ppm-hr is proposed for such a standard. The second proposed option is to continue the practice of equating the secondary standard to the primary standard.

The recent scientific evidence does not support a finding that the present secondary ozone NAAQS fails to provide the requisite protection of public welfare. Indeed, there has been very little new information on the effects of ozone on vegetation since the current standard was established in 1997. CASAC has, in fact, lamented the lack

of funding since the 1980s to study ozone effects on plants. And, as was the case for the primary standard, any possible benefits estimated to result from a more stringent secondary NAAQS are highly uncertain, both because of unrealistically low estimates of uncontrollable background ozone levels and because of uncertainty about the appropriate concentration–response functions to use in characterizing vegetation response to ozone.

Moreover, evidence does not justify a change to a W126 indicator for the secondary NAAQS. As pointed out by Dr. Allen Legge, a CASAC panel member with ecosystem expertise, the case has not been made that the W126 indicator has a biological basis.³⁴ In addition, the W126 standard proposed by the EPA administrator would not provide uniform national protection of vegetation.

COSTS WILL BE REAL

A more stringent ozone standard will burden the states with a new and more difficult target before they complete work on and implement attainment plans for the current standard. As already indicated, tremendous progress is being made cleaning our air while our economy is expanding and vehicle miles traveled are increasing. EPA estimates the cost of meeting a 0.070-ppm standard to be US\$10 billion to US\$22 billion per year in 2020.³⁵ According to EPA, Americans will be investing close to US\$27 billion per

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year in 2010 to improve air quality just to meet the current CAA provisions, including the existing ozone standards.³⁶ If a new standard is adopted, many local communities will be saddled with still more costs that will hurt both large and small businesses and prevent expansion and growth in many urban, suburban, and rural counties. Hurting local economies without a clear scientific basis for selecting a different numeric standard is not a prudent use of resources. EPA's proposed revisions could perturb ongoing and planned implementation processes just now being put into place to meet the most recent changes in the current standard. Instead, EPA and the states can best contribute to better air by helping communities attain the existing standards. Hampering local economies without compelling changes in the science makes no sense.

CONCLUSION

The efforts of EPA, the states, and local communities in providing cleaner air once again need to be acknowledged. Looking forward, further improvements will come through fully implementing current regulations designed to meet the existing standards. Of course, the CAA mandates that the ozone NAAQS be established based solely on science. A group of 10 scientists, knowledgeable about the science and policy issues underlying the setting of the NAAQS for ozone, have reviewed the available scientific information on ambient ozone and its health effects and have concluded that no scientific methodology can define the precise numerical level and related averaging time and statistical form of the ozone standard and that these are policy judgments.³⁷ This highlights the importance of getting the science right, and the uncertainty in the current science does not support tightening the standards and imposing further costs for the uncertain benefits proposed. **em**

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5. The responsibility for making this judgment by law rests with the EPA administrator and cannot be delegated to, for example, either EPA staff or CASAC. See CAA § 301(a)(1), 42 U.S.C. § 7601(a)(1).
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24. See Hazucha, M.J.; Lefohn, A.S. Nonlinearity in Human Health Response to Ozone: Experimental Laboratory Considerations; *Atmos. Environ.* **2007**, *41*, 4559. Moreover, given Adams' report of no statistically significant associations between ozone and health effects at concentrations of 0.060 ppm and 0.040 ppm, "EPA should not rely on the exposure response curve derived from the human laboratory experiment studies below 0.08 ppm." Lefohn, Vol. 3, at 29.
25. Dr. Allen Lefohn points out that EPA conducted a sensitivity analysis to a nonlinear (threshold) model in its assessment of the risk associated with short-term exposure to PM_{2.5} and found that the predicted mortality risk for Detroit was reduced by between 44% and 80%, depending on the threshold modeled. He predicts that using a nonlinear dose-response function for the ozone risk assessment would also reduce substantially the estimated risk. Lefohn, Vol. 3, at 32-33.
26. EPA Staff Paper at 5-13. EPA defines PRB as "the distribution of ozone concentrations that would be observed in the United States in the absence of anthropogenic (man-made) emissions of precursor emissions (e.g., VOC, NO_x, and CO) in the United States, Canada, and Mexico." EPA Staff Paper at 2-48.
27. If EPA had assumed a background of 0.04 ppm as it did in 1997, its estimate of the number of premature deaths per year in Detroit based on 2004 air quality data would have been reduced from 24 to 0.1. See Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone. Report of a Working Conference held in Rochester, NY, June 5-6, 2007.
28. CASAC letter, March 26, 2007, p. 2.
29. Allen S. Lefohn, Ph.D. EPA's Proposed Rulemaking for the Primary Ozone Standard: Volume 2, Underestimated Policy-Relevant Background and Its Effects on EPA's Human Health Risk Estimates, October 8, 2007.
30. EPA Staff Paper at 5-82. Because the PRB levels at the Trinidad Head site are often more than 0.005 ppm higher than those predicted by GEOS-CHEM, the risk estimates would be reduced even further if the Trinidad Head data were used for PRB. Lefohn, Vol. 2 at 6-7.
31. Lefohn, Vol. 2 at 13. Lefohn notes that the estimates of nonaccidental mortality in Los Angeles using 2002 air quality were reduced by 72% and 86% from that predicted using the GEOS-CHEM PRB, respectively, when attainment of a 0.07- or a 0.06-ppm standard was modeled.
32. EPA Staff Paper at 5-81.
33. Lefohn, Vol. 2, at 14. EPA has said that it "intends to conduct addition sensitivity analyses related to policy-relevant background and its implications for the risk assessment." *Fed. Regist.* **2007**, *72*, 37,857/3; n. 40.
34. Legge, A.H. CASAC Review of the EPA's Final Ozone Staff Paper, March 26, 2007, at C-18.
35. *Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone*; U.S. Environmental Protection Agency, Washington, DC, 2007; Table 5.8.
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