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October 2015

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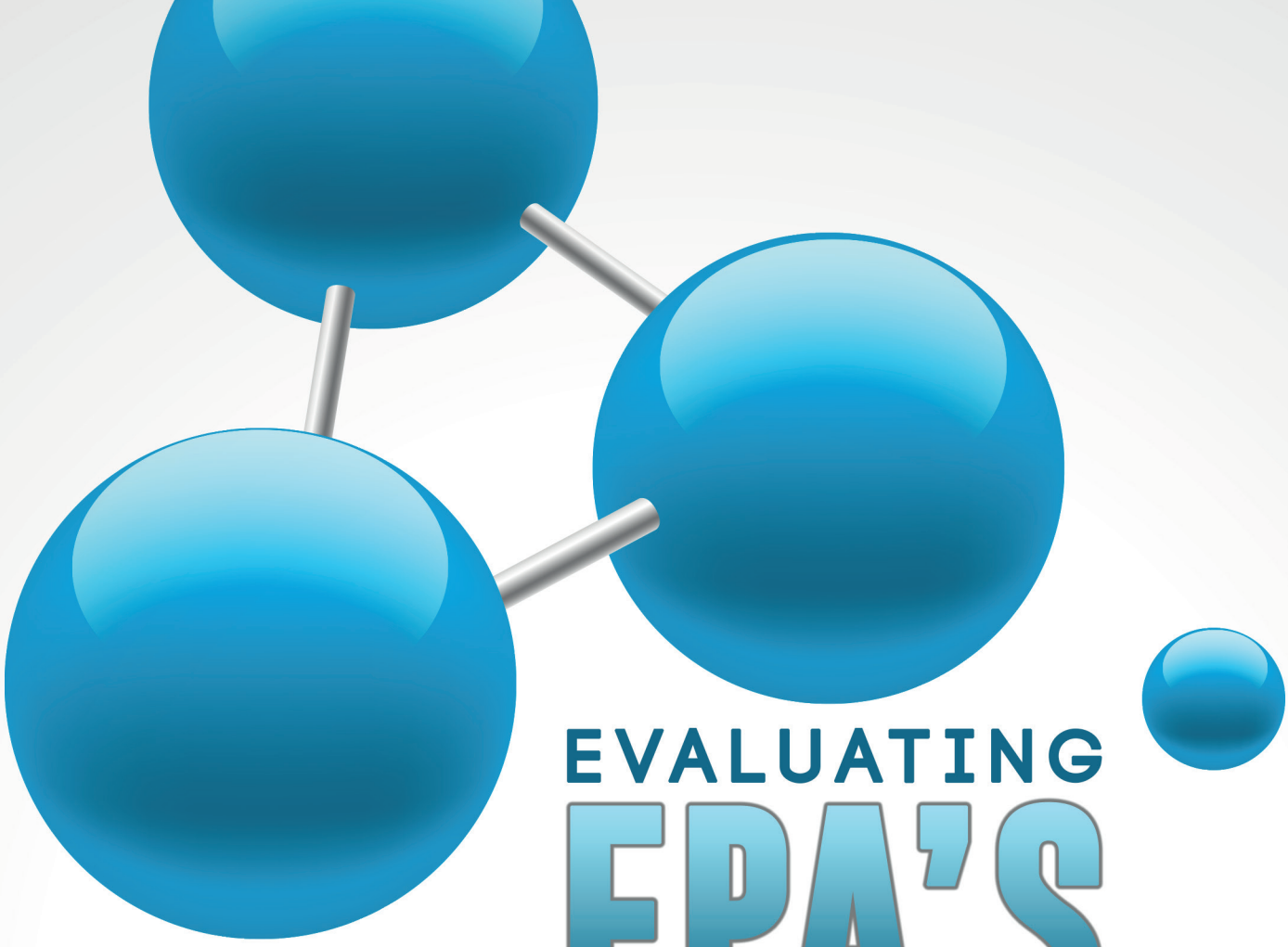
Palladian Publications Ltd
15 South Street, Farnham, Surrey
GU9 7QU, ENGLAND
Tel +44 (0)1252 718999
Fax +44 (0)1252 718992
Email: mail@worldcement.com
Website: www.worldcement.com

Volume 46: Number 10
October 2015
ISSN 02636050



EVALUATING EPA'S PROPOSAL TO LOWER THE OZONE STANDARD

LUCY FRAISER AND THOMAS SULLIVAN, ZEPHYR ENVIRONMENTAL, USA, EXPLAIN THE IMPLICATIONS OF THE SHIFT FROM SCIENTIFIC UNCERTAINTY TO PRESUMPTIVE ADVERSITY.

The U.S. Environmental Protection Agency (EPA) has been creating rules that regulate ozone in the ambient air since 1971. EPA set the current ozone National Ambient Air Quality Standard (NAAQS) at 75 ppb in March 2008. Based on a thorough review of scientific evidence concerning the impact of ambient ozone concentrations on human health and welfare, EPA concluded that a 75 ppb standard was protective at that time.

The EPA is currently undergoing rulemaking to determine if the existing standard should be lowered. Zephyr Environmental Corporation performed an analysis of the health-based studies EPA relied upon to justify the setting of a lower ozone NAAQS. In the current rulemaking, EPA proposes to dramatically lower the NAAQS below the 75 ppb level, requesting public comments on lowering the standard to between 60 and 70 ppb, yet EPA has failed to point to any persuasive body of scientific evidence supporting its proposal. Indeed, EPA has failed to identify any study showing a clear causal relationship between ozone concentrations less than 88 ppb and clinically relevant adverse human health impacts.

The evidence and studies relied upon by EPA indicate that the current ozone NAAQS of 75 ppb continues to be protective of public health and welfare, with an adequate margin of safety. That is, EPA was correct in 2013 when, in response to litigation challenging the 2008 ozone standards, it declined to lower the 75 ppb NAAQS. This conclusion is supported by EPA's own risk assessment as well as the scientific studies that EPA relied upon in that assessment.

Human health impact studies do not support lowering the NAAQS

There are only five published laboratory studies on the impact of short-term ozone exposure on lung function that evaluate ozone concentrations in the range of the proposed ozone NAAQS alternatives (65 ppb – 70 ppb). Not one of those studies supports the conclusion that human health would be improved by lowering the NAAQS below the current 75 ppb level.

In fact, those studies show that significant impairment in lung function does not occur until concentrations of 88 ppb or higher are reached. The current NAAQS of 75 ppb is well below the level at which these effects occur. Therefore, evidence from these controlled human exposure studies suggests that the current NAAQS is protective of public health with an adequate margin of safety.

As shown in Figure 1, the studies replied upon by EPA show that impairments in lung function observed at concentrations below 75 ppb are not consistently statistically significant, are not usually accompanied by respiratory symptoms, and do not reach the threshold that EPA has identified as being clinically meaningful. Accordingly, Zephyr concludes that evidence for lung function impairment from controlled human exposure studies has not materially changed since EPA decided not to lower the NAAQS from 75 ppb in 2013.

Population studies do not support lowering the NAAQS

A review of the population studies that EPA relied upon clearly indicates that the associations between ozone and respiratory health effects and mortality are inconsistent and uniformly weak and that confidence in the associations is generally low.

For example, despite EPA's claims, impairments in lung function do not consistently occur in any population (outdoor workers, adults or children exercising outdoors, asthmatics) in response to increased ozone levels, and neither asthmatic children nor adults consistently respond to ambient ozone levels with an increase in symptoms, medication use or activity limitation.

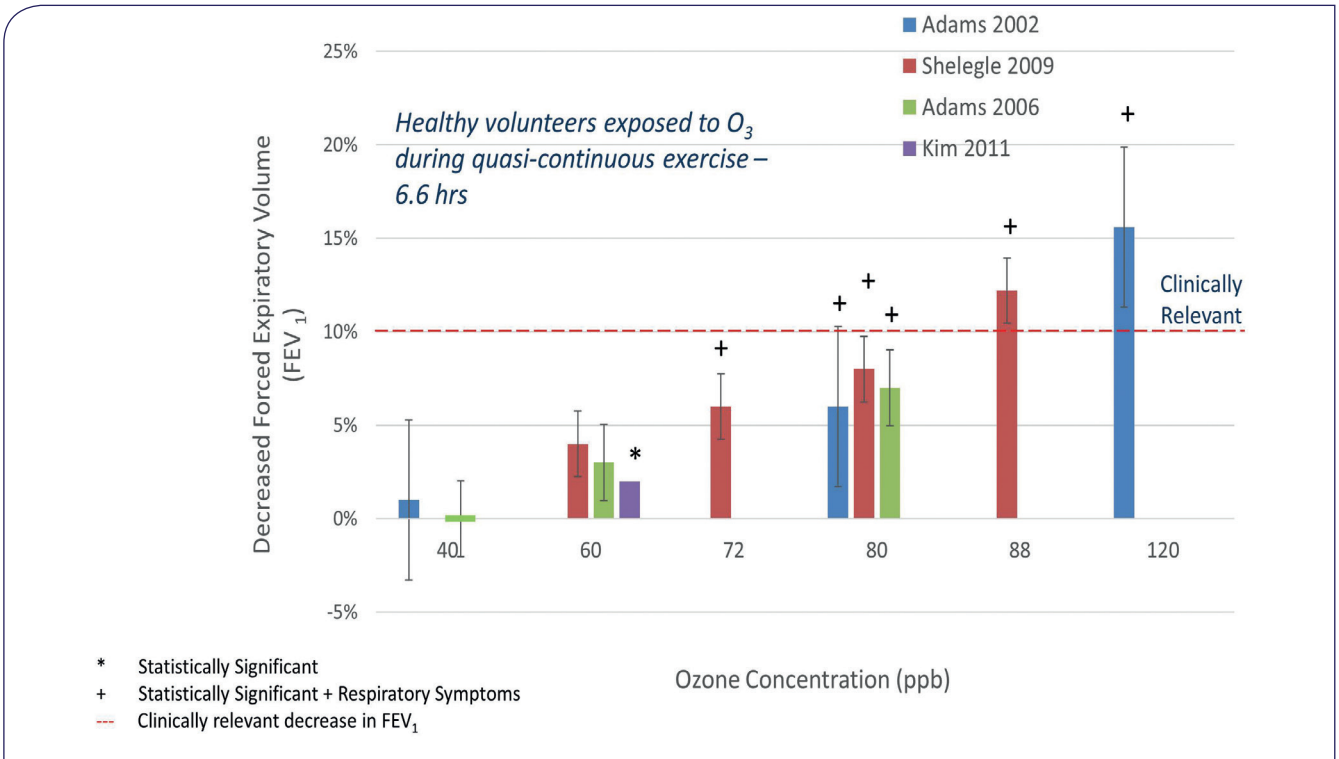


Figure 1. Group mean FEV decreases in young healthy adults exposed to ozone.

In addition, multi-city hospital studies report both positive and negative associations with ozone concentrations depending on latency periods, the particular model used to perform the analysis, and whether the results are adjusted for other co-pollutants. In other words, some studies show that human health actually improves as ozone levels go up. Such a counter-intuitive result casts doubt on the reliability of the scientific evidence that EPA is relying upon.

Moreover, the uniformly small effects reported in population studies for all ozone-related health effects suggest that the associations are weak between ozone concentrations and short-term respiratory effects, hospital admissions and emergency room visits, respiratory symptoms and medication use in asthmatics, and both short and long-term mortality.

There is also enormous uncertainty associated with EPA's conclusion that the relationship between short-term ambient ozone concentrations and premature mortality is 'likely causal' and that the correlation between long-term ozone exposure and mortality is 'suggestive of a likely causal' relationship. Neither classification is supported by the available evidence. Notably, the mortality relationships vary across studies and cities, and appear to be skewed by the co-occurrence of particulate matter. In addition, EPA's questionable practice of averaging individual city mortality coefficients in estimating a national mortality burden dilutes the high and low values and produces overall averaged mortality coefficients that do not accurately characterise the true relationship for any of the cities.

The uncertainty about health impacts below 75 ppb from population studies in the last ozone NAAQS review precluded EPA from establishing the NAAQS at a lower level. Despite many new studies, that uncertainty remains today because of the inconsistent and weak associations reported, not to mention the prevalent methodological problems that continue to plague the population studies.

EPA's Health Risk and Exposure Assessment fails to consider all of the evidence and appears to be an attempt to justify a pre-determined decision to lower the NAAQS

The goal of EPA's Health Risk and Exposure Assessment is to provide information that is helpful in answering questions about the adequacy of the existing ozone NAAQS of 75 ppb. However, EPA's practice of mischaracterising the studies relied upon suggests that, in this case, EPA's risk assessment was not intended to uncover the real facts but instead was a means to justify a pre-determined end.

EPA over-predicts risk by selectively relying upon some studies while ignoring others that might lead to a different conclusion. For example, EPA selectively relies on studies that suggest that increased ozone concentrations lead to increased health effects. EPA also cherry-picks positive findings (ignoring negative results) from studies reporting mixed results and estimates risks associated with all ozone concentrations (down to zero), despite evidence that there is a threshold below which adverse health effects do not occur. The net result is that, in some of the cities evaluated in EPA's risk assessment, increased ozone would actually improve human health. This is a finding that certainly does not support a lowering of the ozone NAAQS.

Impacts of a lower ozone standard

What happens if EPA chooses to lower the ozone NAAQS despite the lack of scientific evidence justifying such a move? Nonattainment Designation triggers more stringent air permit requirements and additional regulatory requirements based on the severity of the designation.

For the cement industry, air permitting gets more difficult and costly over time. The immediate effect is limited to those counties that may be exceeding the new NAAQS but have not yet been designated non-attainment. The designation process, which takes approximately 3 years, is interactive, with individual states recommending county designations and EPA making the final decision on each non-attainment area.

Prior to a change in non-attainment designation, there is no regulatory change for minor Prevention of Significant Deterioration (PSD) projects. For major air permit applications that trigger PSD for volatile organic compounds (VOC) and/or nitrogen oxides (NO_x), 40 CFR 52.21(m) requires:

- Background ozone monitoring data.
- An air quality analysis evaluating whether NO_x and/or VOC project emissions would cause or contribute to a violation of the ozone NAAQS.

This applies to major projects with a net emissions increase of greater than 100 tpy of either VOC or NO_x. The ozone analysis can be a very challenging exercise for facilities located in counties with measured background ozone concentrations that exceed the new standard. In that situation, a qualitative analysis might suffice comparing the VOC-to-NO_x molar ratio of county-wide emissions versus the ratio of project emissions. Photochemical modelling may also be required to quantify the amount of ozone formation from NO_x and VOC project emission increase.

If it cannot be demonstrated that the project increases will have no effect on nearby ozone concentrations, emission offsets may be required. In addition to the expense, there are many uncertainties involved in utilising offsets in undesignated counties, for example:

- What ratio of offsets? 1:1 or higher?
- Where can the offsets occur? Same county, same statistical area?
- Can photochemical modelling be used to support use of more distant offsets?

Additional concerns include the fact that emission reductions may be difficult to find in counties without large point sources and the limited incentive for generating Emission Reduction Credits (ERCs) in attainment counties. This could make emissions reductions difficult to find and potentially expensive. Each of these issues will add

uncertainty in permitting major projects over the next few years. Companies should consider greater contingencies in both project timelines and permitting costs when planning new projects.

Conclusion

Major concerns exist about the scientific rigour of EPA's evaluation of the scientific literature for ozone, as well as EPA's risk assessment process, which adds to the already substantial uncertainty associated with the scientific studies detailed above. Recent laboratory studies that evaluate the association between ozone and lung function at exposures below the current NAAQS of 75 ppb indicate that there are no statistically significant adverse effects with clinical relevance to human health below 88 ppb. Nonetheless, EPA summarises the information as providing positive evidence for adverse effects at levels below the current NAAQS, ignoring widely recognised definitions of what constitutes an 'adverse' effect and the criterion for judging the clinical relevance of health effects developed by EPA itself. Moreover, EPA does not reveal or appear to adequately consider factors that bias the population study results. Instead, EPA repeatedly provides summaries of the available scientific literature that emphasise only positive associations between ozone and human health impairments (i.e. cherry-picking the data). The few positive and statistically significant associations reported in mortality studies are very weak and likely completely swamped by the large error introduced by not adequately adjusting the estimates for confounding variables (especially particulate matter) and regional differences.

The fundamental purpose of the Clean Air Act (CAA) is to address pollution from manmade sources in urbanised areas. By evaluating risk associated with ozone levels down to zero, EPA includes the impacts of biogenic sources, which should not be considered in a NAAQS evaluation. The ozone standards being considered, which represent near background levels, go beyond this basic CAA authorisation by imposing a standard that could cause counties to be in noncompliance, even though they have sparse population density with little to no industrial sources of pollution. Moreover, a nonattainment or noncompliance regulatory label could create a perception of poor air quality that would be less attractive for family and business relocation.

The burdensome and expensive regulatory requirements that will be imposed if the ozone NAAQS is lowered have the potential to substantially slow growth and economic development. Any slowdown in construction will not only have direct negative repercussions on the cement industry, it will ripple through the economy and indirectly affect the population at large. Given the lack of compelling evidence that lowering the ozone NAAQS will be met with a demonstrable improvement in health, the adverse effects of the proposed ozone rule appear to greatly outweigh the benefits.

Disclaimer

The opinions expressed in this article are based on an exhaustive review of the scientific literature. A portion of the literature review was conducted while developing comments on the proposed Ozone rule on behalf of the Texas Pipeline Association.