

EPA's Statutory Obligations under the Clean Air Act

National Ambient Air Quality Standards (NAAQS) are the cornerstone of the Clean Air Act's approach to regulating air pollution. The Act requires EPA to set primary NAAQS at levels requisite to protect public health with an adequate margin of safety. In determining whether proposed NAAQS achieve this mandate, EPA must err on the side of protecting public health, consider health impacts that may be impossible to quantify or are as yet uncovered by science, and ensure that sensitive populations like children and the elderly are protected. In addition, EPA must give due deference to the advice of an independent panel of scientific advisors, the Clean Air Scientific Advisory Committee (CASAC). Finally, the Supreme Court has held that the EPA cannot consider the cost or feasibility of meeting the standard in setting the NAAQS.

Legislative Framework for NAAQS

The Clean Air Act Amendments of 1970 first introduced enforceable NAAQS. The amendments were intended to be “a drastic remedy to what was perceived as a serious and otherwise uncheckable problem of air pollution,” *Union Electric Co. v. EPA*, 427 U.S. 246, 256 (1976). The 1970 amendments “carrie[d] the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health.” 116 Cong. Rec. 42381 (December 18, 1970).

National Ambient Air Quality Standards still drive the Clean Air Act's requirements for controlling emissions of conventional air pollutants. Once EPA establishes a NAAQS, states and EPA identify those geographic areas that fail to meet the standards. 42 U.S.C. § 7407(d). Each state must prepare an “implementation plan” designed to demonstrate what the state will do to reduce air pollution emissions in order to reduce the ambient concentrations of regulated pollutants to levels compatible with the NAAQS (including how the state will initially attain the standards, and how it will maintain and enforce the NAAQS).

The Clean Air Act provides a clear process for establishing the NAAQS. The first step in establishing a NAAQS involves identifying those pollutants “emissions of which, in [EPA's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare,” and “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources. . . .” 40 U.S.C. § 7408(a)(1)(A)(B). Once EPA identifies a pollutant, it must select a NAAQS that is based on air quality criteria reflecting “the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air. . . .” *Id.* § 7408(a)(2).

Primary NAAQS must be set at a level “requisite to protect the public health” with “an adequate margin of safety.” *Id.* § 7409(b)(1).

Thus any standards that EPA promulgates under these provisions must be adequate to (1) protect public health and (2) provide an adequate margin of safety, and (3) to prevent any known or anticipated non health-related effects from polluted air. Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in selecting a level for the NAAQS. In exercising its judgment, EPA (1) must err on the side of protecting public health, (2) must base decisions on the latest scientific knowledge giving due deference to the recommendations of the Clean Air Science Advisory Committee, and (3) may not consider cost or feasibility in connection with establishing the numerical NAAQS or other important elements of the standard (e.g., form of the standard, averaging time, etc.). In short, “[b]ased on these comprehensive [air quality] criteria and taking account of the ‘preventative’ and ‘precautionary’ nature of the act, the Administrator must then decide what margin of safety will protect the public health from the pollutant’s adverse effects – not just known adverse effects, but those of scientific uncertainty or that ‘research has not yet uncovered.’ Then, and without reference to cost or technological feasibility, the Administrator must promulgate national standards that limit emissions sufficiently to establish that margin of safety.” *American Lung Assn. v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also Whitman v. American Trucking Assn.*, 531 U.S. 457, 464-71 (2001). *See* H.Rep. 294, 95th Cong., 1st Sess. 49-51 (1977) (explaining amendments designed *inter alia* “[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs”).

NAAQS Must Protect Public Health with an Adequate Margin of Safety

In setting or revising a NAAQS, Section 109 of the Clean Air Act requires that the EPA achieve one thing at minimum: protect public health with an adequate margin of safety. But other parts of the statute, as well as guidance from the court provide significant limitations on the discretion granted to EPA in selecting a level and form for the NAAQS. The following excerpt from an opinion of the U.S. Court of Appeals for the District of Columbia sums up EPA’s mandate succinctly:

“Based on these comprehensive [air quality] criteria and taking account of the ‘preventative’ and ‘precautionary’ nature of the act, the Administrator must then decide what margin of safety will protect the public health from the pollutant’s adverse effects – not just known adverse effects, but those of scientific uncertainty or that ‘research has not yet uncovered.’ Then, and without reference to cost or technological feasibility, the Administrator must promulgate national standards that limit emissions sufficiently to establish that margin of safety.” *American Lung Assn. v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998)

Likewise, “[s]tandards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment.” 44 Fed. Reg. 8210 (February 8, 1979). Thus, EPA cannot deny protection from air pollution’s effects by claiming that the people experiencing those effects are insufficiently numerous, or that levels that are likely to cause adverse health effects occur only in areas that are infrequently visited. To the contrary, the NAAQS mandate “carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American’s health.” 116 Cong. Rec. 42381 (December 18, 1970)(remarks of Senator Muskie, floor manager of the conference agreement).¹

In implementing this mandate, EPA cannot deny protection against adverse health and welfare effects merely because those effects are confined to subgroups of the population or to persons especially sensitive to air pollution. It is inherent in NAAQS-setting that adverse effects are experienced by less than the entire population, and that we do not know in advance precisely which individuals will experience a given effect. In light of these circumstances, opponents of protective NAAQS often argue that NAAQS-setting involves evaluating "risk" and setting a level of risk that is "acceptable." But where—as here—peer-reviewed science shows that adverse effects stem from a given pollutant concentration, EPA must set NAAQS that protect against those effects with an adequate margin of safety. It cannot, under the guise of risk management, set NAAQS that allow such effects to persist. Indeed, given the scientific evidence documenting the occurrence of adverse effects year after year in numerous individuals at levels allowed by both the current NAAQS and EPA’s proposal, risks are by definition "significant" enough to require protection under the Act’s protective and precautionary approach. *See* H.R. Rep. No. 95-294 at 43-51; *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976). That is all the more true where the effects involved include highly serious ones like death and hospitalization. *See Ethyl*, 541 F.2d at 18 ("the public health may properly be found endangered ... by a lesser risk of a greater harm").

EPA Must Err on the Side of Protecting Public Health

¹ *See also* 116 Cong. Rec. at 32901 (September 21, 1970) (remarks of Senator Muskie) ("This bill states that all Americans in all parts of the Nation should have clean air to breathe, air that will have no adverse effects on their health."); *id.* at 33114 (September 22, 1970) (remarks of Senator Nelson) ("This bill before us is a firm congressional statement that all Americans in all parts of the Nation should have clean air to breathe, air which does not attack their health."); *id.* at 33116 (remarks of Senator Cooper) ("The committee modified the President’s proposal somewhat so that the national ambient air quality standard for any pollution agent represents the level of air quality necessary to protect the health of persons."); *id.* at 42392 (December 18, 1970) (remarks of Senator Randolph) ("we have to insure the protection of the health of the citizens of this Nation, and we have to protect against environmental insults -- for when the health of the Nation is endangered, so is our welfare, and so is our economic prosperity"); *id.* at 42523 (remarks of Congressman Vanik) ("Human health and comfort has been placed in the priority in which it belongs -- first place.").

Quite clearly, the Act’s mandate requires that in considering uncertainty EPA must err on the side of caution in terms of protecting human health and welfare. As the D.C. Circuit held in reviewing the last round of NAAQS revisions, “The Act requires EPA to promulgate protective primary NAAQS even where ... the pollutant's risks cannot be quantified or ‘precisely identified as to nature or degree.’” *Am. Trucking Assoc. v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38653); *id.* (citing Ozone NAAQS, 62 Fed. Reg. 38857 (section 109(b)(1)’s “margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified”). See H.Rep. 294, 95th Cong., 1st Sess. 49-51 (1977) (explaining amendments designed *inter alia* “[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs”).

Courts have properly characterized the NAAQS as “preventative in nature.” *Ethyl Corp. v. EPA*, 541 F.2d 1, 15 (D.C. Cir. 1976). That is all the more true where, as with ozone, the effects involved include highly serious ones like death and hospitalization. See *Ethyl*, 541 F.2d at 18 (“the public health may properly be found endangered ... by a lesser risk of a greater harm”).

NAAQS Must Guard Against Potential Health Effects

In keeping with the cautionary and preventative nature of NAAQS, EPA must set a standard that protects against potential health effects—not just those impacts that have been well established by science.

In the seminal case on the NAAQS, the D.C. Circuit found that Congress “specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement.” *Lead Industries Assn. v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980). Limited data are not an excuse for failing to establish the level at which there is an absence of adverse effect. To the contrary, “Congress’ directive to the Administrator to allow an ‘adequate margin of safety’ alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful.” *Lead Indus. Ass’n*, 647 F.2d at 1154-55.

In another case dealing with the “margin of safety” requirement of Section 109, the D.C. Circuit rejected industry's argument that EPA was required to document “proof of actual harm” as a prerequisite to regulation, instead upholding EPA's conclusion that the Act contemplates regulation where there is “a significant risk of harm.” *Ethyl Corp. v. EPA*, 541 F.2d 1, 12-13 (D.C. Cir. 1976). Noting the newness of many human alterations of the environment, the court found:

Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, ‘reasonable medical concerns’ and theory long precede certainty. Yet the statutes — and common sense — demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable. *Id.* at 25. *Accord, Industrial Union Dept. v. American Petroleum Institute*, 448 U.S. 607, 655-56 (1980) (plurality) (agency need not support finding of significant risk "with anything approaching scientific certainty," but rather must have "some leeway where its findings must be made on the frontiers of scientific knowledge," and "is free to use conservative assumptions in interpreting the data," "risking error on the side of overprotection rather than underprotection")

NAAQS Must Protect Vulnerable Subpopulations

NAAQS must be set at levels that are not only adequate to protect the average member of the population, but also guard against adverse effects in vulnerable subpopulations, such as children, the elderly, and people with heart and lung disease. In fact, courts have repeatedly found that if a certain level of a pollutant “adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” *American Lung Assn. v. EPA*, 134 F.3d 388, 390 (D.C. Cir. 1998) (citations omitted).

The drafters of the 1970 Clean Air Act Amendments made clear that the millions of Americans subject to respiratory ailments are entitled to the protection of the NAAQS. "Included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." S. Rep. No. 1196, 91st Cong., 2d Sess. 10 (1970).

As the U.S. Court of Appeals for the D.C. Circuit has stated: “In its effort to reduce air pollution, Congress defined public health broadly. NAAQS must protect not only average healthy individuals, but also “sensitive citizens” – children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.” *American Lung Assn. v. EPA*, 134 F.3d 388, 390 (D.C. Cir. 1998) (citations omitted). Stated another way, NAAQS must “be set at a level at which there is ‘an absence of adverse effect’ on these sensitive individuals.” *Lead Industries Assn, Inc. v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980). *See also Washington v. Glucksberg*, 521 U.S. 702 (1997) (people near death are of no less worth than other members of society).

Twenty-two million Americans have been diagnosed with heart disease, nine million with chronic bronchitis, three million with emphysema, while twenty million adults and twelve million children have chronic asthma. The standards must set at a level that protects these and other populations with an adequate margin of safety.

EPA Cannot Consider Economic Cost of Meeting NAAQS

In setting or revising NAAQS, EPA cannot consider the economic impact of the standard—only the impact on public health.

Lower courts had long held that costs could not be considered in setting NAAQS, and in 2001, the Supreme Court affirmed this position. Justice Scalia, writing for a unanimous Court, found that the plain language of the statute makes clear that economic costs cannot be considered: “Were it not for the hundreds of pages of briefing respondents have submitted on the issue, one would have thought it fairly clear that this text does not permit the EPA to consider costs in setting the standards.” *Whitman v. American Trucking Assns.*, 531 U.S. 457, 465 (2001).

In addition to the plain language of the Clean Air Act, the Court found that Congress had specifically instructed EPA to consider economic costs in other pollution regulations, and would have included similar instructions if it intended EPA to consider economic costs in setting NAAQS. *Id.* at 466-467.

EPA’s July 11, 2007 ozone proposal quoted extensively from Justice Breyer’s concurrence in *Whitman*. It is the language of the majority opinion that controls, not that of a concurrence.

EPA Must Give Due Deference to the Advice of CASAC

The Act expressly requires EPA, in developing standards, to consider the advice of the statutorily created Clean Air Scientific Advisory Committee (CASAC) and rationally explain any important departure from CASAC’s recommendations. §§ 7409(d)(2)(B), 7607(d)(3). Even if the Act did not so require, settled principles of administrative law would require EPA to reconcile any disparity between its standards and those recommended by CASAC. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).