G R A D I E N T
TRENDS
Risk Science & Application

Winter 2012

Looking at the NAAQS 40+ Years Later

By Chris Long, Sc.D. and Peter Valberg, Ph.D.

NAAQS-related challenges have continued to grow as air quality has improved.

Over 40 years have elapsed since the first National Ambient Air Quality Standards (NAAQS), which seek to regulate levels of major outdoor air pollutants, were adopted. The NAAQS have undoubtedly contributed to vast improvements in air quality across the country. However, as emissions of criteria pollutants have dropped, NAAQS-related challenges have grown. In fact, the NAAQS process faces critical questions, including how much lower single-pollutant standards can be set, and whether it is time for a new paradigm of multi-pollutant standards.

> ***…the scientific evidence supporting each NAAQS revision to lower pollutant levels has become more uncertain…***

The 1970 Clean Air Act mandated the NAAQS process for a set of six criteria pollutants – particulate matter (PM), sulfur dioxide (SO_2), nitrogen dioxide (NO_2), ozone (O_3), hydrocarbons, and carbon monoxide (CO) – selected due to their common occurrence and public health significance. There have been changes to the criteria pollutants themselves, with the 1977 addition of lead and the 1983 removal of hydrocarbons. The PM NAAQS have evolved to address progressively smaller size fractions, with PM_{10} replacing total suspended particulates (TSP) in 1987, and $PM_{2.5}$ being added in 1997. The form and level of the original NAAQS have now been revised for all but CO, and some new NAAQS have been added, most recently 1-hour NO_2 and SO_2 standards. The U.S. EPA has also tuned up the NAAQS review process to improve its transparency and scientific integrity. Importantly, air quality across the country is better today than it has been since 20th century industrialization began (see figure).

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I N S I D E

Letter to our Readers

January 2012

Dear Colleague,

In this issue, we look at current issues and challenges related to the National Ambient Air Quality Standards (NAAQS). Since the passage of the Clean Air Act of 1970 and the subsequent development of the first NAAQS, much has changed both in the levels and form of the air standards themselves and in the way the NAAQS review process is handled by the U.S. EPA. We critically examine the U.S. EPA's framework for causal determination, and delve into the U.S. EPA's continuing efforts to define susceptible and vulnerable populations for purposes of NAAQS development.

Contributors to this issue include Gradient Principals Dr. Chris Long, Dr. Peter Valberg, and Dr. Julie Goodman, as well as Dr. Robyn Prueitt, a Senior Health Scientist at Gradient. Joining us with a guest editorial on why the possibility of multi-pollutant NAAQS could be problematic is Lucinda Minton Langworthy, who is counsel at the law firm Hunton & Williams LLP and a member of its environmental team, focusing on Clean Air Act issues.

As a reminder, all future *Trends* will be paperless. If you are not currently receiving *Trends via* e-mail, please provide us with your e-mail address at www.gradientcorp.com/trends.

We hope that this issue of *Trends* provides you with an understanding of some of the changes and challenges that are currently surrounding the continuously evolving world of air quality standards.

Yours truly,

Teresa S. Bowers

Teresa S. Bowers, Ph.D.
President

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Looking at the NAAQS 40+ Years Later

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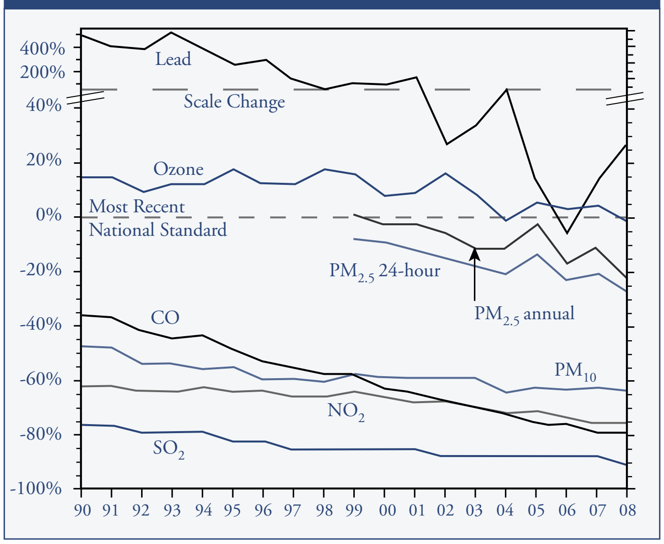
With each recent review by the U.S. EPA, there has been a trend towards increasingly lower standards, including for PM, lead, and ozone. For example, the primary (health-based) lead NAAQS was reduced 10-fold in 2008 from 1.5 to 0.15 µg/m^3, and U.S. EPA staff recently recommended that the annual primary $PM_{2.5}$ NAAQS be reduced from 15 µg/m^3 to a level in the range of 13 to 11 µg/m^3. Despite the ongoing publication of numerous air pollution studies, the scientific evidence supporting each NAAQS revision to lower pollutant levels has become more uncertain, often consisting of a limited number of findings from a single line of health effects evidence. For example, for $PM_{2.5}$, the U.S. EPA has relied nearly exclusively on small epidemiologic associations to support its recommendations for a lower annual standard, because of the general absence of experimental evidence (either human or animal) of adverse effects at such low concentration levels. Recognizing the major uncertainties, the U.S. EPA has formalized approaches for weighing different kinds of scientific evidence, including a framework for causal determination. However, its implementation of these approaches has sometimes fallen short (see related article).

20-Year Trends in Criteria Air Pollutants



Change over time (1990 to 2008) in national-average levels of criteria air pollutants, shown as a percentage of the present day (as of 2010) NAAQS (U.S. EPA, 2010).

Both the scientific issues and policy-related questions faced by the U.S. EPA in recent NAAQS reviews have become more complicated. For example, for PM, the U.S. EPA has grappled with the question of the relative toxicity of the various PM chemical constituents, recently concluding that the evidence for supplementation of the mass-based PM NAAQS with separate indicators for specific PM component(s) is not yet sufficiently reliable. For O_3, there has been extensive scientific debate concerning how low is "natural background," as well as the relationship between ambient O_3 levels and mortality risk. For criteria pollutants as a whole, there continue to be unresolved issues surrounding the existence and levels of any health-effect thresholds, how to separate out the effects of specific pollutants in complex air pollution mixtures (*e.g.*, traffic emissions), and the identity of subpopulations particularly susceptible to air pollution effects (see related article). Finally, key policy-related questions involve what constitutes an "adequate margin of safety" when regulating pollutants with no established threshold concentration, and how to evaluate mortality effects in cost-benefit assessments given that predictions of hypothetical lives presumed saved by small decrements in pollutant levels generally dominate benefits in these analyses.

This past year was a busy one for the NAAQS, and 2012 promises to be similar. Having already indicated its decision to retain the current PM_{10} standard, the U.S. EPA is expected to issue its final PM rule in 2012. Although President Obama's September 2011 administrative decision led to withdrawal of the draft O_3 NAAQS, the U.S. EPA will continue its review of the ozone NAAQS, and of the lead NAAQS. It will also continue its implementation process for the 1-hour SO_2 NAAQS, including its controversial hybrid modeling and monitoring approach. There clearly is much NAAQS-related work to be done, but we can take comfort that, as to air quality improvements, we are now ironing out wrinkles rather than filling in the potholes of the past.

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U.S. EPA, Office of Air Quality Planning and Standards (Research Triangle Park, NC). February 2010. Our Nation's Air - Status and Trends through 2008. EPA-454/R-09-002.

The U.S. EPA's Causality Framework

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Goodman, J.E., D.G. Dodge, and L.A. Bailey. 2010. A framework for assessing causality and adverse effects in humans with a case study of sulfur dioxide. *Regul. Toxicol. Pharmacol.* 58:308-322.

Rhomberg, L.R., L.A. Bailey, and J.E. Goodman. 2010. Hypothesis-based weight-of-evidence: A tool for evaluating and communicating uncertainties and inconsistencies in the large body of evidence in proposing a carcinogenic mode of action - Naphthalene as an example. *Crit. Rev. Toxicol.* 40:671-696.

U.S. EPA, National Center for Environmental Assessment (NCEA). September 2011. Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Second External Review Draft).

The U.S. EPA's Causality Framework

By Julie Goodman, Ph.D., DABT

Assessing causality from uncertain scientific evidence remains a key technical challenge for establishing NAAQS.

In its efforts to establish health-protective NAAQS, the U.S. EPA attempts to identify the lowest pollutant levels at which there is evidence of a causal relationship for adverse health effects. Several types of health effects evidence are generally considered when evaluating causation, including: 1) human epidemiology, 2) toxicology, and 3) mechanistic data. A three-legged stool (see figure) has been used to convey the idea that strong support is needed from multiple lines of evidence to demonstrate causality; when evidence from any single "leg" of evidence is weak or inconsistent, a causal interpretation is undermined (*i.e.*, the stool is wobbly).

> ***…the U.S. EPA's NAAQS causality framework is designed and executed in a way that can result in biased causality assessments.***

One of the key challenges for establishing causality is the selection and implementation of a framework that "weighs" all lines of evidence appropriately, in that it gives full consideration to all data, including those which do not support causation. The U.S. EPA NAAQS causality framework uses a five-level hierarchy intended to classify the weight-of-evidence in support of causation for human health, ecological, and welfare effects. The levels are: (1) causal relationship, (2) likely to be a causal relationship, (3) suggestive of a causal relationship, (4) inadequate to infer a causal relationship, and (5) not likely to be a causal relationship. For health effects, the framework claims to rely heavily on the postulates put forth by Sir Austin Bradford Hill in his address to the British Royal Academy of Medicine in 1965. These include strength of association, consistency, specificity, temporality, dose-response, biological plausibility, coherence, experiment, and analogy. Hill also stressed that alternative explanations should be considered and ruled out.

Closer examination reveals instances where the U.S. EPA's framework deviates from Hill's postulates. For example, the U.S. EPA states in its draft ozone (O_3) Integrated Science Assessment (U.S. EPA, 2011) that an association is likely to be causal "if chance and bias can be ruled out with reasonable confidence *but potential issues remain.*" It goes on to clarify that "potential issues" can include possible co-pollutant effects and limited or inconsistent findings from other lines of evidence. These issues, however, can lead to a statistical association between a pollutant and a health effect that is not indicative of a causal relationship. For example, while statistical associations between ozone and mortality are found in some, but not all, epidemiology studies, there is a general lack of robust experimental evidence (*i.e.*, mechanistic and toxicological results) to support an O_3-mortality effect.

There are also concerns with the U.S. EPA's implementation of its framework. For example, in its evaluation of O_3 health effects, these include: the totality of evidence is not always put forth in a clear, consistent manner; positive associations are often given more weight than null associations; confounders are not always adequately considered; a lack of coherence among epidemiology, toxicology, and mechanistic data is not always addressed; effects that are not adverse are often interpreted as such; and alternative explanations for observed effects are not always given equal weight. The net effect of these issues results in overstated health risks from O_3.

Overall, the U.S. EPA's NAAQS causality framework is designed and executed in a way that can result in biased causality assessments. That is, it tends towards analyses that support stricter regulations that may not provide corresponding health benefits. A number of other causality frameworks do not have the limitations apparent in the NAAQS framework. These include frameworks from different U.S. EPA offices (*e.g.*, the Office of Pesticides Programs), as well as two published by Gradient scientists – the Hypothesis-Based Weight-of-Evidence framework (Rhomberg *et al.*, 2010) and a framework for assessing causation and the adversity of health effects (Goodman *et al.*, 2010). Adopting one of these frameworks could better prevent biased analyses that can occur with the NAAQS framework, contributing to regulations that more effectively benefit public health.

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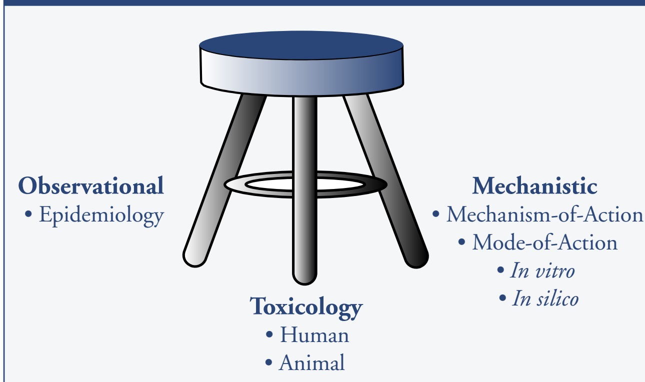
Potential for Health Effects is Established Through Multiple Lines of Investigation



Source: Adapted from R.O. McClellan

Defining Susceptibility and Vulnerability

By Robyn Prueitt, Ph.D.

Redefining what constitutes susceptible and vulnerable populations has critical implications for setting the NAAQS.

The NAAQS provisions require the U.S. EPA to establish standards that provide an "adequate margin of safety" to protect public health. When the Clean Air Act was enacted in 1970, Congress emphasized that the NAAQS were intended to protect "particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment" (U.S. Senate, 1970). Over time, the U.S. EPA has broadened this interpretation of "sensitive" groups, using the terms susceptibility and vulnerability to describe populations believed to be at increased risk of air pollution health effects.

As the NAAQS are reset at lower and lower concentrations that approach background levels, protection of the most susceptible groups with an adequate margin of safety may be unattainable.

There are varying, and sometimes overlapping, definitions of susceptibility and vulnerability. Compared to the general population, *susceptible* populations are often defined as those who are more likely to suffer from health effects for a given pollutant exposure level due to individual-level characteristics such as innate biological differences (*e.g.*, age, genetics, pre-existing disease), or increased dose (*e.g.*, from elevated inhalation rates during strenuous outdoor work or exercise). By contrast, *vulnerable* populations are at risk for exposure to a higher concentration of a pollutant than the general population because of population-level characteristics such as low socioeconomic status (SES), which may be associated with living near busy streets or less availability of home air conditioning. Low SES may also be a characteristic of susceptible populations, however, in that it may increase the risk of an adverse outcome from a given exposure because of poor access to medical care.

In recent criteria pollutant health assessments (*e.g.*, U.S. EPA, 2009), the U.S. EPA included both individual and population-level characteristics in its definition of susceptible groups. Dr. Jonathan Samet, Chair of the U.S. EPA's Clean Air Scientific Advisory Committee (CASAC), stated that this definition is too broad to be useful for determining the NAAQS (Samet, 2011), recommending that the U.S. EPA refine its concept of susceptibility in future assessments. In its second draft of the ozone Integrated Science Assessment (U.S. EPA, 2011), the U.S. EPA responded by clarifying that increased risk for air pollutant-induced health effects can be attributable to intrinsic factors, extrinsic factors, increased dose, or increased exposure, and it defined "at-risk" groups (rather than susceptible groups) to encompass those with any of these characteristics of increased risk. Retaining such a broad definition for those at risk, however, may produce more stringent NAAQS because of the larger number of populations that must be protected. In addition, the "adequate margin of safety" provision was specified by Congress as requiring protection against effects not yet identified by science, adding further stringency to the NAAQS beyond the protection of both general and susceptible populations from currently-known health effects.

As the NAAQS are reset at lower and lower concentrations that approach background levels, protection of the most susceptible groups with an adequate margin of safety may be unattainable. Some CASAC members have voiced the opinion that the susceptible groups requiring specific protection be limited to those with innate biological differences from the general population, rather than voluntary or operational circumstances that can be changed by human behavior to reduce exposure or adversity of outcome. Such a narrowing of the definition of those at-risk in the context of the NAAQS may better allow for standards that remain feasible to implement.

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U.S. EPA. 2009. Integrated Science Assessment for Particulate Matter (Final). National Center for Environmental Assessment (NCEA). EPA/600/R-08/139F. December.

U.S. EPA. 2011. Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Second External Review Draft). National Center for Environmental Assessment (NCEA). EPA/600/R-10/076B. September.

U.S. Senate, Committee on Public Works. 1970. Report Together with Individual Views of the Senate Committee on Public Works re: Amendments to the Clean Air Act. Senator Rep. No. 91-1196, 91st Cong., 2nd Sess.

BY THE WAY...

More people in the U.S. died in 2011 from eating tainted cantaloupe, than from the 1948 Donora (PA) smog event (one of the worst air pollution episodes in U.S. history).

What's New at Gradient

Awards and Announcements

Marc A. Nascarella has been appointed to the Board of Fellows for the School of Mathematics and Science at Norwich University (Northfield, VT).

Recent Publications

Flewelling, S.A., J.S. Herman, G.M. Hornberger, and A.L. Mills. 2011. Travel time controls the magnitude of nitrate discharge in groundwater bypassing the riparian zone to a stream on Virginia's coastal plain. *Hydrological Processes.* DOI:10.1002/hyp.8219.

Greenberg, G.I. and **B.D. Beck**. 2011. DALYs, QALYs and other community measures of environmental health: Use of Years of Potential Life Lost (YPLL) for Risk Assessment at Hazardous Waste Sites. *Encyclopedia of Environ. Health*. (Ed.: Nriagu, J.O.), Elsevier Press, Burlington, MA. 602-607.

Hesterberg, T.W., **C.M. Long**, **S.N. Sax,** C.A. Lapin, R.O. McClellan, W.B. Bunn, and **P.A. Valberg**. 2011. Particulate matter in new technology diesel exhaust (NTDE) is quantitatively and qualitatively very different from that found in traditional diesel exhaust (TDE). *J. Air Waste Mgt. Assoc.* 61:894-913.

Mehler, W.T., H. Li, M.J. Lydy, and J. You. 2011. Identifying the causes of sediment-associated toxicity in urban waterways of the Pearl River Delta, China. *Environ. Sci. Technol.* 45:1812-1819.

Prueitt, R.L., J.E. Goodman, L.A. Bailey, and **L.R. Rhomberg**. 2011. Hypothesis-based weight-of-evidence evaluation of the neurodevelopmental effects of chlorpyrifos. *Crit. Rev. Toxicol.* 41:822-903.

Radloff, K.A., Y. Zheng, H.A. Michael, M. Stute, B.C. Bostick, I. Mihajlov, M. Bounds, M.R. Huq, I. Choudhury, M.W. Rahman, P. Schlosser, K.M. Ahmed, and A. van Geen. 2011. Arsenic migration to deep groundwater in Bangladesh influenced by adsorption and water demand. *Nat. Geosci.* 4:793-798.

Rhomberg, L.R., J.K. Chandalia, C.M. Long, and **J.E. Goodman**. 2011. Measurement error in environmental epidemiology and the shape of exposure-response curves. 2011. *Crit. Rev. Toxicol.* 41(8):651-671.

Upcoming Presentations

Seattle, WA. Feb. 19-22, 2012. Annual conference of the Society for Mining, Metallurgy & Exploration (SME).

- **D. Mayfield** and **N. Grasso**. "Environmental Issues Associated with Expanding Rare Earth Resources."

San Francisco, CA. March 11-15, 2012. Society of Toxicology Annual Meeting.

- **L. Bailey**, **J. Goodman**, and **B. Beck**. 2012. "Revised Reference Concentration for Manganese Oxide Based on Recent Epidemiological and Pharmacokinetic Studies."
- **L. Beyer**, **G. Greenberg**, and **B. Beck**. 2012. "Evaluation of Potential Exposure to Metals in Laundered Shop Towels."
- **D. Dodge**, **B. Beck**, M. BenKinney, and P. Boehm. 2012. "Analysis of Health Risks to Surgical Patients from Instruments Contaminated with Used Hydraulic Fluid."
- **M. Peterson** and **J. Goodman**. 2012. "Infant Risk and Exposure Assessment of Bisphenol A in Polycarbonate and 'BPA-free' Plastic Bottles."
- **R. Prueitt**, **J. Goodman**, **L. Bailey**, and **L. Rhomberg**. 2012. "Hypothesis-based Weight-of-Evidence Evaluation of the Neurodevelopmental Effects of Chlorpyrifos."

Amherst, MA. April 24-25, 2012. The 11th Annual International Conference: Dose-Response: Implications for Toxicology, Medicine, and Risk Assessment.

- **B. Beck**. 2012. "Dose-Response Assessment for Arsenic: A Case Study for Why the LNT Doesn't Work."

Monterey, CA. May 21-24, 2012. The 8th International Conference on Remediation of Chlorinated & Recalcitrant Compounds.

- **A. Bittner** is co-chairing the session "Environmental Remediation in Emerging International Markets."
- **M. Sharma** and **T. Verslycke**. 2012. "Recent Changes and Experiences with Brazil's Risk-Based Site Remediation Framework." Platform Presentation.
- P. Tornatore, M. Ramsdell, D. Costantini, and **A. Bittner**. 2012. "Applying Innovative Remediation Approaches in Emerging International Markets – Making Experience Pay." Poster Presentation.

Guest Editorial: Multi-pollutant NAAQS: The Next Frontier?

By Lucinda Minton Langworthy, Esq.

The idea of multi-pollutant NAAQS is challenging from both a scientific and legal perspective.

Since 1970, the U.S. EPA has been charged by the Clean Air Act (CAA) with setting National Ambient Air Quality Standards (NAAQS) for the most common air pollutants. The Agency is to adopt regulations for each such air pollutant that protect the public health (primary NAAQS) and welfare (secondary NAAQS). Recently, the U.S. EPA and others have shown interest in multi-pollutant NAAQS. Although the concept of multi-pollutant NAAQS is intriguing, it is problematic from both scientific and legal points of view.

The NAAQS program is fundamentally designed to address one pollutant at a time.

The scientific impediments to the development of multi-pollutant NAAQS are illustrated by the U.S. EPA's recent consideration of a joint NAAQS for oxides of nitrogen and sulfur to protect against environmental effects. The Agency spent several years developing the conceptual framework for a multi-pollutant standard that it considered ecologically relevant to the joint effects of those pollutants on aquatic acidification. This past August, however, the U.S. EPA's Administrator reasonably concluded that it would not be appropriate to adopt this NAAQS. The Administrator recognized that, even in a situation where the Agency had developed a framework that it believed reflected the underlying relationships between concentrations of oxides of nitrogen and sulfur in the ambient air and acidification related to their deposition, it was unclear how well the framework's indicator of these complex processes would predict the actual relationship between varying ambient concentrations of the pollutants and acidification. The Administrator went on to describe a research program that was intended to reduce these uncertainties, although it is doubtful that the program she described would reduce them sufficiently to produce a workable multi-pollutant NAAQS based on the current framework.

Even if the scientific uncertainties could be adequately addressed, the consistency of any such NAAQS with the Clean Air Act is questionable. The NAAQS program is fundamentally designed to address one pollutant at a time. Furthermore, each NAAQS specifies a nationally-uniform level of the pollutant requisite to, depending on whether it is a primary or secondary NAAQS, protect public health or welfare. A multi-pollutant NAAQS that would permit tradeoffs between allowable levels of the regulated pollutants appears antithetical to this regulatory scheme.

In light of these obstacles to multipollutant NAAQS, the U.S. EPA would be well-served by instead considering how to implement multiple single-pollutant NAAQS most efficiently. Ideally, implementation planning would take into account not only multiple NAAQS, but also other environmental requirements affecting the same pollution sources. Such an approach to implementation, which should be conducted with input from the pollution sources themselves, could potentially reduce the overall cost of environmental compliance and assist with the business planning of those subject to control requirements for meeting NAAQS and other environmental standards.

The author is counsel at the law firm Hunton & Williams LLP where she is a member of the firm's environmental team, focusing on Clean Air Act issues. She can be reached at clangworthy@hunton.com.

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U.S. Congress. 2009. National primary and secondary ambient air quality standards. 42 USC 7409.

U.S. EPA. August 1, 2011. Secondary national ambient air quality standards for oxides of nitrogen and sulfur (Proposed rule). Fed. Reg. 76:46084-46147.

The next issue will focus on: *Rare Earth Elements*

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