



**EDISON ELECTRIC
INSTITUTE**

QUINLAN J. SHEA, III
Executive Director, Environment

November 9, 2007

James L. Connaughton
Chairman, Council on Environmental Quality
722 Jackson Place, NW
Washington, DC 20503

Susan E. Dudley
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Mr. Connaughton and Ms. Dudley:

On behalf of the Edison Electric Institute (EEI) and its member companies, I am writing to express our concerns about the inconsistent and conflicting positions that two federal agencies are publicly taking with regard to sulfur dioxide (SO₂). We understand that, among their other responsibilities, the Council of Environmental Quality (CEQ) and the Office of Information and Regulatory Affairs (OIRA) are in charge of coordinating environmental and regulatory policy across the Executive branch. We request that your offices intervene in this situation to ensure that there is a uniform and scientifically sound policy among federal agencies regarding acceptable ambient levels of SO₂.

Under the Clean Air Act, the Environmental Protection Agency (EPA) has an obligation to establish national ambient air quality standards (NAAQS) for SO₂ and to review and update these standards every five years. As you know, the process for setting and reviewing these standards is extremely rigorous, and involves scientific experts from the federal government, academia, industry, and environmental and public health advocacy groups. By statute, these standards must also be reviewed, through a public process, by the Clean Air Scientific Advisory Committee (CASAC), a group of outside experts appointed based on their research into the health and environmental effects of air pollutants.

Unfortunately, another federal agency – the Agency for Toxic Substances and Disease Registry (ATSDR) – has established its own, very different standards for acceptable ambient concentrations of SO₂. In its *Toxicological Profile for Sulfur Dioxide*, ATSDR takes the position that very low concentrations of SO₂ – concentrations that EPA has determined to be safe – have adverse impacts on human health. According to records in the public docket, EPA scientists objected to this portion of the *Tox Profile* at the time it was proposed, taking issue with ATSDR's interpretation of the scientific data and noting that ATSDR's position was inconsistent with the views expressed by CASAC. ATSDR ignored these objections, however, and proceeded to finalize its *Tox Profile* for SO₂ in 1998.

At that time, little attention was paid to the *Tox Profile*, and even ATSDR continued to use EPA's standards in evaluating the health risks of exposure to SO₂. Recently, however, ATSDR has started to publish "health risk assessments" of specific communities using its own standards for SO₂ based on the *Tox Profile*. These reports "inform" the residents of these communities that their health has been, or may be, harmed by exposures to SO₂ that EPA and the greater scientific community consider to be of no real consequence.

Over the last several months, we have tried to meet with ATSDR regarding this issue. Recently, however, ATSDR informed us that there was no need for such a meeting because it is going to convene its own "expert panel" to review this issue. We pointed out that EPA, as required under the Clean Air Act, is currently reviewing the NAAQS for SO₂, and will be evaluating exactly the same issue in a rigorous scientific and public process. We have encouraged ATSDR to defer to this process, but ATSDR has taken the position that it wants to choose its own experts and have its own standard for exposure to SO₂. We are requesting that CEQ and OIRA intervene to ensure that there is a uniform and scientifically sound policy across the Executive branch regarding acceptable ambient levels of SO₂.

EPA, not ATSDR, has Authority to Evaluate the Health Effects of SO₂ Exposure

ATSDR was created by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 – the legislation that created the Superfund Program. In this legislation, ATSDR was tasked with creating (1) a national register of serious diseases possibly related to exposure to toxic substance contamination at Superfund sites and (2) an inventory of scientific and medical literature regarding the health effects of toxic substances. When Congress amended CERCLA in 1986, it expanded ATSDR's role, giving

the Agency authority to develop "toxicological profiles" for certain hazardous substances.

This authorization, however, does not give ATSDR license to publish tox profiles for any substance it chooses. By statute, ATSDR is required to work with EPA to develop the so-called CERCLA hazardous substance priority list of 275 substances. 42 U.S.C. § 9604(i)(2). ATSDR is only authorized to develop tox profiles for substances on this priority list. In fact, ATSDR must prepare tox profiles for "those substances highest on the list of priorities . . . for which profiles have not previously been prepared." 42 U.S.C. § 9604(i)(3). ATSDR's own website recognizes this fact, noting that toxicological profiles "are developed from a priority list of 275 substances." The statute also requires ATSDR to review and update these profiles every 3 years.

Significantly, SO₂ is not on the CERCLA priority list and was not on this list when ATSDR developed its SO₂ toxicological profile. In 1988, while the priority list of 275 was under development, SO₂ was temporarily added to the list, but it was removed in 1991, after EPA and ATSDR had designed and implemented an algorithm for prioritization. It was in 1991 that ATSDR and EPA jointly published the final list of 275 priority substances. ATSDR clearly overstepped its statutory authority when it started the process of developing a toxicological profile for SO₂ in 1997 and finalized that profile in 1998.

There is no public record of why ATSDR decided to evaluate SO₂ in the first place. We have reviewed all the materials in the docket, and also talked with a number of ATSDR officials and outside contractors involved in the review, but we have not been able to find any explanation as to why SO₂ was targeted. Given that ATSDR's mandate is to provide information about hazardous substances at Superfund sites, it makes no sense whatsoever. SO₂ is a gas, not a liquid or solid, at all ambient temperatures. Under environmental law, it is (and always has been) regulated solely as an air pollutant. It has never been a chemical of concern with regard to Superfund site remedial investigations, feasibility studies, or actual clean-ups at any such sites.

It is more than a little puzzling that ATSDR would devote its resources to reviewing a substance that is not part of the Superfund program – especially when EPA is required to conduct, on a regular basis, such a comprehensive scientific effort to evaluate the health effects of exposure to SO₂. We suspect that it would be especially puzzling to Congress, which required ATSDR to work with EPA in identifying the "priority substances" for which toxicological profiles would be developed. It simply does not make sense for ATSDR to duplicate EPA's efforts.

Under the Clean Air Act, EPA is required to develop and review, at least every five years, national ambient air quality standards for six criteria pollutants, including SO₂. Pursuant to this requirement, EPA has established annual, 24-hour, and 3-hour ambient air quality standards for SO₂. As part of its review process, EPA has also considered and published guidelines for five-minute ("acute" or "short-term") ambient air exposures. EPA continues to review and revise its understanding of the health effects of SO₂ and to establish standards and guidelines for acceptable ambient levels. EPA performs these actions pursuant to its clear and explicit statutory mandate under the Clean Air Act. As both a legal and practical matter, EPA, not ATSDR, is the right agency to identify acceptable ambient levels of SO₂.

ATSDR's Standards for SO₂ Are Scientifically Unsound and Differ Substantially from the Standards and Guidelines Established by EPA

It is well known that elevated levels of SO₂ in ambient air can cause adverse health and environmental effects. EPA and the Occupational Safety and Health Administration (OSHA) have studied these effects since at least the early 1970s, and found that they are caused by both long-term and short-term exposures to SO₂. As a result, EPA has established a set of NAAQS to deal with different types of exposures: 30 ppb (averaged over a year); 140 ppb (averaged over 24 hours); and 500 ppb (averaged over 3 hours).

In the 1980s, some researchers began to express concern that these standards might not be stringent enough to protect certain asthmatics. A large percentage of asthmatics have exercise-induced asthma, meaning that when they are engaged in moderate to vigorous exercise – without concurrent use of medication – they may experience bronchoconstriction, a transient condition that makes it more difficult to breathe and may force them to stop exercising temporarily. For this reason, asthmatics are generally advised to take medication before exercising. Among people with exercise-induced asthma, a subset are particularly sensitive to SO₂. Although medication also prevents or largely mitigates against SO₂-induced bronchoconstriction, several studies have found that some unmedicated exercising asthmatics experience bronchoconstriction when exposed to relatively low concentrations of SO₂ for periods as short as 5 minutes.

In response to studies of asthmatics exposed to SO₂ while exercising in a clinical setting, in 1994 EPA proposed three different approaches to limiting 5-minute ambient air exposures to no more than 600 ppb. 59 FED. REG. 58958 (November 15, 1994). In 1996, however, EPA concluded that such short-term peak levels of SO₂ do not pose a wide-spread public health problem that would be appropriate to address by means of a national standard. 61 FED. REG. 25566, 25575 (May 22, 1996).

Nevertheless, based on the scientific data, the Agency noted that 600 ppb (averaged over 5 minutes) was a level at which some unmedicated exercising asthmatics might be adversely affected. 61 FED. REG. 25576 (May 22, 1996). The Agency also noted that infrequent exposures "in the range of [600 – 1,000 ppb] . . . may not be a cause for significant concern," whereas more frequent exposures above this range would pose an increasing concern. *Id.* As a result, EPA has recommended a "concern level" at 600 ppb and an "intervention level" of 2,000 ppb (both averaged over 5-minutes) to state and local governments that want to address short-term exposures in their SO₂ management programs.

For reasons that are not clear, ATSDR decided to address this same issue – the effects of short-term exposures on exercising asthmatics – when it developed its toxicological profile of SO₂ in 1997-1998, immediately after EPA had completed its NAAQS review. Rather than weighing the body of scientific and clinical studies, as EPA had done, ATSDR focused on a single 1981 study of 13 subjects (which EPA had also included in its broader evaluation and found to be nonrobust and methodologically limited). Based on this study, ATSDR "established" a "lowest observed adverse effects level" (LOAEL) of 100 ppb and a "minimum risk level" (MRL) of 10 ppb for peak short-term (five-minute) exposures to SO₂. *U.S. Department Of Health And Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, Toxicological Profile for Sulfur Dioxide, Appendix A (December, 1998)* (available at <http://www.atsdr.cdc.gov/toxprofiles/tp116.html>). Thus, according to ATSDR, 5-minute exposures to SO₂ must be 10 ppb or below to be considered safe, and exposures at 100 ppb and above are expected to cause adverse effects. ATSDR has recently started using these standards to conduct and publish "health risk assessments" of communities located near power plants, even though they are much lower than EPA's standards.

EPA believes that public health is protected, with an adequate margin of safety, if people are exposed to 30 ppb continuously for a year or to 140 ppb for 24 hours, while ATSDR is telling communities near power plants that it may be unsafe to be exposed to more than 10 ppb for even 5 minutes. It is true that ATSDR's standards are designed to protect unmedicated exercising asthmatics, but EPA has stated publicly that 600 ppb (averaged over 5 minutes) is a health protective level for this subgroup.

EPA has been openly critical of ATSDR's approach with regard to five-minute exposures and asthmatics. Lester Grant, Ph.D., former director for EPA's National Center for Environmental Assessment, has stated that he and others at EPA were "frustrated" that ATSDR would decide to develop a toxicological profile for SO₂ at all – and especially in such a superficial way – when EPA had just gone through its very comprehensive process of reviewing the SO₂

NAAQS. The public docket shows that Dr. Grant submitted very strongly worded written comments to ATSDR in 1998 indicating that EPA had serious concerns regarding ATSDR's calculation of its MRL and LOAEL, and that such calculation "ignores much of the scientific guidance provided to EPA" by the Clean Air Scientific Advisory Committee. Letter to Dr. Selene Chou, ATSDR, from Dr. Lester D. Grant, EPA, March 23, 1998.

Unfortunately, ATSDR never responded to EPA's comments. Although ATSDR's process allows 90 days for public comments on draft toxicological profiles, ATSDR does not discuss or respond to such comments. It simply "considers" the comments, then finalizes the profiles and distributes them via the National Technical Information Service (and the Internet), without responding to concerns raised during the comment period. This stands in stark contrast to the type of rigorous public and scientific review process that EPA follows when it addresses the same issues as part of the NAAQS review.

When EPA completed its NAAQS review in 1996, the Agency specifically said that it would "continue to assess the scientific information on health effects associated with 5-minute, 24-hour and annual SO₂ exposures as it emerges from research and ongoing SO₂ monitoring programs, and will update the air quality criteria for sulfur oxides accordingly." *Id.* at 25576. As part of that continuing assessment, EPA has recently published a draft "Integrated Science Assessment for Sulfur Oxides – Health Criteria" (September, 2007; available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm>). This Integrated Science Assessment, or "ISA," comprehensively addresses the same short-term SO₂ exposure to asthmatics as ATSDR's SO₂ toxicological profile. The draft ISA does not discuss any new research that calls into question the adequacy of the Agency's existing concern level.

At this point, EPA is seeking public comment on this draft ISA – one of the key steps in its scientific review of the health effects of SO₂ and its reassessment of the SO₂ NAAQS. At the end of this process, the Agency may or may not conclude that a revision of the NAAQS is appropriate. Although the results of any NAAQS review may be controversial, there is no doubt that the process will be conducted in an open, scientifically rigorous manner by the Agency with the mandate, resources, and expertise to evaluate the health effects of SO₂. It seems odd, to say the least, that ATSDR would convene its own "expert panel" to review these same issues right in the middle of this process.

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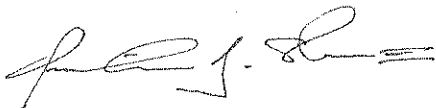
This issue is of considerable importance to the power industry. By establishing scientifically unjustifiable standards for SO₂, and then using those standards to conduct and publish "health risk assessments" of power plants, ATSDR is misleading the public and harming companies that are in full compliance with all

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federal, state, and local requirements. We believe that ATSDR should retract the SO₂ toxicological profile and coordinate with EPA, CEQ, and OMB to ensure that there is uniform and scientifically sound policy among federal agencies regarding acceptable ambient levels of SO₂.

We appreciate your attention to this important matter. If you have any questions or would like further information, please contact me at 202-508-5027, John Kinsman at 202-508-5711, or Jeff Holmstead of Bracewell & Giuliani at 202-828-5852.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Quinlan J. Shea, III". The signature is fluid and cursive, with a horizontal line at the end.

Quinlan J. Shea, III

cc: Julie Gerberding, ATSDR
Howard Frumpkin, ATSDR
Richard McKeown, HHS
Robert Meyers, EPA
Steve Page, EPA
Charles Ingebretson, EPA