No. 99-1426

IN THE

Supreme Court of the United States

AMERICAN TRUCKING ASSOCIATIONS, INC., CHAMBER OF COMMERCE OF THE UNITED STATES, *et al.*,
Petitioners,

v.

CAROL M. BROWNER, ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Respondents.

On a Writ of Certiorari to the United States Court of Appeals For the District of Columbia Circuit

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AMENDED DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, the following list amends the corporate disclosure statement filed in the Brief for Respondents Appalachian Power Co., *et al.*, In Support of Petitioners on July 20, 2000.

Baltimore Gas and Electric Co.
(now referred to as Constellation Power Source Generation, Inc.)
Carolina Power & Light Co.
(a subsidiary of CP&L Energy, Inc.)
(State Street Bank & Trust Company Boston is no longer a 10% or greater owner)
Illinois Power Co.
(a subsidiary of Dynegy, Inc.)
PacifiCorp
(a subsidiary of Scottish Power plc)

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GLOSSARY

The following is a glossary of acronyms and abbreviations used in this brief.

Act	Clean Air Act
Administrator	Administrator of the United States Environmental Protection Agency
Agency	United States Environmental Protection Agency
App.	Appendix to Brief for Respondents Appalachian Power Company, *et al.*, in Support of Petitioners (99-1426)
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
EPA	United States Environmental Protection Agency
NAAQS	National Ambient Air Quality Standards
OJA	Joint Appendix in D.C. Cir. Case No. 97-1441
OSP	Ozone Staff Paper (1996)

PM	Particulate Matter
PM_{10}	Particulate Matter with an aerodynamic diameter less than or equal to 10 microns
$PM_{2.5}$	Particulate Matter with an aerodynamic diameter less than or equal to 2.5 microns
PMJA	Joint Appendix in D.C. Cir. Case No. 97-1440
PPM	Parts Per Million
Reply App.	Appendix to Reply Brief of Appalachian Power Company, *et al.* (99-1426)
RIA	Regulatory Impact Analyses

INTRODUCTION[1]

EPA and its supporters assert that a federal agency directed by Congress to protect the public health *must* blind itself to factors showing that its decisions *would not* benefit the public. This Court should reject EPA's remarkable abandonment of the mission given it by Congress.

Appalachian Power Co., *et al.* ("APC") do *not* question that EPA may regulate to protect the "public health" when confronted with uncertain science. Rather APC asks this Court to address whether the Clean Air Act ("CAA") constrains EPA's exercise of policy judgment to manage uncertain public health risks and, if so, what are the constraints. This question is critically important because if Congress has provided no legal standards to guide how EPA manages such risks, then § 109 is an unconstitutional delegation of lawmaking power.

In order to answer this question, it is necessary to understand the nature of the regulatory action required under the NAAQS program. For most air pollutants, as for those at issue here, science has not identified a threshold below which health effects might not be *predicted* to occur.[2] In other words, unless there is a proven threshold below which there are no demonstrated effects from a pollutant, EPA *assumes*

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[1] This brief is filed in support of American Trucking Ass'ns, *et al.*

[2] *See, e.g., Air Pollution—1970: Hearings on S. 3229, S. 3466, S. 3546, Before the Subcomm. on Air and Water Pollution of the Sen. Comm. on Pub. Works*, 91st Cong., pt. 4, at 1489 (1970) [hereinafter *1970 Hrg.*], *reprinted in* 2 Sen. Comm. on Pub. Works, *A Legislative History of the Clean Air Amendments of 1970*, at 1184 (Comm. Print 1974) [hereinafter *1970 Legis. Hist.*] (testimony of Dr. Middleton) ("To identify a no-known-effects level is . . . very likely not possible."); H.R. Rep. No. 95-294, at 127 (1977), *reprinted in* 4 Sen. Comm. on Env't and Pub. Works, *A Legislative History of the Clean Air Act Amendments of 1977*, at 2594 (Comm. Print 1978) [hereinafter *1977 Legis. Hist.*].

effects will become fewer, but continue, down to a "zero" concentration level.

As a result, with large populations, an assessment of health risk will always predict effects, even when concentrations of a pollutant approach or fall below naturally occurring background concentrations.[3] This is a "potential" health risk driven by an assumption that, because science cannot prove a threshold, *no threshold exists*. In circumstances of ever-diminishing risk of harm, agencies must exercise "risk management" judgment unless the statute calls for elimination of all potential health risk.[4]

In §§ 108 and 109 of the Act, Congress directed EPA to regulate where pollution "endanger[s]" public health, CAA § 108(a)(1), and then to set air quality standards that are "requisite" to protect "public health," allowing an "adequate margin of safety." CAA § 109(b)(1). This is not a "zero risk" mandate. Rather, in exercising its § 109 regulatory authority, EPA must make two types of policy judgments. First, it must determine what level of predicted health risk

[3] In this case, for example, EPA's science advisers recognized that the level of the revised ozone NAAQS (0.08 ppm) approaches background concentrations in pristine areas. Clean Air Scientific Advisory Committee ("CASAC") Tr. (3/22/95) 296, OJA 278; EPA, *Review of the National Ambient Air Quality Standards for Ozone* 20 (1996) [hereinafter *OSP*], OJA 1830 (noting annual average hourly values at "clean" sites may be 0.075 ppm). Yet, EPA's risk assessment predicts health effects at levels as low as 0.04 ppm. *Id.* 116, OJA 1926.

[4] *See* Science Advisory Board, EPA, *Toward Integrated Environmental Decisionmaking* 13 (August 2000) [hereinafter SAB] (Risk management involves selection of a preferred option after "explicit consideration of the trade-offs involved . . . ."), Reply App. 9a; NAS/NRC, *Risk Assessment in the Federal Government: Managing the Process* 18-19 (1983) (describing risk assessment as "characterization of the potential adverse health effects of human exposures" and risk management as "the process of evaluating alternative regulatory actions and selecting among them"), Reply App. 6a-7a.

constitutes a potential "public health" problem (i.e., what level presents a "significant" adverse public health risk).

Second, EPA must determine what regulatory response is "requisite" to address that potential public health problem, allowing an "adequate" margin of safety. As described by Congress, in defining an "adequate" margin of safety, EPA must provide a "reasonable degree of protection" in response to scientific uncertainty. S. Rep. No. 91-1196, at 10 (1970), *reprinted in* 1 *1970 Legis. Hist., supra* note 2, at 410, OJA 3687; *see* EPA Br. (99-1426), at 33.

EPA argues strenuously that CAA § 109 "unambiguously" requires that primary air quality standards be based *solely* on the direct inhalation health effects of a pollutant, regardless of other considerations. EPA Br. (99-1426), at 18, 19. But if this were true, how does EPA determine what constitutes a potential "public health" problem? Is 50,000 predicted coughs in a population of fifty million a public health problem? Is it twice that amount, or one-half that amount? How are uncertainties inherent in such predictions to be accounted for in determining whether predicted effects might constitute a potential "public health" problem?

Once EPA determines that there is a significant adverse public health risk, how does EPA determine a "reasonable degree of protection" (i.e., an "adequate" margin of safety) in response to that problem? Does a standard that is predicted to reduce that risk in the affected population by 10 percent (or 2 percent or 20 percent) afford a "reasonable degree of protection" for the "public health"? And what if there is great uncertainty whether the "sensitive population" actually experiences the effect? What if the revised standard is predicted to deprive those with lower earnings of affordable electricity, affordable health care, or affordable heating fuel, thereby imposing adverse health and welfare consequences?[5]

[5] *See Union Elec. Co. v. EPA*, 427 U.S. 246, 271-72 (1976) (Powell, J., concurring).

Finally, what if the Administrator's science advisers conclude there is no significant difference in potential public health protection afforded by existing and revised standards, but the revised standard will impose additional costs on society of $9 billion annually with associated adverse public health risks flowing from those costs?

These are questions that can be addressed in a manner that promotes the "public health" only after considering the potential adverse impacts of the proposed regulatory action. For the reasons discussed below, and contrary to the court of appeals holding based on *Lead Industries Ass'n v. EPA,* 647 F.2d 1130 (D.C. Cir. 1980), Congress did *not* prohibit EPA from considering factors essential to the exercise of sound judgment in making NAAQS decisions that require the management of uncertain health risks.

ARGUMENT

In its brief, EPA claims that the Court need not look at the record, EPA Br. (99-1426), at 8, but then argues that the record shows that the NAAQS decisions here were *not* the product of risk management judgment. According to EPA, its decisions were based on "real and significant effects, not merely hypothetical risks." *Id.* 8, 10.

Both courts and commentators have counseled caution where agencies attempt to disguise policy judgment as science, and EPA's argument here presents a striking example of this problem. EPA's claim that the Administrator's decision was driven by demonstrated effects, not risk predictions, is both implausible and inconsistent with the record. More fundamentally, EPA's argument fails to appreciate the difference between a *demonstrated public health effect* (e.g., "asthma") and a *predicted cause of that effect* (e.g., a particular type and level of pollution), which requires judgment as to how to manage uncertain risks.

Based on *Lead Industries*, the lower court held that the Administrator had no authority to consider the impacts of her

decision on society in exercising judgment as to whether predicted health risk requires regulation as a potential public health problem and, if so, what is a "reasonable degree of protection" in response. 175 F.3d 1027, 1040-41; App. 18a-21a. For the following reasons, the CAA does not constrain the Administrator's authority in that fashion, and the court of appeals holding to the contrary in this case and in *Lead Industries* must be overruled.

I. EPA BASED ITS NAAQS DECISIONS ON RISK PREDICTIONS, WITHOUT DEFINING ANY PRINCIPLE FOR DETERMINING HOW MUCH RISK IS ACCEPTABLE.

These rulemakings addressed the potential risk of harm, not demonstrated health effects. As EPA explains, the rulemaking records for the NAAQS included new studies not considered in prior standard reviews. EPA Br. (99-1426), at 10. These studies, however, addressed the same types of health effects that EPA has long considered when regulating these pollutants. For ozone, for example, these include predicted respiratory symptoms (e.g., coughs) and physiological changes (e.g., changes in airway resistance).[6] For PM, they include predicted excess mortality, bronchitis, lung function and symptom responses.[7]

Reflecting this science, EPA's exposure and risk analyses for ozone addressed the *same* health effects for all of the standards under consideration, including the existing 1-hour standard.[8] And, EPA concluded that these health effects could be addressed by *either* a 1-hour or 8-hour standard.[9]

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[6] *Compare* 44 Fed. Reg. 8215-16, OJA 3493-94, *with* 62 Fed. Reg. 38864-65, OJA 9-10.

[7] *Compare* 52 Fed. Reg. 25641-44, PMJA 215-18, *with* 62 Fed. Reg. 38676, PMJA 26.

[8] *See OSP*, *supra* note 3, at 86, 123-24, 128, OJA 1896, 1933-34, 1938.

[9] 62 Fed. Reg. 38861, OJA 6.

Furthermore, as EPA observes, "CASAC clearly understood" that the ozone record "showed a continuum of risk," with statistically significant decreases in risk for more stringent standards. EPA Br. (99-1426), at 12. Nevertheless, CASAC *disagreed* with EPA's assertion that these decreases in risk also reflected "corresponding increases in public health protection." *Id.*[10]

Instead, CASAC concluded, the science does not allow one to "distinguish[] any of the proposed [ozone] standards . . . as being significantly more protective of public health." [11] While EPA claims that CASAC meant only that ozone is a non-threshold pollutant, EPA Br. (99-1426), at 11-12, EPA is wrong. CASAC explained that it reached its conclusion because "the difference in percent of outdoor children [the sensitive population] . . . responding [to ozone] between the present [i.e., 1-hour] standard and the most stringent proposal are small and their ranges overlap for *all* health endpoints." *Id.* Even the EPA staff observed that an 8-hour standard equivalent to the existing ozone standard provided some "margin of safety" for these ozone-related health risks.[12]

As a result, CASAC concluded that any decision on ozone NAAQS revision would be driven *not* by science, but by "policy judgment."[13] In other words, because the current standards provide a "margin of safety," the Administrator would have to determine that the existing "margin" was not "adequate" and some other "margin" was.

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[10] *Compare* Letter from Dr. George T. Wolff, Chair, CASAC, to Hon. Carol M. Browner 3 (Nov. 30, 1995) [hereinafter CASAC Ozone Letter], OJA 238, *with* EPA Br. (99-1426), at 12.

[11] CASAC Ozone Letter, *supra* note 10, at 3, OJA 238.

[12] *OSP*, *supra* note 3, at 167, OJA 1977; 62 Fed. Reg. 38858, OJA 3.

[13] CASAC Ozone Letter, *supra* note 10, at 3, OJA 238; *see also* Letter from Dr. George T. Wolff, Chair, CASAC, to Hon. Carol M. Browner 4 (June 13, 1996) [hereinafter CASAC PM Letter], PMJA 3164.

For PM, EPA "concluded that the available evidence 'provide[s] ample reason to be concerned that there are detectable human health effects attributable to PM at levels *below* the current NAAQS.'" EPA Br. (99-1426), at 10 n.6.[14] But a "concern[]" that there may be health effects below a given level does not by itself establish a "public health" problem. Nor does it establish what regulatory response will provide a "reasonable degree of protection" for that problem.

Thus, while CASAC concluded that the PM_{10} NAAQS should be revised, it also observed that there remained "many unanswered questions and uncertainties associated with establishing causality" of health effects by $PM_{2.5}$, which prevented *any* consensus on what $PM_{2.5}$ standard would be necessary (i.e., "requisite") to protect public health.[15] CASAC therefore concluded that the decision on PM

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[14] CASAC agreed that the Criteria Document from which the statement is drawn would, after revision, provide "an adequate scientific basis for regulatory decisions on PM," *see* Letter from Dr. George T. Wolff, Chair, CASAC, to Hon. Carol M. Browner 3 (Mar. 15, 1996), PMJA 3151, but did not endorse *any* specific statements such as this one. *Clean Air Act: Ozone and Particulate Matter Standards: Hearings Before the Subcomm. on Clean Air, Wetlands, Private Property and Nuclear Safety and the Sen. Comm. on Env't and Pub. Works*, 105th Cong., pt. 1, at 104 (1997) (Responses by Dr. Wolff).

[15] CASAC PM Letter, *supra* note 13, at 2-3, PMJA 3162-63. EPA characterizes its PM standards as "toward the mid-portion of the range of protection afforded by . . . the CASAC panel members who chose to express individual views." EPA Br. (99-1426), at 11 n.7. In fact, CASAC did not endorse the EPA Staff's recommended ranges for $PM_{2.5}$ standards, *see* CASAC PM Letter, *supra* note 13, at 2, 5, PMJA 3162, 3165, and thirteen CASAC panel members recommended either *no* annual standard or one *less* stringent than the one adopted by EPA as the controlling standard (including five who favored a standard higher than the top of EPA's range). *Id.* 5-6, PMJA 3165-66. Only two of the 21 panel members supported an annual standard as stringent as the one EPA adopted. *Id.*

standard revision required "policy" judgment by the Administrator to address a potential public health problem.[16]

The Administrator confirmed that her decisions here called for "policy" judgment.[17] This policy judgment addressed whether more "margin of safety" was appropriate in response to uncertain health risks, which the Administrator explained "may not be amenable to quantification in terms of what . . . is 'acceptable' or any other metric."[18] While EPA would now like to avoid discussing how it exercises risk management judgment in the face of uncertain science regarding the cause of a predicted health effect, the nature of EPA's risk management authority in revising NAAQS, therefore, is the critical issue in this case.

II. THE CLEAN AIR ACT PROVIDES GUIDANCE FOR PUBLIC HEALTH RISK MANAGEMENT JUDGMENT.

EPA argues that the language of § 109 "unambiguously" requires it to base NAAQS decisions "*solely* on the health and welfare effects" of the pollutant, and not on "other considerations." EPA Br. (99-1426), at 14, 18, 19. To the contrary, EPA's response brief, as well as the statute's language, legislative history, and purposes, confirm that Congress did not tell EPA to ignore the consequences of its public health policy decisions.

A. The Language of Section 109

EPA argues that "[s]ection 109's command that NAAQS be set at levels 'requisite' to protect public health and welfare unambiguously directs that the levels be set to achieve *that objective* . . . ." EPA Br. (99-1426), at 19 (emphasis added). But this tells us nothing, for the "objective" to which EPA

[16] *Id.* 4, PMJA 3164.

[17] 62 Fed. Reg. 38857, 38859, 38861, 38862, 38863, 38867, OJA 2, 4, 6, 7, 8, 12; *id.* 38653, 38668, 38669, 38671, 38672, PMJA 3, 18, 19, 21, 22.

[18] 62 Fed. Reg. 38883, OJA 28; *id.* 38688, PMJA 38.

refers is protecting the "public health." While EPA asserts elsewhere that it regulates in response to a "risk of adverse effects" or "medically significant risks," EPA Br. (99-1426), at 14, 33, EPA never explains what standards guide its "public health" decisions when confronted with, at most, a *potential* public health risk.

For example, in the case of ozone, a cough or a tightening of the chest on inhalation (a symptom one might experience by stepping out-of-doors on a cold morning) was observed during prolonged exercise under controlled laboratory conditions.[19] Based on these studies, EPA *predicted* that coughs would occur in a population (exercising children) that did *not* experience these symptoms when studied.[20] Furthermore, EPA's risk assessment predicted, based on a no-threshold assumption, that such *undemonstrated* effects would occur at levels below the lowest level tested in the controlled studies (i.e., below 0.08 ppm).[21]

EPA concedes that the statutory "public health" language requires that it focus on the "'health of the community at large.'" EPA Br. (99-1426), at 36 n.28. But how severe, how frequent or how certain must the *risk of an effect* be before it constitutes a potential "adverse" *public health* effect? The "endangerment" standard of the statute requires

[19] *See OSP*, *supra* note 3, at 28, 107-110, OJA 1838, 1917-20.

[20] *Id.* 55, OJA 1865 ("[C]hildren respond [functionally] to low-level [ozone] . . . albeit without symptoms [e.g., coughs].").

[21] *See* CASAC Tr. (9/19/95) 109, OJA 298 (noting exposures between 0.06 ppm and 0.08 ppm contribute the most risk); EPA Br. (99-1257), at 13-14. In the case of $PM_{2.5}$, EPA's risk assessment assumed a causal association between $PM_{2.5}$ and effects to "background" levels of PM. EPA, *Review of the National Ambient Air Quality Standards for Particulate Matter* VI-1, VI-3 (1996), PMJA 2051, 2053. The Agency acknowledges, however, that both the causal mechanism and the existence of an effects threshold are unknown. *See* 62 Fed. Reg. 38657, 38664-65, PMJA 7, 14-15.

that EPA make a policy judgment as to what constitutes a "significant risk" to public health.[22] This policy judgment requires EPA to address explicitly the uncertainties inherent in its risk predictions and then to put those predictions in context, for example, of the risks federal agencies or the public have found acceptable, and of the public health risks that might be increased by regulation.[23]

Once it has articulated its basis for concluding that there is a potential public health problem (which EPA failed to do here), EPA may then set a standard at a level "requisite to protect" the public health, allowing an "adequate margin of safety." As EPA explained *after* the lower court's decision, the "requisite to protect" standard of § 109(b) contemplates air quality standards that are "neither more nor less stringent than necessary" to protect the public health.[24]

Even if this were EPA's position on remand,[25] how does EPA select an option that is neither more nor less stringent than "necessary" to protect "public health" where risk management options reflect similar levels of health

[22] *See* H.R. Rep. No. 95-294, at 3, 48-49, *reprinted in* 4 *1977 Legis. Hist.*, *supra* note 2, at 2470, 2515-16; APC Br. (99-1426), at 37 n.87; ALA Br. (99-1257), at 20-21.

[23] *See* APC Br. (99-1426), at 30-32; GE Br. (99-1426), at 22-25; Mfrs. Alliance/MAPI, *et al.*, Br. (99-1257), at 15-20; 1 Presidential/ Congressional Comm'n on Risk Assessment and Risk Management, *Framework for Environmental Health Risk Management* 5, 35 (1997) (Risk management requires putting problems into real world context and considering "the potential . . . to increase one type of risk while reducing the risk of concern."), Reply App. 5a.

[24] *See* 195 F.3d at 6, App. 71a; *cf. Union Elec.*, 427 U.S. at 263 ("[T]he most natural reading of the 'as may be necessary' phrase in context is simply that the Administrator must assure that the minimal, or 'necessary,' requirements are met . . . .").

[25] EPA's proffered "intelligible principle" at rehearing was, of course, a post hoc rationalization that only confirms the correctness of the lower court's decision. *See* APC Br. (99-1257), at 26 n.60.

protection (as in the case of ozone)?[26] When a pollutant is associated with but not necessarily *the cause* of the effect (as with $PM_{2.5}$), how can EPA identify the NAAQS that is no more stringent than "necessary" to protect "public health"?[27]

As risk becomes more certain and differences between risk management options more apparent, more health protection may be "necessary." Where uncertainty is large and differences in risk small, a different judgment might result. In either case, what is necessary to protect the public health depends on an evaluation of whether marginal reductions in predicted risk are worth the collateral adverse health, environmental or economic costs of those reductions.

Congress also emphasized that the "adequate margin of safety" language of § 109 is intended to provide a "reasonable degree of protection" in response to uncertain science and unknown hazards.[28] Providing a "reasonable" degree of protection contemplates more than tallying predictions of uncertain health effects.[29] As this Court has

[26] For example, is a revised ozone NAAQS that imposes an estimated $9.6 billion in annual costs on society *on top of the cost of attaining the 1-hour standard*, *see* EPA, *Regulatory Impact Analyses for Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule* ES-12 (1997) [hereinafter *RIA*], OJA 2919, for no significant improvement in public health protection, "requisite" to protect "public health"?

[27] For example, is a revised NAAQS that is estimated to cause between 1,600 and 27,000 premature deaths, *see* APC Br. (99-1426), at 18, while preventing 3,700 to 16,600 predicted premature deaths (based on an uncertain, "assumed" causal relationship), *RIA, supra* note 26, at ES-18, OJA 2925, "requisite" to protect the "public health"?

[28] S. Rep. No. 91-1196, at 10, *reprinted* in 1 *1970 Legis. Hist.*, *supra* note 2, at 410, OJA 3687; *see also* EPA Br. (99-1426), at 33-34 (describing margin of safety requirement in terms of a "reasonable degree of protection"); Mass/NJ Br. (99-1426), at 21 n.39.

[29] *See* SAB, *supra* note 4, at 14, 20 ("[T]echnical risk rankings, in isolation, offer[] insufficient guidance for policy decisions." What is needed is "open and comprehensive examination of environmental

observed, the concept of reasonableness contemplates a "balancing of costs and benefits."[30]

Finally, where there is a NAAQS in place, and the States have put in place (or are putting in place) a program to meet that standard, EPA must determine whether a change in its earlier NAAQS risk management decision is "appropriate" in light of new information.[31] EPA argues that § 109(d)'s requirement that the Administrator revise NAAQS "*as may be appropriate* in accordance with [§§ 108 and 109(b)]" (emphasis added) adds nothing to § 109(b)'s requirement that NAAQS be set at levels "requisite" to protect "public health" with an "adequate margin of safety."

But whether additional "margin of safety" is an "appropriate" response to uncertain risk, or whether existing control programs should remain in place while additional scientific investigations are completed, can be resolved only based on the advice that CASAC must give to "the Administrator" (*not* the States) on the need for and adverse impacts of standard revision. CAA § 109(d)(2). Only with that information can the Administrator determine whether standard revisions are "appropriate." To ignore this

problems."); *cf. Chemical Mfrs. Ass'n v. EPA*, 899 F.2d 344, 359 (5th Cir. 1990) ("[Q]uantity . . . without more, is . . . of little help in understanding what is meant by 'substantial.'").

[30] *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 510 n.30 (1981); *see also Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1222 (5th Cir. 1991) (citing *Forester v. CPSC*, 559 F.2d 774, 789 (D.C. Cir. 1977)); *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 642 (D.C. Cir. 1973) (Regulation in the face of uncertainty requires weighing the "nature and consequences of risk of error."). Indeed, the D.C. Circuit has acknowledged such balancing by EPA when setting standards to protect the public health with an "ample margin of safety." *See NRDC v. EPA* ("*Vinyl Chloride*"), 824 F.2d 1146, 1165 (D.C. Cir. 1987) (*en banc*).

[31] This is an especially important question here, in light of the *statutory* program for ozone reductions that would be disrupted by EPA's standard revision. APC Br. (99-1257), at 42-50.

information, as EPA and its supporters urge, could result in decisions that disrupt control programs under an existing NAAQS with no significant improvement in (or perhaps reduction in) public health protection. *See* APC Br. (99-1257), at 47-48.

B. The Structure of the Act and Its Legislative History

Section 109(b)(1) requires that NAAQS be "based on" the air quality "criteria" document that EPA issues under § 108. *See* EPA Br. (99-1426), at 19. The § 108 criteria document is to contain scientific information on the effects "which may be expected to result from the presence of such pollutant in the ambient air." CAA§ 108(a)(2). Based on this language of §§ 108 and 109, EPA argues that it is precluded, in setting NAAQS, from considering factors *not* addressed in the criteria document. EPA Br. (99-1426), at 19.

As EPA and its supporters explain, however, the criteria are "*descriptive*; that is, they describe the *effects that have been observed* to occur when the ambient air level of a pollutant has reached or exceeded specific figures . . . ."[32] The criteria in fact "stress[] the *difficulties* of drawing a bright line between pollution that is harmful and pollution that is not."[33]

In revising NAAQS, however, the Administrator must exercise judgment in light of uncertain risk predictions. The words "based on" in § 109(b) therefore cannot suggest that the information in the § 108 criteria document is the exclusive record upon which NAAQS may be based. Rather, consistent with their plain meaning,[34] the words "based on"

[32] CBT Br. (99-1426), at 21 (emphasis added) (citations omitted); *see* Mass/NJ Br. (99-1426), at 18-19; EPA Br. (99-1426), at 24.

[33] Mass/NJ Br. (99-1426), at 9 (emphasis added); *see id.* 20 ("air quality criteria cannot be interpreted as threshold values").

[34] *See* 1 *The New Shorter Oxford English Dictionary* 187 (1993) ("act as a foundation for").

merely call for consideration of the information in the criteria document in determining what potential risks should be regulated, and to what level.

Indeed, if the language in § 109(b) means that standards must be "based on" the criteria document *exclusively*, there would be no need for notice and comment rulemaking on the standard. Under EPA's interpretation, all the Administrator would have to do is announce a NAAQS "based on" the criteria document and go home. CASAC advice, necessary information not included in the criteria document (e.g., EPA and others' risk and exposure analyses, and EPA's "staff paper"), and public comments would be irrelevant.

EPA next turns to the legislative history, arguing that it confirms that "Congress made a policy choice [in 1970] not to base NAAQS on consideration of the technological feasibility or cost-effectiveness of pollution control measures." EPA Br. (99-1426), at 21. But all this legislative history shows is that Congress, in § 110 of the Act, (1) authorized the States in 1970 to consider cost and feasibility of pollution controls in implementing the NAAQS, so long as the State's "control strategy" program would bring about timely attainment of the NAAQS, and (2) prohibited EPA from overriding the State's control program on cost or feasibility grounds. *See id.* at 20.

This says *nothing* about what EPA is required to consider, or prohibited from considering, when exercising judgment under § 109 on how potential public health risks should be managed in setting NAAQS. Indeed, because EPA claims it is prohibited from considering cost and feasibility at the implementation stage, and because States may often have to ignore these factors to achieve expeditious attainment, unless EPA's public health policy judgment under § 109 reflects consideration of the overall societal impacts, those impacts

might never be considered. *See* Ohio, *et al.*, Br. (99-1426), at 9.[35]

EPA also argues that the legislative history shows that Congress made "a deliberate policy judgment that the NAAQS would have a 'technology-forcing character.'" EPA Br. (99-1426), at 25, *quoting Union Elec. Co.*, 427 U.S. at 257. The *Union Electric* Court observed, however, that the NAAQS program is "technology forcing" because, under § 110(a), States must develop programs to attain the NAAQS in three years or sooner *regardless* of cost or feasibility. *See* 427 U.S. at 258. As the Court noted, "so long as the national standards are being attained and maintained, there is no basis in the present Clean Air Act for forcing further technological developments." *Id.* at 257; *see also id.* at 261.[36]

Union Electric therefore does *not* say that EPA must ignore real world impacts when evaluating risk management options under § 109.[37] Nevertheless, further developing its

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[35] The records here indicate that EPA could *not* identify technologically feasible measures for attaining these NAAQS. *RIA*, *supra* note 26, at ES-11 to ES-12, OJA 2918-19. When EPA *assumed* the existence of cost-effective measures to bring about national attainment, contrary to EPA's characterization of the RIA, EPA Br. (99-1426), at 46 n.41, costs exceeded the quantifiable benefits of the ozone NAAQS while the range of quantifiable benefits for the PM NAAQS fell within the estimated cost range. *RIA*, *supra* note 26, at ES-20, OJA 2927. Historically, EPA has sometimes overestimated and sometimes underestimated control costs, although accuracy has improved over time. *See* Winston Harringon, *et al.*, *On the Accuracy of Regulatory Cost Estimates*, 19 J. Pol. Analysis & Mgmt. 297, 307, 309 (2000).

[36] *See NRDC v. Train*, 421 U.S. 60, 91 (1975) (The NAAQS program is "technology forcing if the NAAQS adopted requires this result.").

[37] Similarly, Congress' statement in 1990 that primary NAAQS are to protect the public health "without regard to the economic or technical feasibility of attainment," EPA Br. (99-1426), at 30 (citation omitted), must be understood, if relevant at all, *see* APC Br. (99-1426), at 48-49; Inhofe, *et al.*, Br. (99-1426), at 17-30, as a reaffirmation that once EPA sets a NAAQS, that NAAQS must be met.

§ 110 *non sequitur*, EPA argues that Congress has changed § 110 attainment deadlines, and asserts that this confirms that EPA must ignore the consequences of its § 109 NAAQS decisions. EPA Br. (99-1426), at 27-30.

That Congress has acted to give States more flexibility in implementing NAAQS under § 110 says nothing about how EPA sets the NAAQS under § 109. To the contrary, that Congress in 1990 enacted a comprehensive ozone risk management program in Subpart 2, CAA §§ 181-185A, shows that Congress decided to override EPA's failed ozone risk management program and, in so doing, to preclude EPA from establishing a more stringent ozone NAAQS.[38]

Regarding whether and how the Act constrains EPA's authority to manage potential public health risks, the legislative history tells a different story than that told by EPA. Congress in 1970 adopted statutory language to protect the "public health" as opposed to "the health . . . of any persons."[39] At the same time, Congress understood that EPA would have to draw a line "between the point of no known effects and the maximum effects."[40] Congress therefore authorized EPA to regulate in response to "significant" public health risk, *see supra* note 22, and required EPA to make practical judgments in drawing lines in order to provide a "reasonable degree of protection" in responding to such

[38] APC Br. (99-1257), at 42-50; Ohio, *et al.*, Br. (99-1257), at 10-31. As EPA's supporters recognize, Congress in Subpart 2 "itself has balanced the public health and welfare goals of the statute against the economic and technological challenges posed by meeting these goals." Mass/NJ Br. (99-1426), at 28.

[39] *Compare* Air Quality Act of 1967 § 108(a), Pub. L. No. 90-148, 81 Stat. 485, 491 (1967), *with* CAA § 109(a); *see* Mass/NJ Br. (99-1257), at 13 (In 1970, "Congress instructed EPA to target health effects in *populations* rather than in single individuals.").

[40] *See 1970 Hrg.*, *supra* note 2, at 1487, *reprinted in* 2 *1970 Legis. Hist.*, *supra* note 2, at 1182 (Sen. Muskie).

potential public health problems.[41] In enacting the "Prevention of Significant Deterioration" program in 1977, CAA §§ 160-169B, Congress confirmed that the NAAQS program requires judgments as to when predicted health risks become a *public health* problem. *See* APC Br. (99-1426), at 43-45.

As a result, while protecting public health is the end that implementation of the NAAQS must achieve, the Act does not restrict the factors relevant to the Agency's exercise of risk management judgment in achieving that endpoint.

C. The Requirement to Protect "Public Health" and the Statutory Purposes Language of the Act Must Guide EPA's Exercise of Discretion in Revising NAAQS.

As discussed above, protecting the "public health" contemplates balancing to ensure that EPA's NAAQS decisions promote society's health and well-being. *See* APC Br. (99-1426), at 27-31.[42] As EPA recognizes, this statutory provision must be read "with due regard for the Act's purpose." EPA Br. (99-1257), at 22.

Congress explained that the Act is intended to "ensure the protection of the public health and the environment . . . while at the same time considering the energy and economic needs of this Nation."[43] Congress codified that intent in § 101(b)(1), which emphasizes *in statutory language* the importance of balancing to promote the "public health" and the "productive capacity" of the Nation. EPA has interpreted

[41] S. Rep. No. 91-1196, at 10, *reprinted in* 1 *1970 Legis. Hist.*, *supra* note 2, at 410, OJA 3687; *see also* H.R. Rep. No. 95-294, at 127, *reprinted in* 4 *1977 Legis. Hist.*, *supra* note 2, at 2594, OJA 3678.

[42] *See also* ATA Reply Br. (99-1426), Arg. § II; ALA Br. (99-1257), at 19 ("public health disciplines . . . furnish a detailed context for § 109(b)(1)'s 'public health' mandate.").

[43] H.R. Rep. No. 95-294, at 34-35 (1977), *reprinted in* 4 *1977 Legis. Hist.*, *supra* note 2, at 2501-02.

this provision as calling for a "balancing of the social and economic considerations with the environmental implications" of its decisions. 39 Fed. Reg. 31000 (1974).

EPA responds that the statutory purposes have no relevance here, because they cannot "take precedence over the CAA's specific language in Sections 108 and 109." EPA Br. (99-1426), at 42. But, as discussed above, nothing in the language of §§ 108 or 109 restricts the factors that EPA is to consider when exercising judgment as to what "margin of safety" is "adequate" in selecting from a range of health protective options. The statutory language of § 101(b) is therefore blindingly relevant to defining the factors that will govern the exercise of such judgments.

EPA argues next that the reference in § 101(b) to promoting the public health and welfare and the "productive capacity" of the Nation's population means only that improved air quality will "reduc[e] the harm that air pollution causes." EPA Br. (99-1426), at 43. But EPA counsel's characterization of congressional purpose as "less pollution is better" is inconsistent with both Congress' understanding and the Agency's prior interpretations of this language.

As EPA has explained, under § 101(b), "[i]t would be counterproductive if, in protecting public health through clearing the air, EPA were to create or exacerbate conditions that endangered public health or safety. [According to EPA, i]n its major regulatory rulemakings, EPA has carefully weighed any potential adverse environmental and public safety impacts against the benefits from its actions."[44]

Because §§ 108 and 109 do not "unambiguously" restrict factors relevant to managing risks, the Agency must turn to the statutory purposes to inform its exercise of discretion, and exercise that discretion in a way that achieves the balance contemplated by Congress in § 101(b).

[44] 55 Fed. Reg. 41204, 41211-12 (1990).

III. THIS COURT CAN IDENTIFY PRINCIPLES THAT GUIDE EPA'S EXERCISE OF PUBLIC HEALTH RISK MANAGEMENT JUDGMENT.

EPA argues that "[t]he principle that a statute must be construed so as to avoid doubts as to its constitutionality applies only when the statute's meaning is unclear." EPA Br. (99-1426), at 48 n.43. Here, EPA views the statute as "unmistakably clear," *id.*, and argues that requiring the Agency to consider more factors would compound the nondelegation problem by giving EPA too much to consider.

Merely characterizing a range of risk and picking a point from the spectrum while reciting risk characterization factors, however, sheds no light on why there is a public health problem, and what is a "reasonable" degree of protection. As the Court observed in *Mistretta*, to avoid a nondelegation problem, Congress must not only have "clearly delineate[d] the general policy" of the statute but also "the boundaries of th[e] delegated authority." 488 U.S. 361, 372-73 (1989).

The constitutional problem perceived by the lower court arose precisely out of EPA's refusal to define the boundaries of its public health authority under § 109. *See* APC Br. (99-1257), at 25-31. If Congress provided *no* standards for EPA's public health decisions, then the Act would present a clear nondelegation problem. *See* GE Br. (99-1257), at 21-23, 29-30.

What then are the legal standards that flow from the Act's language, including the purposes section, and that can provide "reasonable coherence" for selecting a NAAQS?

As discussed above, the focus of the NAAQS program is on pollution that "endangers" the "public health," CAA § 108(a)(1), and its goal is establishing air quality levels that are "requisite to protect the public health." CAA § 109(b)(1). This language requires a determination whether the health risks at issue create a potential "public health" problem (i.e., a *significant risk* of adverse public health impacts). To make this determination, EPA must specifically address whether

the estimated risks are of sufficient magnitude and certainty to affect adversely the health of the community in light of, *inter alia*, other risks that EPA has found worthy of regulation, or that society is willing to accept.

If the Agency finds a potential public health problem, the Agency must then address what is a "reasonable" degree of protection. In exercising this judgment, EPA must address, *inter alia*, how differing risk management options compare with the status quo, and with the cost to society (e.g., health, environmental or economic costs) of any additional margin of safety. The balancing required by these risk management judgments is no secret; relevant factors have been described repeatedly by EPA and its science advisers.[45]

A balancing approach to risk management that assures protection of "public health and welfare" and the "productive capacity" of the Nation, backed up by a reasoned explanation of how the balance was struck, avoids the nondelegation problem perceived by the lower court. Furthermore, it assures the "reasonable coherence" necessary to avoid "arbitrary and capricious" decisionmaking and to enable judicial review. 175 F.3d at 1038-40, App. 13a-18a. Finally, because *Lead Industries* stands for the proposition that the overall costs to society of risk management options may play no role in NAAQS decisions, that decision must be overruled. *See* APC Br. (99-1426), at 45-49.

CONCLUSION

For the reasons discussed above, the revised PM and ozone NAAQS must be vacated, because EPA has failed to consider factors relevant to the exercise of its public health risk management judgment under § 109 of the Act.

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[45] *See, e.g.*, SAB, *supra* note 4, at 13 (Relevant factors for risk management decisions include "the societal values that both influence and are affected by the decision, including values relating to economic efficiency, sustainability, equity, and quality of life."), Reply App. 9a; *see generally supra* note 4; Marchant, *et al.*, Br. (99-1257), at 6-8. The balancing, of course, need not be strictly quantitative.

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APPENDIX

Framework for Environmental Health Risk Management

The Presidential/Congressional Commission on Risk Assessment and Risk Management

Final Report
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* * *

The Commission's Risk Management Framework

The Framework is general enough to work in a wide variety of situations. The level of effort and resources invested in using the Framework can be scaled to the importance of the problem, potential severity and economic impact of the risk, level of controversy surrounding it, and resource constraints. The Framework is primarily intended for risk decisions related to setting standards, controlling pollution, protecting health, and cleaning up the environment. It is useful for addressing these types of decisions at a local community level (e.g., siting an incinerator or cleaning up a hazardous waste site) or a national level (e.g., developing a national program for controlling motor vehicle emissions). The Framework need not be invoked for risk situations that are routinely and expeditiously managed—for example, by hazardous materials response teams, emergency room physicians, firefighter rescue teams, and voluntary product recalls.

Every stage of the Framework relies on three key principles:

Broader contexts. Instead of evaluating single risks associated with single chemicals in single environmental media, the Framework puts health and environmental problems in their larger, real-world contexts. Evaluating

problems in context involves evaluating different sources of a particular chemical or chemical exposure, considering other chemicals that could affect a particular risk or pose additional risks, assessing other similar risks, and evaluating the extent to which different exposures contribute to a particular health effect of concern. The goal of considering problems in their context is to clarify the impact that individual risk management actions are likely to have on public health or the environment and to help direct actions and resources where they will do the most good.

Stakeholder participation. Involvement of stakeholders—parties who are concerned about or affected by the risk management problem—is critical to making and successfully implementing sound, cost-effective, informed risk management decisions. For this reason, the Framework encourages stakeholder involvement to the extent appropriate and feasible during all stages of the risk management process. "Establish a Process for Engaging Stakeholders" on page 15 discusses in depth the value of and approaches to involving stakeholders.

Iteration. Valuable information or perspective may emerge during any stage of the risk management process. This Framework is designed so that parts of it may be repeated, giving risk managers and stakeholders the flexibility to revisit early stages of the process when new findings made during later stages shed sufficiently important light on earlier deliberations and decisions. ("The Importance of Iteration" on page 47 provides more information.)

Principles for Risk Management Decision-Making

A good risk management decision...

- Addresses a clearly articulated problem in its public health and ecological context.
- Emerges from a decision-making process that elicits the views of those affected by the decision, so that differing technical assessments, public values, knowledge, and perceptions are considered.
- Is based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.
- Is made after examining a range of regulatory and nonregulatory risk management options.
- Reduces or eliminates risks in ways that:
  - Are based on the best available scientific, economic, and other technical information.
  - Account for their multisource, multimedia, multichemical, and multirisk contexts.
  - Are feasible, with benefits reasonably related to their costs.
  - Give priority to preventing risks, not just controlling them.
  - Use alternatives to command-and-control regulation, where applicable.
  - Are sensitive to political, social, legal, and cultural considerations.
  - Include incentives for innovation, evaluation, and research.
- Can be implemented effectively, expeditiously, flexibly, and with stakeholder support.
- Can be shown to have a significant impact on the risks of concern.
- Can be revised and changed when significant new information becomes available, while avoiding "paralysis by analysis."

Advantages of the Commission's Risk Management Framework

Traditionally, risk management has relied on command-and-control approaches that often require environmental protection standards to be met using specific technologies. Risk management has generally focused on controlling single hazards in single environmental media. Many risk management failures can be traced to not including stakeholders in decision-making at the earliest possible time and not considering risks in their broader contexts. In contrast, the Commission's Risk Management Framework is intended to:

- ✓ Provide an integrated, holistic approach to solving public health and environmental problems in context.
- ✓ Ensure that decisions about the use of risk assessment and economic analysis rely on the best scientific evidence and are made in the context of risk management alternatives.
- ✓ Emphasize the importance of collaboration, communication, and negotiation among stakeholders so that public values can influence risk management strategies.
- ✓ Produce risk management decisions that are more likely to be successful than decisions made without adequate and early stakeholder involvement.
- ✓ Accommodate critical new information that may emerge at any stage of the process.

Potential Adverse Consequences

Analysis must consider whether an option may cause any adverse consequences. One of the most important is the potential for an option to increase one type of risk while reducing the risk of concern:

- While reducing pollutant concentrations in one environmental medium, the option may increase pollutants in another medium. For example, using aeration reduces pollutants in drinking water by releasing them to the air. (Of course, if exposure to air is considerably less than exposure to drinking water, this tradeoff may be worthwhile.)
- While reducing long-term health risks for community members, an option may produce short-term health risks and injury for workers, as can happen during cleanup of sites contaminated with hazardous chemical and radioactive wastes.
- Banning one pesticide because it might cause cancer may increase the use of another pesticide that is known to cause birth defects or to harm wildlife, or whose health effects are not known.

Thus, tradeoffs among different risks must be identified and considered.

Other adverse consequences may be cultural, ethical, political, social, or economic, such as:

- Economic impacts on a community, including reduced property values or loss of jobs.
- Environmental justice issues, such as inequitable distribution of costs and benefits as mentioned above; disregard for a particular population group's dietary needs, preferences, or nutritional status; or giving priority to site cleanup efforts in more affluent areas.
- Harming the social fabric of a town or tribe by relocating the people away from a highly contaminated area.

Risk Assessment in the Federal Government: Managing the Process

Committee on the Institutional Means for Assessment of Risks to Public Health

Commission on Life Sciences

National Research Council

National Academy Press
Washington, D.C. 1983

* * *

Risk Assessment and Risk Management

We use risk assessment to mean the characterization of the potential adverse health effects of human exposures to environmental hazards. Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgments as to the number and characteristics of persons exposed at various intensities and durations; and summary judgments on the existence and overall magnitude of the public-health problem. Risk assessment also includes characterization of the uncertainties inherent in the process of inferring risk.

The term risk assessment is often given narrower and broader meanings than we have adopted here. For some observers, the term is synonymous with quantitative risk assessment and emphasizes reliance on numerical results. Our broader definition includes quantification, but also

includes qualitative expressions of risk. Quantitative estimates of risk are not always feasible, and they may be eschewed by agencies for policy reasons. Broader uses of the term than ours also embrace analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decisions--functions that we assign to risk management.

The Committee uses the term risk management to describe the process of evaluating alternative regulatory actions and selecting among them. Risk management, which is carried out by regulatory agencies under various legislative mandates, is an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard. The selection process necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control.

* * *

Toward Integrated Environmental Decision-Making

United States Environmental Protection Agency

Science Advisory Board
(1400A)
Washington, DC

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* * *

2.3 Analysis and Decision-Making (Phase II)

In Phase II of the IED Framework, the analysts take the information and general directions gained in Phase I and generate more detailed, more fully supported assessments of risks and risk reduction options. For integrated decision-making, options analysis should include consideration of risk reduction opportunities with regard to their technical feasibility, aggregate risk reduction to be obtained (e.g., reductions in "target" risks and collateral reduction in all affected risks), full economic consequences of various risk reduction scenarios, and so forth. Decision-makers also should request analysis of potential options with regard to sustainability, equity, and other potential decision criteria.

Options analysis generally is more "analytic" than "deliberative" (NRC, 1996) although a continued level of interaction between the participants in the overall process (scientists, risk managers, and interested and affected parties) is important. Options Analysis is also more resource-intensive than Problem Formulation.

In the decision-making portion of Phase II, the Agency or other decision-makers should a) utilize outputs from the analyses of risk and risk reduction options, b) consider widely-held public values, as well as the views of

participating stakeholders, c) consider the legal, economic, and institutional constraints, and d) ultimately, make the decision. Clearly, this process is not totally scientific. However, the best science should inform and contribute to decision-making. Developments in the social and decision sciences, for example, are providing improved methods for value elicitation and multi-attribute decision-making. The documentation supporting the decision should make explicit a) the implications of the chosen management option(s) to the health of ecological or human systems, b) the economic costs and benefits associated with the selected option, and c) the societal values that both influence and are affected by the decision, including values relating to economic efficiency, sustainability, equity, and quality of life. Integrated decision-making requires explicit consideration of the trade-offs involved in pursuing multiple environmental goals and/or in simultaneously pursuing environmental and non-environmental goals. In some cases, analysis may indicate that a particular management option is not worth doing because of the greater good that might be achieved by investing those resources toward the achievement of another goal.

It is important that the scientific and technical analyses prepared during Phase II articulate clearly the uncertainties associated with the estimates of risk, the estimates of risk reduction that may be achieved by different management options, and the economic assessments of various risk management scenarios. Integrated decision-making does not eliminate the uncertainties associated with making decisions. However, by encouraging an open and comprehensive examination of environmental problems, integrated decision-making should lead to a clearer identification of the nature, extent, and consequences of the uncertainties associated with the available information. In any event, environmental decision-making must proceed in the presence of

uncertainties, and nothing in the proposed Framework should be construed as precluding environmental decisions simply because uncertainties remain.

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3.1.2 What We Need

During the design of the Framework, the SAB participants acknowledged that technical risk rankings, in isolation, offered insufficient guidance for policy decisions. Given the multitude of problems and issues to be addressed, a more comprehensive and systematic framework for analyzing and reducing environmental health, ecological, and quality of life risks appeared necessary. During Problem Formulation, the Agency needs methods for comparing risks that are robust, transparent, effective, and inexpensive. As noted, some initial steps have been taken for ranking risks within categories; e.g., human health, quality of life, or ecosystem risks.

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