

The Use of Scientific Information in Setting Ambient Air Standards

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The Clean Air Act, as amended in 1977, requires periodic review and revision of all national ambient air quality standards (NAAQS) to insure that they are based on the latest scientific information. This article presents an overview of how EPA currently reviews and establishes NAAQS. The role of scientific information and expertise in the process is illustrated by a review of several key issues faced in the development of the proposed revisions to the carbon monoxide NAAQS. Finally, a risk analysis framework being developed within EPA's Office of Air Quality Planning and Standards for possible future use in NAAQS reviews is described. The principal objective of the risk analysis framework is to provide more formal treatment of uncertainties in the scientific data base.

In 1971, six national ambient air quality standards (NAAQS) were set by the U.S. Environmental Protection Agency (EPA). NAAQS are set for air pollutants that not only contribute to adverse effects at high enough concentrations, but also result from ubiquitous emissions by numerous mobile and stationary sources. The regulatory statute requiring that NAAQS be set and ultimately met, the Clean Air Act, stipulates that these standards be set and periodically reviewed on the basis of the latest state of scientific knowledge. The six original NAAQS were for photochemical oxidants, hydrocarbons, nitrogen dioxide, carbon monoxide, particulate matter and sulfur dioxide.

In the period 1976-1982, EPA has striven to improve the procedures by which it reviews and establishes NAAQS. This article presents an overview of the current standard-setting process. It also illustrates how scientific information and expertise are used in the process by reviewing several key issues faced in the development of the proposed revisions to the carbon monoxide NAAQS. Finally, a conceptual risk analysis framework is briefly described that would more

formally treat uncertainties unresolved by the scientific data base. This framework would utilize scientific expertise and probabilistic models to better inform EPA decision makers as they review and revise NAAQS.

NAAQS Issues

A NAAQS defines allowable distributions of ambient pollutant concentrations in such a way that it can be operationally determined whether a given geographical area is in compliance. There are two types of NAAQS: primary standards that are designed to protect public health and secondary standards that are designed to protect public welfare.

Protection of public welfare includes preventing: (1) economic losses due to vegetation or materials damage, (2) degradation in visibility, (3) negative aesthetic impacts and (4) personal discomfort. We are concerned only with primary ambient air standards in this article.

The setting of ambient standards by the U.S. Environmental Protection Agency is governed by Sections 108 and 109 of the Clean Air Act (42 U.S.C. 7408 and 7409). Section 108 requires EPA to develop "air quality criteria" for a potential NAAQS pollutant. These criteria summarize the latest state of scientific knowledge concerning a pollutant and its effects on man and the environ-

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ment. The criteria for each pollutant are published in a "criteria document" that is widely circulated for review and comment.

EPA's Office of Environmental Criteria and Assessment develops the criteria document mostly under contract to individual and university experts in the various areas of concern (1). Among other things, the document critically reviews health effects research evidence from a scientific point of view. For example: were the studies designed and conducted properly? Were appropriate statistical techniques used? Were potentially confounding influences controlled for? Thus, the criteria document provides an assessment of the scientific credibility of particular research efforts.

Section 109 requires EPA to establish an ambient air quality standard for "any pollutant for which air quality criteria are issued." This section also requires that a primary NAAQS be set at a level "requisite to protect public health," with an adequate margin of safety. Both the Clean Air Act and its legislative history make it clear that an ambient air quality standard is to be solely health based, designed to protect the most sensitive group of individuals—but not necessarily the most sensitive members of that group—against adverse health effects (2). This focus on sensitive groups was reaffirmed by Congress during its debates on the 1977 Clean Air Act Amendments (3). As a recent article indicates (4), predicating ambient air standards on the protection of sensitive or highly susceptible people is controversial because of the high control costs associated with a stringent NAAQS and the problems associated with defining pollutant-specific sensitive population groups.

EPA's interpretation of the Clean Air Act is that costs incurred by industry and the public to attain an ambient air quality standard are not to be considered in setting such standards, although these costs may be considered to some extent by state air pollution control agencies in implementing attainment measures. This interpretation has been upheld in two recent judicial decisions (5, 6).

In setting NAAQS to protect public health with an adequate margin of safety, EPA must make difficult decisions concerning inherently imprecise concepts: "public health" and "adequate margin of safety." Neither the Clean Air Act nor its legislative history is precise in defining what is meant by these terms. Rather, Congress used these terms to define the objective of preventing adverse health effects from being experienced by sensitive population groups, and the population as a whole, upon exposure to ambient air.

To implement the concept of protecting public

health with an adequate margin of safety, EPA must address the issue of what categories of effects are to be considered "adverse." For some categories of effects (e.g., changes in lung function), a relatively small change may be regarded as an insignificant physiological response, while a larger change may be considered significantly adverse to health. Clearly, the scientific and medical communities are the most qualified to offer guidance concerning which categories of effects and/or degree of responses are medically significant. EPA tries to take full advantage of existing medical expertise on such matters. However, at the margin, where effects are often subtle and reasonable scientists disagree about their importance, the administrator must ultimately judge which effects are to be regarded as adverse for standard-setting purposes.

Another aspect of making a NAAQS operational is stating it in terms of one or more pollutant concentration averaging times. Different averaging times may be needed for a pollutant because the time pattern of concentrations can be a determining factor in whether the pollutant causes an adverse effect. For example, total dose of a pollutant over a relatively long period may be more important for one adverse effect, whereas dose rate over a relatively short period may be more important for another adverse effect of the same pollutant. In such a case two different averaging times may be needed.

In the process of reviewing health effects evidence relevant to determining a NAAQS, it becomes apparent that considerable uncertainty exists regarding certain key relationships. These uncertainties include: uncertainty in the dose-effect relationships between dose of a NAAQS pollutant and the fraction of a group adversely affected, particularly at low dose levels; uncertainty about human exposures to NAAQS pollutants; and uncertainty about the existence of effects in humans when they have only been demonstrated in animal studies. These uncertainties are compounded by ethical limitations regarding research with susceptible individuals in controlled exposure studies and difficulties of sorting out numerous confounding and covarying factors in community (epidemiological) studies.

EPA deals with these uncertainties through the margin of safety language in section 109 of the Clean Air Act. While an operational definition of the margin of safety concept was not given, the legislative history and precautionary nature of the Act make it clear that the intent of providing an adequate margin of safety is to protect against health effects not yet identified by scientific re-

search, or those identified but not well understood (7). How EPA judges what constitutes an adequate margin of safety is another important determinant of an ambient air standard. A review of the carbon monoxide (CO) standard is used below to illustrate the difficulties involved in making this type of judgment.

As discussed above, in setting ambient standards EPA has to make decisions based on data bases which usually include considerable uncertainties. In addition, EPA has to make concrete judgments and decisions involving imprecise concepts. How the agency procedurally accomplishes this difficult task is discussed next.

The NAAQS Standard-Setting Process

Setting a national ambient air quality standard involves literally scores of people performing many different tasks. Most of the activities involve coordination or consultation with groups outside of EPA, so communication is a major part of the standard-setting process. In addition, most of the analyses and position papers produced along the way are formally reviewed by the public and/or scientific community. Thus, the process is highly interactive.

The main elements of EPA's NAAQS decision-making activities are shown in Figure 1. Not depicted on the diagram are activities undertaken for items associated with an air standard but not directly health related. These activities include analyses to determine the need for a secondary (welfare effects related) NAAQS, technical and analytic work done on the "federal reference method" associated with air quality monitoring, and economic analyses of the projected impacts that attaining alternative NAAQS will have on society.

As mentioned, the scientific basis of a standard is condensed in a criteria document. This document undergoes intensive review by the scientific and medical community prior to its release. An initial working draft is circulated and reviewed at a workshop, where agency and consulting authors responsible for individual chapters discuss their findings and conclusions with nonagency experts. Afterwards, revisions are made as needed and a "first external review draft" is released for review to the public and the Clean Air Scientific Advisory Committee (CASAC), an independent advisory committee to EPA. Appropriate changes based on comments from CASAC and/or the general public are incorporated in a "second external review draft" of the criteria document. The process is repeated until EPA's Environmental and Criteria Assessment Office (ECAO), which is responsible for development of the document, achieves "final closure" on the criteria document with CASAC. Final closure means that CASAC, as a body, has no substantive criticisms concerning the criteria document. It is achieved when CASAC, in a written report to the EPA administrator, states that the document is of appropriate quality for use as the scientific basis for proceeding with an ambient air quality standard.

When the criteria document appears to be substantially complete, EPA analysts in the Office of Air Quality Planning and Standards (OAQPS) develop a "staff paper" evaluating key studies in the criteria document and identifying critical elements to be addressed in the standard-setting process (8). The staff paper critically reviews the medical evidence summarized in the criteria document and addresses implications of the evidence for standard-setting purposes. It helps bridge the gap between science contained in the criteria document and judgments required of the administrator in setting ambient standards (8). Recently,

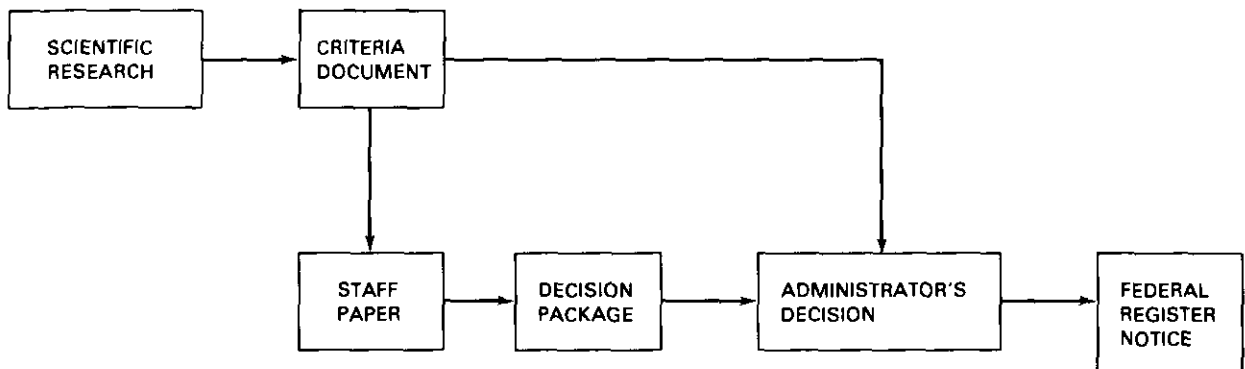


FIGURE 1. Overview of NAAQS standard-setting process.

staff papers have begun to recommend ranges for alternative standards.

The staff paper is reviewed by the public and CASAC in an open meeting. Thus, interpretations of the medical evidence by the regulatory staff are closely scrutinized by the scientific community prior to formulation of standards. After closure is obtained, the paper becomes the basis for staff recommendations for a NAAQS to the EPA administrator. These recommendations are explained in a draft *Federal Register* notice preamble, which becomes part of a "decision package" on a standard. Also included are various technical analyses, such as environmental and regulatory impact analyses, and exposure assessment. This material is circulated extensively within EPA to obtain the views and criticisms of other agency offices. This is commonly known as "red border" or "associate administrator" review. It is only the last of a number of internal coordination efforts utilized during any regulatory development effort, including setting an ambient air quality standard. For instance, a working group is established early in the process to coordinate staff-level activities. A standing "steering committee" coordinates reviews among higher-level decision-makers. An in-depth study of these internal procedures, has been published (9).

Changes in the decision package are inevitably made because of this review. The process is repeated until a final package is developed and sent to the administrator for a decision. This decision formally appears in the *Federal Register*. If the action taken is to propose a NAAQS or propose changes in an existing NAAQS, EPA solicits public comments on the proposal and holds public meetings. EPA carefully reviews these comments and makes changes to the decision package as appropriate. The internal review process discussed above is repeated until a final decision on a standard is reached by the EPA Administrator. The NAAQS is then promulgated in the *Federal Register* and becomes law.

Review of the Carbon Monoxide Ambient Standards

In this section EPA's current approach to addressing the difficult scientific and health issues noted earlier is illustrated by examining how they were dealt with in the on-going review of the primary carbon monoxide (CO) ambient air quality standard. The CO standard was the second NAAQS to undergo review under the 1977 Clean Air Act Amendments. Procedurally, the review and revision of the criteria and standards for CO

followed the process described earlier. EPA published a revised criteria document and a staff paper, both of which were favorably reviewed by CASAC (1, 10). A regulatory decision package was prepared and extensively reviewed within the agency, and EPA issued proposed revisions to the CO NAAQS on August 18, 1980, in the *Federal Register* (11). The proposed standards are still undergoing review.

Briefly, the agency proposed: (1) to retain the 8-hr (averaging time) standard level at 9 ppm, (2) to lower the 1-hr (averaging time) standard level from 35 to 25 ppm and (3) to revise the "form" of the standard from a deterministic to a statistical form; that is, to change the statement of the standard from allowing no more than one exceedance of the standard level in any given year to allowing one expected exceedance per year. As it revises the NAAQS, EPA is changing to statistical forms because they provide a more stable target for control programs designed to attain the standards. This is because unpredictable and uncontrollable factors, such as meteorological variables, affect ambient concentrations that result from any given pollutant emissions regime, which is what can be controlled (12).

EPA Handling of Health/Science Issues for CO

Adverse Health Effects

The existing medical evidence summarized in the revised criteria document indicates that CO affects the human body by combining with hemoglobin to form "carboxyhemoglobin" (COHb). By reducing the amount of functional hemoglobin in the blood, CO reduces the oxygen transport capacity of blood. The resulting reduction in oxygen supply to body organs and tissues causes impairment of cardiovascular, central nervous, and pulmonary systems.

EPA staff concluded that effects on the cardiovascular system (e.g., aggravation of angina) were of greatest concern due to potential impacts on the cardiovascular system of sensitive subjects and the relatively low COHb levels (2.7-2.9%) at which effects had been reported in human exposure studies. Effects on the central nervous system (e.g., impairment of visual sensitivity and reaction times) were judged to be less serious in their impact and appeared to start only at higher COHb levels (roughly 4-6%). Other effects associated with CO exposure were deemed less critical for developing a primary standard because they either occurred at higher COHb levels (greater

than 4%) or occurred at unknown levels in humans (e.g., effects that had been demonstrated only in animal studies). Therefore, EPA focused on aggravation of angina in developing proposed revisions to the CO NAAQS.

Angina is a form of heart disease in which mild exercise or excitement produces symptoms of pressure and/or pain in the chest due to insufficient oxygen supply to the heart muscle. Angina patients exposed to relatively low levels of CO under controlled conditions exhibited reduced time to onset of chest pain and increased duration of pain while exercising.

In determining whether aggravation of angina should be considered an adverse health effect, some cardiologists have argued that no permanent harm accompanies angina attacks, while other medical scientists have expressed concern that damage may be occurring that is simply unquantifiable using current medical technology. At a minimum, EPA judged that additional and/or longer angina attacks impair the ability of individuals to engage in normal activities and result in additional pain and suffering. The fact that angina patients were affected by low levels of CO also suggests that individuals with more severe forms of heart disease (e.g., those who have suffered heart attacks) may experience more serious effects at the same or lower COHb levels. These considerations and the precautionary nature of the Clean Air Act led both CASAC and the EPA administrator to conclude that the aggravation of angina observed at COHb levels of 2.7-2.9% should be considered an adverse health effect.

Sensitive Population Groups

On the basis of the effects data, EPA identified persons with angina and other types of cardiovascular disease as the groups at greatest risk from low-level ambient exposures to CO. Based on the 1960-1962 National Health Examination Survey, EPA estimated that in 1979 there were approximately 7.7 million individuals with angina and other types of cardiovascular disease (13).

The criteria document and staff paper identified a number of other population groups as potentially sensitive to ambient CO levels on the basis of existing scientific evidence. These groups included fetuses, those who are anemic and persons with lung diseases. The lack of human effect levels for these population groups, however, led EPA to consider the potential effects on such persons only in determining which CO standard would provide an adequate margin of safety.

Lowest Convincingly Demonstrated Effect Level(s)

The CO criteria document supports the conclusion that a clear threshold of adverse health effects cannot be identified with certainty for CO or even for COHb levels, which are more directly related to health effects than ambient CO concentrations. In the *Federal Register* proposal, EPA recognized that no absolutely safe level existed, other than zero. However, this does not mean that there is no threshold for a suitably defined effect and population group for CO; it simply means that no clear threshold can be identified with certainty based on existing medical evidence (11). The best EPA could do was to identify those levels at which scientists generally agreed that adverse health effects had been convincingly shown.

The CO criteria document indicated that three human exposure studies have reported aggravation of angina and other cardiovascular diseases after 2- to 4-hr CO exposures that resulted in group mean COHb levels in the range of 2.7 to 2.9% (14-16). CASAC concluded that the medical evidence to date best supports this range as the lowest level convincingly linked to adverse health effects in sensitive persons (17).

Another human exposure study reported aggravation of angina at a lower COHb range (1.8 to 2.3%), but these COHb levels were obtained by exposure to cigarette smoke (18). The criteria document and CASAC concluded that other components of tobacco smoke, such as oxides of nitrogen, nicotine, and hydrogen cyanide, may have contributed to the effect observed and, therefore, that these COHb levels should not be regarded as the lowest effect levels convincingly demonstrated.

Scientific Uncertainties and Margin of Safety

A variety of important questions remain unanswered about the impact of ambient CO exposures on human health. These questions and uncertainties include the following: (1) Whether decreased time to onset of angina demonstrated in several human exposure studies means that there are a greater number of or more severe angina attacks due to ambient CO exposures. (2) Whether angina patients or more severe heart disease patients are adversely affected at COHb levels lower than 2.7-2.9%. (3) What are the dose-effect relationships for population groups that are likely to be affected by CO (e.g., fetuses, those who are anemic, and individuals prone to heart attacks), but which

have not been tested in controlled human exposure studies for ethical reasons? (4) What is the relationship, if any, between ambient CO exposures and incidence and severity of heart attacks?

In developing proposed revisions to the CO primary NAAQS, EPA assessed a variety of factors and uncertainties in the medical evidence (including those noted above) which had to be considered in selecting a standard which would provide an adequate margin of safety. While some uncertainties were addressed quantitatively, (e.g., variation in COHb levels that would result from a given CO exposure due to different physiological characteristics of the population and different patterns of air quality (19), others by necessity were qualitatively integrated to arrive at a judgment on what constituted an adequate margin of safety. These included the lack of negative human exposure studies at COHb levels below 2.7-2.9%, concern for sensitive population groups not yet tested in controlled studies, and less conclusive evidence suggesting that adverse effects might occur at lower COHb levels but which were confounded by the presence of other pollutants contained in tobacco smoke.

In developing the CO proposal, EPA estimated that attainment of a 9 ppm, 8-hr standard would keep more than 99% of the sensitive population (the approximately 7.7 million individuals suffering from cardiovascular heart disease) from exceeding COHb levels of 2.1%. After considering the lowest convincingly demonstrated effects level range of 2.7-2.9% COHb and strengths and weaknesses of the scientific data base, the admin-

istrator judged that a 9 ppm, 8-hr CO standard would provide an adequate margin of safety.

It should be noted that there is no collection of facts or medical evidence for carbon monoxide that permits selection of an undisputed value for the ambient air standard level. This is true for all NAAQS pollutants. Rather, the EPA administrator must exercise the informed judgment that Congress has authorized her or him to bring to bear on these difficult problems dealing with interpretation of scientific information.

Risk Analysis

An ongoing OAQPS risk analysis program is attempting to develop techniques which explicitly address uncertainties in scientific information used in NAAQS standard setting (20). These techniques involve disaggregating the standard-setting process into three main components that are considered in the final decision: a scientific assessment, a risk assessment, and a risk evaluation/decision analysis (see Fig. 2). This approach is compatible with EPA's current legal mandate regarding ambient air quality standards. It is also compatible with alternative decision bases, such as those proposed by the National Commission on Air Quality (21) and the Business Roundtable (22). The emphasis, or weight, given individual components in making a final decision is the main difference among these competing standard-setting approaches and the conceptual process outlined below can be used with all of them.

The objective of the scientific assessment com-

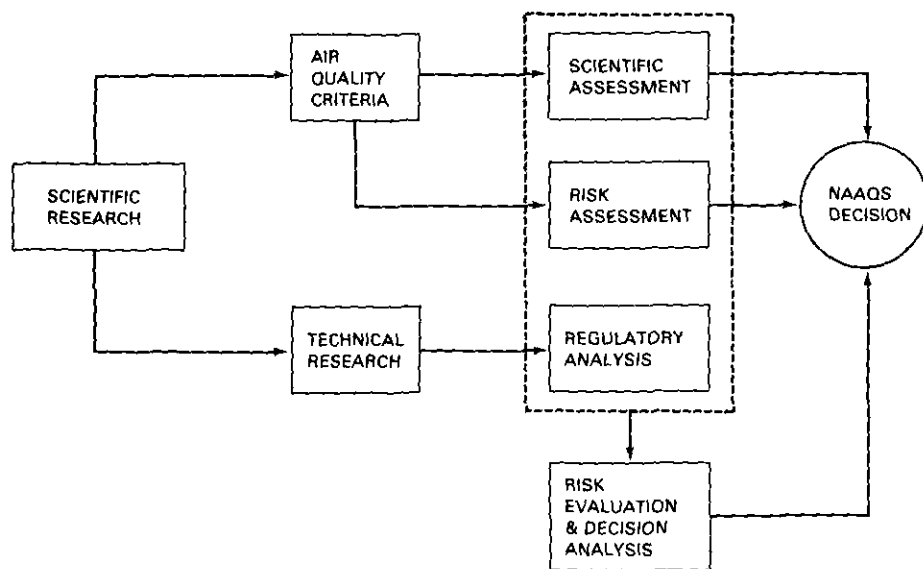


FIGURE 2. Conceptual overview of a NAAQS decision-making process using formal risk analysis.

ponent is to present an accurate picture of the scientific knowledge base regarding health and other effects of the pollutant in question. This assessment builds upon the criteria document, and focuses on determining what information is generally accepted as scientific fact based on available empirical evidence. Thus, emphasis is placed on describing reported effect levels, uncertainties in the evidence, conflicting results, and untested hypotheses.

The objective of the risk assessment component is to estimate the probability of occurrence and expected number of certain specified adverse events given the current state of information. With respect to NAAQS, this means the probability of exceeding the level at which adverse health effects associated with alternative ambient air standards would occur and the probability distribution of the number of adverse health effects that would occur in the sensitive population.

Main elements of the risk assessment include: (1) a qualitative and quantitative judgmental assessment of adverse health effects as delineated in the criteria document, and (2) an exposure analysis. The health effects assessment is based on recognized health experts' views at the time regarding scientific evidence of adverse health effects associated with the pollutant being analyzed. The qualitative assessment provides a description of the basis for the experts' probabilistic judgments and a discussion of the nature and severity of potential adverse health effects. The quantitative assessment represents the experts' judgments concerning what are the exposure-response relationships for various types of health effects, who are the sensitive groups of concern, and what pollutant concentration levels will result in adverse health effects being experienced in the sensitive population. The use of judgmental encoding, which goes beyond strict scientific interpretation of data, makes the risk assessment trans-scientific (23). Probability judgments are made using available information, even if that information does not meet classical scientific criteria of acceptance. Each expert individually decides how much weight is placed upon individual studies comprising the scientific data base.

The needed exposure analysis should also be done probabilistically, using both expert opinion and "hard" frequency data on air quality distributions, human activity patterns, and human ventilation rates (roughly equivalent to exercise level, which is a function of the activity being undertaken). The exposure modeling analysis is designed to estimate how many sensitive persons are exposed to potentially harmful levels of air

pollution when alternative NAAQS standards are just attained (24). Describing the models needed for an exposure analysis and how uncertainties in their input data are handled is beyond the scope of this paper. The important point to be made for our purposes here is that the inherent uncertainties in exposure modeling have to be addressed explicitly and probabilistically.

The use of, and the need for, expert judgments in handling uncertainty in both the health effects and exposure modeling elements of a risk assessment requires a different mode of thinking than science. It means recognizing that in general there is no true value for a probability that a given adverse event will occur within a given period of time; that is, there is no true value for the risk in question. One important reason there is no true value is that in general there is no true probabilistic model for assessing the probability that a given event will occur. While probabilistic models may be refined and improved, there is no absolute best model. These ideas are expanded upon in an article by Feagans and Biller (25).

Scientists play a key role in probabilistic risk assessment. They contribute substantive expertise in constructing probabilistic risk models and then provide judgments in defining values used in the models. These judgments may be based on (1) objective data, (2) classical statistical analyses of that data, including the relative frequency interpretation of probability, and (3) biological "models." Thus, the expert is not constrained in the types of information used to synthesize a model or to assign a variable.

The objective of the third component of a NAAQS decision, risk evaluation and decision analysis, is to present a clear picture of alternative valuation systems associated with the decision. This component has a number of interrelated activities, focusing on the valuation and impacts of alternative NAAQS. The risk evaluation part focuses on how alternative health risks, obtained via the risk assessment component, are valued and compared. Since health risks involve numerous impacts occurring to different sensitive groups or persons, some formal analytic procedure is needed to delineate what health risk trade-offs have to be made when alternative NAAQS standards are chosen. These analyses will aid agency decision makers in grappling with the clearly normative, social value judgments concerning which standard provides an adequate margin of safety (i.e., an acceptable level of risk).

The decision analysis part of the third component includes a focused trade-off analysis of various impacts associated with alternative NAAQS

standards. These impacts could include all the nonhealth aspects currently analyzed under varying Congressional and Presidential directives, such as benefits and environmental impacts. (On Figure 2, these are called "Regulatory Analysis.") The decision analysis also could include a focused evaluation of the policy impacts of alternative NAAQS on other EPA offices and other NAAQS pollutants.

The risk evaluation and decision analyses together have the potential to provide EPA decision makers with knowledge concerning trade-off functions among health, environmental, and regulatory impacts associated with a NAAQS decision. These analyses can assist decision makers in the difficult task of balancing incommensurables and exercising judgment, and the authors believe that the approach can potentially lead to better informed decisions regarding national ambient air quality standards.

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