Executive Summary

The American Petroleum Institute (API) supports the option EPA included in the proposal to retain the current primary National Ambient Air Quality Standards (NAAQS) for ozone at the level of 0.075 parts per million (ppm). Further, API supports EPA's proposal to retain the form of the secondary standard equal to the primary standard, in this instance at 0.075 ppm. API finds that the science does not support a change in these standards and that the current standards protect public health and welfare with an adequate margin of safety.

API finds the current standards protect public health.

Under Section 109(b) of the Clean Air Act, the primary NAAQS must be set at a level requisite to protect public health with an adequate margin of safety. While the protection of sensitive subpopulations is an important part of establishing protectiveness with an adequate margin of safety, Congress did not intend for EPA to identify and impose a standard that guaranteed zero risk to all populations. The existing 2008 standard of 0.075 ppm, or 75 ppb, is protective of public health with an adequate margin of safety, accounting for sensitive subpopulations.

EPA claims a substantial amount of new scientific evidence since the last ozone NAAQS review supports a potential change in the level of the primary and secondary standards. API however, finds little in this evidence is truly new, and that this evidence does not reduce the uncertainties and limitations of the science so therefore does not support changing the current standards. In particular, the conclusions of EPA's review relied heavily on the results of the clinical, controlled exposure studies (Adams, 2002, 2006; Schelegle *et al*., 2009; Kim *et al*., 2011),[1] correctly placing more weight on these results than epidemiological studies. In these clinical studies ozone's impact was assessed by measuring lung function, specifically, a decrease in the forced expiratory volume in 1 second (FEV_1). In each study a small number of people (fewer than 60) were exposed, and very few subjects responded with FEV_1decrements greater than 10% at exposures below 0.080 ppm. Adams (2002, 2006) found no effects of ozone at exposures below the current standard. Kim *et al*. (2011) tested only 0.060 ppm ozone and reported responses in only three subjects, but found no correlation between ozone exposure and symptoms. Schelegle *et al.* (2009) reported responses in six subjects at 0.072 ppm, but the severity of symptoms was not correlated with the subjects' FEV_1 decrements. In these studies, subjects were engaged in quasi-continuous strenuous exercise for an extended period of time, leading to worst-case exposure scenarios that almost no one, including outdoor workers, children and other sensitive subgroups, experiences in the real world. It is thus inappropriate to extrapolate such findings as typical of the general US population or groups of sensitive individuals in the population.

[1] Adams, WC. 2002. "Comparison of chamber and face-mask 6.6-hour exposures to ozone on pulmonary function and symptoms responses." *Inhal. Toxicol.* 14(7):745-764. Adams, WC. 2006. "Comparison of chamber 6.6-h exposures to 0.04-0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses." *Inhal. Toxicol.* 18(2):127-136. Schelegle, ES; Morales, CA; Walby, WF; Marion, S; Allen, RP. 2009. "6.6-Hour inhalation of ozone concentrations from 60 to 87 parts per billion in healthy humans." *Am. J. Respir. Crit. Care Med.* 180(3):265-272. Kim, CS; Alexis, NE; Rappold, AG; Kehrl, H; Hazucha, MJ; Lay, JC; Schmitt, MT; Case, M; Devlin, RB; Peden, DB; Diaz-Sanchez, D. 2011. "Lung function and inflammatory responses in healthy young adults exposed to 0.06 ppm ozone for 6.6 hours." *Am. J. Respir. Crit. Care Med*. 183:1215-1221.

Many of the "new" epidemiology studies cited in the review were re-analyses of datasets that were considered in previous EPA reviews and thus do not constitute new evidence. Those "new studies" that are available have uncertainties similar to those in previous studies, including exposure measurement error, sensitivity to model specification, and unresolved confounding. Finally, new evidence of effect modifiers of ozone risk such as genetic variants, age, and nutrient intake is limited and inconsistent in most cases.

There are problems with EPA's application of the models used to estimate increases in health effects from ozone exposure, as the approaches employed result in systematically overestimates of true risk and mask the associated uncertainty. EPA used the Air Pollutants Exposure (APEX) model and the McDonnell, Stewart, and Smith (MSS) response model, which is based on the results of controlled human exposure studies, to estimate ozone exposures and associated lung function decrements. In applying the MSS model, EPA did not use the version that accounts for the responder's body mass index (BMI); even though it provides a better fit of the exposure study data. EPA compounded conservative assumptions that resulted in overestimates of the number of individuals in susceptible population groups, such as children, that would experience lung function decrements caused by ozone. The uncertainty in the APEX projections was absent from the Health Risk and Exposure Assessment document that informed the Proposed Rule. As a result, the Agency portrayed the projections of lung function decrements as having a level of certainty that is not scientifically supportable.

EPA also used the Benefits Mapping and Analysis Program (BenMAP) model, which is based on epidemiology data, to estimate mortality and morbidity risks from ozone exposures. The Administrator acknowledged significant limitations of the BenMAP risk estimates, but she did not discuss the inadequate consideration of concentration-response function thresholds, despite evidence supporting threshold modes of action which lead to overestimates of mortality. A full consideration of thresholds highlights the considerable degree of uncertainty associated with these risk estimates.

Finally, due to the complexity of atmospheric chemistry and the interplay between naturally occurring and human-influenced ozone formation, EPA cannot assume that a lower NAAQS for ozone will provide substantial health benefits. Without an improved understanding of these atmospheric processes, a lowering of the NAAQS as proposed will not necessarily lead to that benefit.

EPA should address issues related to implementation of a lower ozone NAAQS before lowering it.

API finds numerous concerns with the proposed implementation changes as well as the lack of guidance and regulations for other areas to address implementation of a lower NAAQS including:

- Problems with the proposed Appendix U to 40 CFR 50 related to treatment of monitoring data.
- Issues with the proposed changes to monitors and monitoring methods.
- Lack of designation guidance, infrastructure SIP guidance, rules on nonattainment area classification, SIP due dates, and attainment dates.

- Lack of modeling guidance for the contribution of a single source of ozone and no defined significant impact level for ozone for prevention of significant deterioration (PSD) and nonattainment new source review.
- Insufficient time proposed for grandfathering PSD permit applications.
- EPA's failed approach to address background ozone issues through the Exceptional Events, Rural Transport, and International Transport Rules.
- Failure to provide guidance or rules for how to address conformity.

EPA should give state and local governments a chance to meet the most recent standards before changing them again.

API encourages the EPA Administrator complete the current review of the ozone standards by affirming that the standards finalized on March 12, 2008 continue to protect the public health with an adequate margin of safety. These standards are only now being implemented. In fact, EPA only finalized the State Implementation Plan (SIP) Requirements Rule during this comment period on March 6, 2015. States have a number of new deadlines looming as a result of this new rule. In fact, several deadlines have actually already passed:

- Emission inventories and emission statement SIPs are due from states with Marginal and higher area no later than July 20, 2014 (already passed).
- Reasonably Available Control Technology (RACT) SIPs for Moderate and higher areas, and all states in the Ozone Transport Region (OTR), are due no later than 2 years [from effective date of designation], July 20, 2014 (already passed).
- 15% Reasonable Further Progress (6-year ROP/RFP) SIPs for Moderate and higher areas are due no later than 3 years (July 20, 2015) (in 4 months).
- Non-attainment NSR (NNSR) SIPs are due no later than 3 years (July 20, 2015) (in 4 months).
- Attainment plan with Reasonably Available Control Measures (RACM) and attainment demonstration SIPs are due no later than 3 years (Moderate) or 4 years (Serious and higher) (July 20, 2015 or July 20, 2016) (in 4 to 16 months).
- RFP SIPs showing an average of 3% reduction in emissions per year after the initial 6-year period for Serious and higher areas are due no later than 4 years (July 20, 2016) (in 16 months).

Some of the tools needed to begin the implementation of the 2008 standard are only now beginning to appear. For example, states may need to make attainment demonstrations and often rely on EPA guidance to make those determinations. EPA only recently released guidance for public comment, which ended March 13, 2015, and states will still need to wait until later this year for EPA to issue the finalized guidance.

EPA should not set standards that cannot be achieved because of background ozone levels.

The Clean Air Act is clear that NAAQS are not intended to reduce ozone concentrations to or below natural background levels. NAAQS levels are required to be set at concentrations that can be achieved by regulation of US man-made contributors to ozone. Section 107(a) of the Act requires that the implementation plans submitted by the states specify the manner in which the NAAQS "will be achieved and maintained," and Section 110(a)(2)(C) requires that such state implementation plans (SIPs) must include an enforcement and regulation program "as necessary **to assure that [NAAQS] are achieved**" (emphasis added). For the ozone NAAQS to be achievable as required under the Clean Air Act, it must be set at a level above that of peak natural background concentrations.

Changing the standards levels at or below peak background levels, as proposed in this rulemaking, would result in many areas of the country facing the huge economic burden of a non-attainment designation, with some of these areas never being able to achieve attainment. EPA has never established a NAAQS at background levels.

EPA should not set standards that threaten America's competitiveness and American jobs.

The February 2015 study by NERA Economic Consulting[2], commissioned by the National Association of Manufacturers, showed this could be the most expensive regulation ever imposed on the American public. The analysis found that the EPA's proposed regulation could reduce US gross domestic product by $140 billion per year, result in 1.4 million fewer job equivalents, and cost the average US household $830 per year in the form of lost consumption.

This analysis, besides enumerating the potential economic consequences of this proposal, highlights a related mechanism to the potential adverse health consequences related to the tightening of the standards. As described by Amy Gutman in the Harvard Public Health magazine[3], there is substantial evidence linking job losses to shorter lives and more health-related problems. Gutman cites Sullivan and von Wachter[4] as having found that in the year after workers lose a job in mass layoffs, their chances of dying doubled. And though the heightened risk tapered off over the years, it was still significantly higher 20 years later. In testimony, von Wachter indicated that job loss is also typically followed by an extended period of instability of employment and earnings and that during this period, those who lost a job can also experience declines in health. Furthermore, von Wachter indicates that the consequences of job loss are also felt by workers' children, who can suffer from the consequences even as adults, and by their families[5]. Before dismissing what could be taken as a purely economic argument, policy makers should weigh the known consequences of job impacts from tightened standards. It is well established in

[2] NERA Economic Consulting (NERA). 2015. "Economic Impacts of 65 ppb National Ambient Air Quality Standard for Ozone Executive Summary." Prepared for National Association of Manufacturers (NAM). Accessed at http://www.nam.org/Issues/Ozone-Regulations.
[3] http://www.hsph.harvard.edu/magazine-features/failing-economy-failing-health/
[4] Sullivan, Daniel and Till von Wachter. 2009. "Job Displacement and Mortality: An Analysis using Administrative Data." *Quarterly Journal of Economics* Vol.124 (3): 1265-1306.
[5] Testimony before the Subcommittee on Income Security and Family Support of the Committee on Ways and Means "Responding to Long-Term Unemployment" Till von Wachter, June 10, 2010.

epidemiology that income is an inverse predictor of illness and early mortality[6]. Also, unemployment is also an established risk factor to elevated illness and mortality rates.[7] These adverse impacts to the economy will also impact human health. No analysis has been done to-date by CASAC or EPA on the health effects from the cost to the economy and loss of jobs. CASAC has a statutory obligation to provide advice to EPA on any adverse social, economic, and energy effects from efforts to attain revised ozone NAAQS, as required by Section 109(d)(2)(C) of the Clean Air Act.

Therefore, API recommends that EPA retain the current primary NAAQS for ozone at the level of 0.075 ppm. Further, API supports EPA's proposal to retain the form of the secondary standard equal to the primary standard, and supports the level of 0.075 ppm for the secondary standard as well.

[6] *See, e.g.*, Anderson I., Gamborg M., Osler M., Prescott E., Diderirschsen F. 2005. Income as mediator of the effect of occupation on the risk of myocardial infarction: does the income measurement matter. *Journal of Epidemiology and Community Health*. 59:1080-1085;
Ecob R., Davey Smith G. 1999, Income and Health: What is the nature of the relationship? *Social Science and Medicine* 48:693-705;
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Lynch JW, Smith GD, Kaplan GA, House JS. 2000. Income inequality and mortality: importance to health of individual income, psychosocial environment, or material conditions. *BMJ*. 320:1200-1204 (29 April).

[7] Bambra C, Elkemo T. 2008. Welfare state regimes, unemployment, and health: a comparative study of the relationship
Catalano R. 1991. The health effects of economic insecurity. *Am J Public Health*. Sept. 81(9):1148-52;
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Martikaninen P, Ma N, Ja M. 2007, The effects of unemployment on mortality following workplace downsizing and workplace closure: a register-based follow-up study of Finnish men and women during economic boom and recession. *American Journal Epidemiology*. 165(9): 1070-1075;
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