ARTICLES

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EPA Authority to Consider Cumulative Effects and Cumulative Risk Assessments in Decision Making under the Clean Air Act***

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INTRODUCTION AND PURPOSE

The U.S. Environmental Protection Agency (EPA, or Agency) often supports or justifies its decision making using the results of risk assessments, which are analyses that characterize the nature, likelihood, and magnitude of health risks to humans and ecological receptors (e.g., birds, fish, wildlife) from chemical pollutants and other stressors that may be present in the environment.¹ Conventionally, the Agency has evaluated the effects and risks associated with a single pollutant in a single exposure medium, such as lead in drinking water. In reality, people are exposed to mixtures of pollutants and to the same pollutant through a variety of media. including air, water, and food.² Moreover, "[c]hemical, biologic, radiologic, physical, and psychologic stressors are all acknowledged

¹ Basic Information. What is Risk Assessment?. EPA, http://epa.gov/risk assessment/basicinformation.htm#risk (last updated July 31, 2012). At its most general, risk assessment involves "the evaluation of scientific information on the hazardous properties of environmental agents and on the extent of human exposure to those agents. The product of the evaluation is a statement regarding the probability [expressed quantitatively or qualitatively] that populations so exposed will be harmed, and to what degree." AM. BAR ASS'N, THE LAW OF ENVIRONMENTAL JUSTICE: THEORIES AND PROCEDURES TO ADDRESS DISPROPORTIONATE RISKS 354 (Michael B. Gerrard & Sheila R. Foster eds., 2d ed. 2008) (quoting NAT'L RESEARCH COUNCIL, COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 25-26 (1994) [hereinafter NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT]).

² EPA's Stochastic Human Exposure and Dose Simulation (SHEDS) Model, EPA, http://www.epa.gov/heasd/research/sheds.html (last updated Aug. 9, 2013); EPA, OFFICE OF RESEARCH AND DEVELOPMENT, HUMAN HEALTH RESEARCH STRATEGY 2-6 (2003). available at http://www.epa.gov/nheerl/download files/publications/HHRS final web. pdf.

as affecting human health." Consequently, to arrive at a realistic assessment of exposure risks, regulatory authorities arguably should consider cumulative stressors and exposure data derived from cumulative risk assessment in decision making.

In particular, the EPA should further explore the value of applying a cumulative risk analysis to decision making in many contexts, including setting air quality and emissions control standards and making permitting decisions under the Clean Air Act (CAA).⁵ In a 2009 report, the National Research Council (NRC) issued a series of recommendations to improve the EPA's use of risk assessment, one of which focused on the need for cumulative risk assessments.⁶ The

³ COMM. ON IMPROVING RISK ANALYSIS APPROACHES USED BY THE U.S. EPA NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 213 (2009) [hereinafter NAT'L RESEARCH COUNCIL, ADVANCING RISK ASSESSMENT] (citing Michael A. Callahan & Ken Sexton, *If Cumulative Risk Assessment Is the Answer, What Is the Question?*, 115 ENVTL. HEALTH PERSP. 799 (2007). According to the U.S. EPA's Framework for Cumulative Risk Assessment, a stressor is any "physical, chemical, biological, or other entity that can cause an adverse response in a human or other organism or ecosystem." RISK ASSESSMENT FORUM, EPA, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT 74 (2003) [hereinafter EPA, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT], *available at* http://www.epa.gov/raf/publications/pdfs/frmwrk_cum_risk_assmnt.pdf.

Exposure to a chemical, biological, or physical agent (e.g., radon) can be a stressor, as can the lack of, or destruction of, some necessity, such as a habitat. The stressor may not cause harm directly, but it may make the target more vulnerable to harm by other stressors. A socioeconomic stressor, for example, might be the lack of needed health care, which could lead to adverse effects.

Id. In another example, "chemicals such as toluene can damage the auditory system and have been shown to potentiate the effects of a physical stressor, noise, on hearing loss." Id. at 47. Examples of non-chemical stressors include: lack of health care; personal activities (e.g., smoking, diet, and alcohol consumption); natural phenomena (e.g., forest fires, floods); biological pathogens; psychosocial stress; noise; and heat. Id. at 51–52. See generally Callahan & Sexton, supra; Ari S. Lewis et al., Non-chemical Stressors and Cumulative Risk Assessment: An Overview of Current Initiatives and Potential Air Pollutant Interactions, 8 INT'L J. ENVTL. RES. PUB. HEALTH 2020 (2011).

4 EPA, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT, *supra* note 3, at 2; Callahan & Sexton, *supra* note 3. According to the EPA's Framework for Cumulative Risk Assessment, cumulative risk assessment involves an "analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors." EPA, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT, *supra* note 3, at 72. Cumulative risk assessments may include both human health and ecological effects. *Id.* at 30. Cumulative risk refers to the combined threats from exposure to multiple stressors via all relevant routes. Callahan & Sexton, *supra* note 3, at 801.

⁵ Clean Air Act, 42 U.S.C. §§ 7401–7671 (2011).

⁶ NAT'L RESEARCH COUNCIL, ADVANCING RISK ASSESSMENT, supra note 3, at 9–10.

NRC also recommended that the EPA expand its current risk assessment model to view risk assessment "as a method for evaluating the relative merits of various options for managing risk rather than an end in itself." The NRC's cumulative risk assessment recommendation stated that unless the EPA takes account of cumulative risks, risk assessment itself might become irrelevant in many decision contexts because a primary aim of risk assessment should be to inform decision makers about the public health implications of various strategies for reducing environmental exposure, and omission of cumulative risks may not provide the information needed to discriminate among competing options accurately. These statements may add impetus to the Agency's shift toward cumulative risk analysis.

Moreover, cumulative risk assessment can be particularly helpful in addressing environmental justice concerns, because numerous studies have shown that minority, low-income, and indigenous communities are impacted by multiple environmental hazards, such as industrial facilities, landfills, transportation-related air pollution, poor housing, leaking underground tanks, pesticides, and incompatible land uses. The chemical-specific focus of conventional risk assessment fails to account for these populations cumulative exposure to several different pollutants and to nonchemical stressors as well. Analyzing

⁷ *Id.* at 5, 12 ("Under the traditional paradigm, the question has been, 'What are the probability and consequence of an adverse health (or ecologic) effect posed by the signal?' In contrast, the recommended framework asks, implicitly, 'What *options* are there to reduce *hazards* or *exposures* that have been identified, and how can risk assessment be used to evaluate the merits of the various options?"").

⁸ See id. at 213.

⁹ NATIONAL ENVIRONMENTAL JUSTICE ADVISORY COUNCIL, ENSURING RISK REDUCTION IN COMMUNITIES WITH MULTIPLE STRESSORS: ENVIRONMENTAL JUSTICE AND CUMULATIVE RISKS/IMPACTS 11–13 (2004), available at http://www.epa.gov/compliance/ej/resources/publications/nejac/nejac-cum-risk-rpt-122104.pdf. The EPA defines "environmental justice" as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. See Environmental Justice, Basic Information, EPA, http://www.epa.gov/environmentaljustice/basics/index.html (last updated May 24, 2012). See generally Stella M. Čapek, The "Environmental Justice" Frame: A Conceptual Discussion and an Application, 40 Soc. Probs. 5 (1993).

¹⁰ EPA, EPA'S ACTION DEVELOPMENT PROCESS: INTERIM GUIDANCE ON CONSIDERING ENVIRONMENTAL JUSTICE DURING THE DEVELOPMENT OF AN ACTION 8 (2010) [hereinafter EPA, ACTION DEVELOPMENT PROCESS], available at http://www.epa.gov/compliance/ej/resources/policy/considering-ej-in-rulemaking-guide-07-2010.pdf.

¹¹ *Id*.

cumulative risks from multiple stressors allows a more realistic evaluation of a population's risk from pollutants than does assessing risks from a single source or stressor.¹²

The EPA's shift from a narrow focus on single stressors, endpoints, sources, pathways, and environmental media to a broad focus on multiples of these factors has resulted in a continuing, if uneven, transition to the use of cumulative risk assessment as a methodology to determine probable cumulative effects. 13 The EPA has publicly embraced and encouraged the transition in Administrator announcements dating back to 1995,14 in both the 2010 Interim Guidance on Considering Environmental Justice During the Development of an Action (Interim Guidance), issued by the EPA Administrator, ¹⁵ and in the 2011 EPA Office of General Counsel document, Plan EJ 2014: Legal Tools (EJ Legal Tools). Addressed to the EPA program managers, the Interim Guidance states that managers should consider cumulative effects in Agency action that may affect environmental justice populations.¹⁷ The EJ Legal Tools document provides an overview of several discretionary legal authorities that are or may be available to the EPA to address environmental justice considerations under federal statutes and programs, including CAA programs. 18 However, because the EPA has often faced legal challenges alleging that the Agency is overreaching. the EPA program offices may hesitate to apply a broad interpretation of the Agency's public health statutory authority. The Agency might anticipate such challenges in the context of considering a broad construct of cumulative effects in CAA program decisions, because none of the CAA legislative provisions specifically mention considering background pollutants or non-chemical stressors.¹⁹

¹² Id.

¹³ Callahan & Sexton, *supra* note 3, at 804; *see generally* EPA, ACTION DEVELOPMENT PROCESS, *supra* note 10, at 8; EPA, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT, *supra* note 3, at 72.

¹⁴ See Callahan & Sexton, supra note 3, at 804 (quoting various EPA announcements).

¹⁵ EPA, ACTION DEVELOPMENT PROCESS, supra note 10.

¹⁶ EPA, PLAN EJ 2014: LEGAL TOOLS (2011), available at http://www.epa.gov/compliance/ej/resources/policy/plan-ej-2014/plan-ej-2011-09.pdf.

¹⁷ EPA, ACTION DEVELOPMENT PROCESS, supra note 10, at 8.

¹⁸ EPA, supra note 16, at 1.

¹⁹ In this article, "cumulative effects" refers to the qualitative and quantitative impacts from exposure to multiple chemical and non-chemical stressors—including the effects on

Nevertheless, given the broad statutory mandates in the CAA to protect the public health, and the judicial principle of deference to an agency's reasonable interpretation of ambiguous legislative language, it seems plausible that the Agency could make a legally defensible assertion that its CAA authority permits the EPA to consider cumulative risk assessment in setting permissible emission limitations and establishing policies for permit determinations.²⁰

This Article examines court decisions reviewing the EPA's exercise of authority in CAA rulemakings and published Agency administrative and policy decisions to support a case for EPA authority to engage in cumulative risk-based decision making under the National Ambient Air Quality Standards (NAAQS), National Emissions Standards for Hazardous Air Pollutants (NESHAPs), and Prevention of Significant Deterioration (PSD) programs. Although there are many other CAA programmatic decisions (both relating to standard setting and permitting) for which the EPA could also incorporate cumulative effects or cumulative risk issues, the analysis in this article is limited to these three program areas where the Agency's exercise of CAA authority is challenged most often.²¹ We begin with a brief overview of risk assessment.

I HOW THE EPA USES RISK ASSESSMENT

At its most general, quantified risk assessment involves the evaluation of scientific information on the hazardous properties of environmental agents, the extent of human exposure to those agents, and the risks of adverse effects (human health or ecological effects)

the ecological environment, on human health, or both. This broad term includes (but is not limited to) cumulative exposures, cumulative risks, and measurable cumulative impacts. In this article, cumulative risk assessment methodology was chosen as the paradigm for the analysis because it provides a concrete example of a methodology with which to discuss hypothetical court review of an EPA decision.

20 Given the uncertainties inherent in risk assessment methodologies and consequent outputs, even if the EPA has authority to base decisions on cumulative risk assessment methods and data, there remains the challenge of demonstrating the rationality both of the approach itself and the use of the analytical results. For a discussion of the judicial framework for analyzing the rationality of agency decision making based on the scientific uncertainty inherent in risk assessment, see Sarah Alves, Joan Tilghman, Arlene Rosenbaum & Devon C. Payne-Sturges, U.S. EPA Authority to Use Cumulative Risk Assessments in Environmental Decision-Making, 9 INT'L J. ENVTL. RES. PUB. HEALTH 1997 (2012).

²¹ For a discussion of other CAA program decisions under which the EPA might consider cumulative effects or cumulative risk, see EPA, *supra* note 16, at 1–2.

associated with the exposure.²² The product of the evaluation is a statement regarding the probability, expressed quantitatively or qualitatively, that populations so exposed will be harmed, and to what degree.²³ Essentially, risk assessment is the process that leads to a characterization of risk.²⁴ "[The] EPA considers risk to be the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor."²⁵

An EPA risk assessment typically follows four basic steps:

- (1) Hazard Identification. First, the EPA examines whether a stressor has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances.
- (2) Dose-Response Assessment. The EPA then examines the numerical relationship between exposures and effects.
- (3) Exposure Assessment. The EPA then examines what is known about the frequency, timing, and levels of contact with a stressor.
- (4) Risk Characterization. Finally, the EPA summarizes and integrates information from the proceeding steps of the risk assessment to synthesize an overall conclusion about the nature and presence or absence of risk.²⁶

Cumulative risk assessment is a type of risk assessment that the NRC defines as "analysis, characterization, and possible quantification of the combined risks to health or the environment posed by multiple agents or stressors." According to NRC, these stressors may be chemical, biologic, radiologic, physical, or psychologic. Further, these stressors may be quantitative or

²² See NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT, supra note 1, at 26; AM. BAR ASS'N, supra note 1, at 354.

²³ See NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT, *supra* note 1, at 26; Am. BAR ASS'N, *supra* note 1, at 354.

²⁴ NAT'L RESEARCH COUNCIL, ADVANCING RISK ASSESSMENT, supra note 3, at 15.

²⁵ EPA, supra note 1.

²⁶ Human Health Risk Assessment, EPA, http://www.epa.gov/riskassessment/health-risk.htm (last updated July 31, 2012); Risk Assessment: Step 4–Risk Characterization, EPA, http://epa.gov/riskassessment/risk-characterization.htm (last updated July 31, 2012). Note that these steps are conducted after a planning and scoping stage.

 $^{27~\}rm NAT'L$ RESEARCH COUNCIL, ADVANCING RISK ASSESSMENT, supra note 3, at 213 (citing EPA, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT, supra note 3).

²⁸ *Id.* at 213 (citing Callahan & Sexton, *supra* note 3).

qualitative elements of an analysis, based on the complexity and context of the decision at issue.²⁹ Thus, a risk assessment may be cumulative even if it lacks a quantitative analysis of all relevant non-chemical stressors.³⁰ For example, the EPA's Office of Pesticide Programs and Office of Solid Waste and Emergency Response conduct cumulative risk assessments to aid in decisions about pesticide regulation and Superfund sites, respectively.³¹ However, these offices generally do not consider non-chemical stressors in cumulative risk assessments.³²

Because risk assessments are based on methodologies that necessarily involve a series of assumptions that are estimated to best reflect the understanding of real-world conditions, the analysis will inevitably contain some amount of uncertainty. On its website, the EPA states.

In the ideal world, all risk assessments would be based on a very strong knowledge base (i.e., reliable and complete data on the nature and extent of contamination, fate and transport processes, the magnitude and frequency of human and ecological exposure, and the inherent toxicity of all of the chemicals). However, in real life, information is usually limited on one or more of these key data needed for risk assessment calculations. This means that risk assessors often have to make estimates and use judgment when performing risk calculations, and consequently all risk estimates are uncertain to some degree. For this reason, a key part of all good risk assessments is a fair and open presentation of the uncertainties in the calculations and a characterization of how reliable (or how unreliable) the resulting risk estimates really are.³³

The EPA policy makers use the information developed through risk assessments to help decide how to protect humans and the environment from stressors or pollutants. Although the value and relevance of risk assessments have been questioned, the NRC asserts

²⁹ Id. at 215.

³⁰ Id. at 217-19.

³¹ See Pesticides: Health and Safety, Assessing Pesticide Cumulative Risk, EPA, http://www.epa.gov/oppsrrd1/cumulative/ (last updated May 9, 2012); RCRA Risk Assessment: Ecological: Planning and Scoping, EPA, http://www.epa.gov/oswer/riskassessment/rcra eco planning.htm (last updated Dec. 24, 2012).

³² See Pesticides: Health and Safety, Cumulative Risk Assessment Methods and Tools, EPA, http://www.epa.gov/oppsrrd1/cumulative/methods_tools.htm#guidance (last updated May 9, 2012); EPA, SCIENCE POLICY COUNCIL, GUIDANCE ON CUMULATIVE RISK ASSESSMENT. PART 1. PLANNING AND SCOPING (1997), available at http://www.epa.gov/osa/spc/pdfs/cumrisk2.pdf.

³³ EPA, supra note 1.

that risk assessment remains an appropriate method for measuring the relative benefits of the many possible interventions available to improve human health.³⁴

II JUDICIAL REVIEW OF THE EPA INTERPRETATION OF CLEAN AIR ACT AUTHORITY

A. The Chevron Framework

To survive a legal challenge to a decision under a CAA program that the EPA has justified by relying, in part, on the results of a cumulative risk assessment, the Agency must make two showings: (1) that its CAA statutory authority permits considering such an analysis as a factor in the EPA's decision; and (2) that the EPA acted rationally in the exercise of this authority. As noted above, this article will focus on the first of these inquiries.³⁵ That is, how have courts examined assertions of authority to interpret broad statutory mandates in the CAA to permit the EPA to consider unspecified factors in decision making (such as cumulative risk assessment)?

In reviewing a federal agency's interpretation of a statute it implements, courts analyze the issue under the framework laid out in the 1984 Supreme Court decision, *Chevron U.S.A., Inc. v. Natural Resources Defense Council (Chevron)*. In *Chevron*, the Supreme Court created a two-part framework for reviewing agency interpretations in such circumstances. First, a reviewing court must examine statutory language to decide whether Congress has directly spoken to the precise question at issue. If the statute is clear, the court "must give effect to the unambiguously expressed intent of Congress," and strike down any conflicting agency interpretation (*Chevron* Step One). However, if the relevant statutory terms do not

³⁴ NAT'L RESEARCH COUNCIL, ADVANCING RISK ASSESSMENT, supra note 3, at 15.

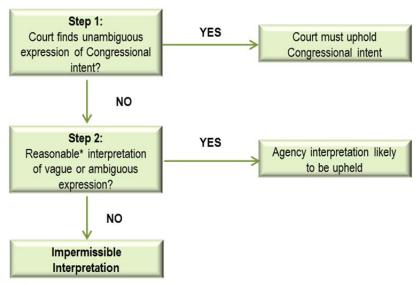
³⁵ The authors acknowledge that courts often intertwine the two questions. *See* Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 843–44 (1984) (explaining that where Congress has not spoken on an issue, courts must give controlling weight to an agency's legislative regulations "unless they are arbitrary, capricious, or manifestly contrary to the statute"); Arent v. Shalala, 70 F.3d 610, 619–20 (D.C. Cir. 1995) (discussing the "overlap" between the *Chevron* and Administrative Procedure Act's arbitrary-and-capricious tests).

³⁶ Chevron, 467 U.S. 837 (1984).

³⁷ Id. at 842-43.

unambiguously resolve the issue, courts must defer to the agency's interpretation as long as it is a "permissible" or reasonable one (*Chevron* Step Two).³⁸

FIGURE 1. *Chevron* test—two-part framework for resolving agency interpretations of statutes.³⁹



^{*} Reasonableness is assessed based on the specific factual circumstances.

Under *Chevron* Step One, the court analyzes the relevant statute and determines whether Congress has unambiguously either banned or required what the agency proposes to do. 40 If a court does find a statute ambiguous under *Chevron* Step One, it must defer to any reasonable agency interpretation under *Chevron* Step Two. In *Chevron*, the Supreme Court explained that the power of an administrative agency to administer a congressionally created program "necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." In fact, the "agency's interpretation need not be the only

³⁸ Id. at 842-45.

³⁹ See Alves et al., supra note 20, at 2004.

⁴⁰ See Cass R. Sunstein, Cost-Benefit Default Principles, 99 MICH. L. REV. 1651, 1667 (2001) (citing Chevron, 467 U.S. at 842).

⁴¹ Chevron, 467 U.S. at 843 (citing Morton v. Ruiz, 415 U.S. 199, 231 (1974)).

permissible reading of the statute, nor the interpretation that the court might have originally given the statute."⁴²

Chevron suggests that if an agency interprets its enabling statute to permit making a policy decision rationally based on some factor or analysis that the applicable federal statute did not specifically prohibit the agency from considering (e.g., cumulative risk assessment), a court would not overturn the decision simply because of reliance on the unstated factor or analysis. 43 For example, courts have made clear that agencies may consider substitute risks of proposed regulations (e.g., "risk-risk" or 'health-health' tradeoffs [that] arise when regulation of one health problem gives rise to another health problem"), even where the statute the agency is implementing does not direct the agency to consider tradeoffs. 44 Courts have also often found it permissible for agencies to consider cost factors in promulgating decisions where the statute does not mention cost or feasibility. 45 Although the EPA use of cumulative risk assessment is a different issue, the point here is that courts have repeatedly found that in implementing a statue charged to its discretion, an agency has authority to consider criteria not mentioned in that statute.

Some EPA offices may hesitate to use cumulative risk assessment in program decision making where the Agency previously has not

⁴² New Jersey v. EPA, 517 F.3d 574, 581 (D.C. Cir. 2008) (citing *Chevron*, 467 U.S. at 843).

⁴³ See Sunstein, supra note 40, at 1667–68, 1676–78 (The Sunstein article analyzes case law mainly relating to agency consideration of cost, and concludes that to achieve regulatory goals—for example, to allocate resources so that they save more lives or produce a cleaner environment—regulators must often take account of all of a proposed regulation's adverse effects, at least where those effects clearly threaten serious and disproportionate public harm. Therefore, the author concludes that courts should read silences or ambiguities in the language of regulatory statutes as permitting, not forbidding, rational consideration of all consequences of regulation); See id. at 1652 (citing Whitman v. Am. Trucking Ass'ns, Inc., 531 U.S. 457, 490 (2001) (Breyer, J., concurring in part and concurring in the judgment)) (Although the Sunstein article addresses an agency's discretion to consider cost where a statute is silent, the analysis can be analogized, in part, to an agency's considering cumulative risk assessment results where a statute is silent as to risk.)

⁴⁴ See Sunstein, supra note 40, at 1672–74 (citing Symposium, Risk-risk Analysis, 8 J. RISK AND UNCERTAINTY 5 (1994)); Am. Water Works Ass'n v. EPA, 40 F.3d 1266 (D.C. Cir. 1994); Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin., 956 F.2d 321 (D.C. Cir. 1992)).

⁴⁵ See Sunstein, supra note 40, at 1676–78 (citing Michigan v. EPA, 213 F.3d 663 (D.C. Cir. 2000); George E. Warren Corp. v. EPA, 159 F.3d 616 (D.C. Cir. 1998); Grand Canyon Air Tour Coal. v. FAA, 154 F.3d 455 (D.C. Cir. 1998)).

considered cumulative risks in implementing that program. However, *Chevron* Step Two deference to reasonable agency interpretations applies even where an agency changes its interpretation of a statute (e.g., the EPA asserting that a broad statutory directive permits it to rely on some factor not named in the statute, when the Agency had not relied on that factor in past action under that authority). In such a circumstance, the court might question a reinterpretation if the earlier one received court approval or appears to be more consistent with other congressional and agency action. However, the Supreme Court has recognized that agency interpretations of their substantive authorities are mutable, and thus may be changed when appropriate. In *Chevron*, the Supreme Court stated, "An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." So

Therefore, judicial deference to reasonable EPA interpretations under *Chevron* Step Two extends not only to the EPA's initially selected interpretation, but also to subsequent decisions to change its preferred interpretation.⁵¹ In such cases, the court would apply the

⁴⁶ Chevron, ⁴⁶⁷ U.S. at ^{863–64} ("An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis.").

⁴⁷ See Maislin Indus., U.S., Inc. v. Primary Steel, Inc., 497 U.S. 116, 131 (1990) (explaining that "once we have determined a statute's clear meaning, we adhere to that determination . . . and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning").

⁴⁸ See FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 138–39 (2000) (refusing to find FDA authority to regulate cigarettes under the Food Drug and Cosmetic Act (FDCA) because Congress had directly addressed the problem of tobacco and health through other legislation, and had otherwise foreclosed the removal of tobacco products from the market, even though the FDCA could arguably be interpreted as requiring FDA to ban cigarettes).

⁴⁹ Chevron, 467 U.S. at 863–64 (Note that under the Administrative Procedure Act (APA) the EPA must provide adequate notice of and opportunity to comment on such a methodology change); see 5 U.S.C. § 553(b)–(c) (2013).

⁵⁰ Chevron, 467 U.S. at 863-64.

⁵¹ See Smiley v. Citibank (S.D.), N.A., 517 U.S. 735, 742 (1996) ("Sudden and unexplained change . . . 'may be arbitrary, capricious, [or] an abuse of discretion.' But if [this pitfall is] avoided, change is not invalidating.") (citations omitted); Greater Bost. Television Corp. v. FCC, 444 F.2d 841, 852 (D.C. Cir. 1970) ("An agency's view of what is in the public interest may change, either with or without a change in circumstances."); New York v. EPA, 413 F.3d 3, 22–27 (D.C. Cir. 2005) (upholding the EPA's change to a longstanding interpretation of what constitutes "increases" in emissions under the New Source Review program where the EPA supported its conclusions "with 'detailed and

presumption that when Congress left an ambiguity in a statute meant for implementation by an agency, Congress understood that the implementing agency—not the reviewing court—would have discretion to resolve the ambiguity.⁵² A court is most likely to uphold the EPA's interpretation of its broad CAA authority as permitting consideration of cumulative effects derived from a cumulative risk assessment methodology where the EPA has strong scientific evidence to support the assertion that cumulative effects are a significant concern in the circumstance at issue. 53 However, assuming that a court would uphold the EPA's interpretation or reinterpretation of an ambiguous statutory provision to permit the consideration of the results of a cumulative risk assessment, there remains a further legal hurdle. A challenger could still assert that even assuming the Agency had authority to use the methodology and results of the analysis, there were flaws in the conduct of the analysis itself or in the use of the results. In such a case, the EPA must show that there was a "rational basis" for its decision—that its actions were not "arbitrary and capricious" under the Administrative Procedure Act (APA).⁵⁴

B. APA "Arbitrary and Capricious" Review

As noted above, the EPA often supports its decision making by estimating risks associated with various pollutants or stressors. Assuming a court has found that the EPA has authority to consider cumulative risk in an ambiguous CAA directive, how might a court assess whether there is a rational basis for using a particular cumulative risk assessment methodology and the results deriving from it? This inquiry is particularly important given that the product of any risk assessment is a qualitative or quantitative statement regarding the probability of, and degree to which exposed populations or systems will be harmed.⁵⁵ In other words, how does the EPA survive the arbitrary and capricious test when it employs a methodology that necessarily involves a series of assumptions which

reasoned' analysis based on its experience and expertise" (quoting *Chevron*, 467 U.S. at 865)).

⁵² See Smiley, 517 U.S. at 740–41 (citing Chevron, 467 U.S. at 843–44).

⁵³ See AM. BAR ASS'N, supra note 1, at 378.

⁵⁴ Administrative Procedure Act, 5 U.S.C. §§ 553–559, 701–706 (2011).

⁵⁵ See AM. BAR ASS'N, supra note 1, at 354; NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT, supra note 1, at 26.

are estimated to best reflect the Agency's understanding of real-world conditions and inevitably contain some amount of uncertainty?⁵⁶

The APA provides the basic framework within which federal agencies must operate in promulgating rules, issuing policy statements, and adjudicating rights. ⁵⁷ Under this statute, a court may assess the validity of regulatory agency decision making, and "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." ⁵⁸ In applying this arbitrary and capricious standard, a court must conduct a searching and careful review of the agency's record. ⁵⁹ The court will find an agency decision arbitrary and capricious if:

[T]he agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.⁶⁰

Although the APA requires courts to perform a "searching and careful" inquiry into the facts underlying the agency's decisions, courts will, "presume the validity of agency action as long as 'a rational basis for it is presented." Courts generally give an "extreme degree of deference to [an] agency [that] is evaluating scientific data within its technical expertise," reviewing the agency's action to "ensure that [the agency] has examined the relevant data and has articulated an adequate explanation for its action." Indeed, most courts will grant an agency considerable deference for its "scientific procedures as long as there has been sufficient evidence in the record and sufficient explanation for the action, even though different inferences might have been drawn from the same data and theories and even though courts themselves sometimes suggest they might have drawn different conclusions."

⁵⁶ NAT'L RESEARCH COUNCIL, ADVANCING RISK ASSESSMENT, supra note 3, at 19.

⁵⁷ See 5 U.S.C. §§ 553-559, 701-706.

^{58 5} U.S.C. § 706(2)(A).

⁵⁹ Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983).

⁶⁰ *Id*.

⁶¹ Am. Trucking Ass'ns, Inc. v. EPA, 283 F.3d 355, 362 (D.C. Cir. 2002) (quoting Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1145 (D.C. Cir. 1980)).

⁶² City of Waukesha v. EPA, 320 F.3d 228, 247 (D.C. Cir. 2003) (internal quotation marks omitted).

⁶³ AM. BAR ASS'N, supra note 1, at 377.

In cases where courts have explained and illuminated the scope of judicial review in the face of administrative decision making where, as in the case of cumulative risk assessment, the process contains inherent technical judgment and complexity, it is apparent that a court will find an EPA decision arbitrary and capricious if the EPA fails to show a rational relationship between its conclusions or assumptions and the evidence before the Agency as contained in the record. ⁶⁴ That is, challengers tend to succeed when the record under review shows data gaps or missing steps in the EPA's logic that preclude meaningful review of the EPA's decision-making process. ⁶⁵ In contrast, when a stakeholder challenges the quality of the data or technical process relied on by the EPA or suggests that other data is more persuasive, courts are likely to defer to the EPA's expertise and uphold the final agency action. ⁶⁶

64 See Nw. Coal. for Alt. to Pesticides v. EPA, 544 F.3d 1043, 1052 (9th Cir. 2008) (rejecting the EPA's choice of safety factor as arbitrary where the court was unable to determine whether there was reliable data supporting the Agency's choice of that factor; finding that the EPA failed to explain the connection between the toxicological data and the safety factor selected); Mossville Envtl. Action Now v. EPA, 370 F.3d 1232, 1243 (D.C. Cir. 2005) (remanding an EPA determination to use vinyl chloride as a surrogate for other hazardous air pollutants because the court could not assess the rationality of the Agency's analysis, because the EPA failed to memorialize evidence of the correlation the Agency claimed existed between vinyl chloride and the other pollutants in the record).

65 David T. Buente Jr. et al., Limited Oversight: The Role of the Federal Courts Vis-à-Vis the Environmental Protection Agency in Air Pollution Control Under the Clean Air Act, 21 DUKE ENVTL. L. & POL'Y F. 309, 318–19 (2011).

66 See Coal. of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 618-19 (D.C. Cir. 2010) (upholding EPA's shift in focus from blood lead levels in the original 1978 lead NAAQS to IQ decrements in children in the revised lead NAAQS, noting that the EPA explained in both the proposed and final rule that current scientific evidence no longer recognized a safe blood level for lead, that epidemiological studies of cognitive effects and lead exposure commonly used IQ scores, and that the scientific literature supported the conclusion that lead exposure causes IQ loss in children); Tucson Herpetological Soc'y v. Salazar, 566 F.3d 870, 881-82 (9th Cir. 2009) (upholding the Department of Interior's assessment of threats to a lizard's habitat in its decision not to list the species as threatened under the Endangered Species Act; explaining that the merits of the challengers' and the agency's conflicting scientific studies are not a proper subject for the court to resolve; citing a 1989 Supreme Court opinion explaining that when specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if a court might find contrary views more persuasive) (citing Marsh v. Or. Natural Res. Council, 490 U.S. 360, 378 (1989) and Nw. Ecosystem Alliance vs. U.S. Fish & Wildlife Serv., 475 F.3d 1136, 1150 (9th Cir. 2007)); Miami-Dade Cnty. v. EPA, 529 F.3d 1049, 1063-71 (11th Cir. 2008) (upholding the EPA's Underground Injection Control Program rule against challenges that the rule's risk assessment both underestimated and overestimated risks; explaining that the court was obligated to uphold

Given the inherent scientific judgment in the selection of data and assumptions at various steps of a risk assessment, a court will attempt to ensure that the EPA "performed the most rigorous analysis possible given the available data."67 If the data and assumptions upon which a cumulative risk assessment is based are such that a reasonable policymaker could not interpret the results of the risk assessment with reasonable confidence that those results bear a rational relation to the real world (i.e., if the uncertainty of the risk assessment findings is too high), a court would likely find it inappropriate to consider such health effects in agency decision making. 68 This is because a court will overturn an agency decision where the agency fails to provide sufficient information to demonstrate a rational connection between the factors the agency examined and the conclusions it reached.⁶⁹ A plausible way for the EPA to demonstrate this rational connection, i.e., to show that its use of results from a cumulative risk assessment was not arbitrary and capricious is to present evidence that the cumulative risk assessment was based on reasonable methodologies and assumptions, given the available data, and that the EPA's use of the risk assessment results were reasonable based on the analysis.⁷⁰

the EPA's technical judgment where the assumptions the EPA applied in its risk assessment methodology bore a rational relationship to the real world, given the incomplete information faced by the Agency).

68 See Nw. Coal. for Alt. to Pesticides, 544 F.3d at 1052 n.7 (9th Cir. 2008) (quoting Ctr. for Auto Safety v. Peck, 751 F.2d 1336, 1373 (D.C. Cir. 1985) (Wright, J., dissenting)) ("Although the ultimate scope may be narrow, the depth must be sufficient for us to be able to comprehend the agency's handling of the evidence cited or relied upon. The purpose of this in-depth review is to educate ourselves so that we can properly perform our reviewing function: determining whether the agency's conclusions are rationally supported. For, although data interpretation and analysis are functions that often lie within an agency's realm of expertise, it is our duty to review those functions to ascertain whether the agency's actions were complete, reasoned, and adequately explained. The mere fact that an agency is operating in a field of its expertise does not excuse us from our customary review responsibilities. And, where the agency's reasoning, although complex, is rational, clear, and complete, we must affirm. Contrarily, where the agency's reasoning is irrational, unclear, or not supported by the data it purports to interpret, we must disapprove the agency's action.").

69 For example, in *Northwest Coalition for Alternatives to Pesticides v. EPA*, the 9th Circuit Court of Appeals rejected the EPA's choice of a safety factor as arbitrary where the court was unable to determine whether there was reliable data supporting the Agency's choice of that factor. The court found that the EPA failed to explain the connection between the toxicological data and the safety factor selected. *See Nw. Coal. for Alt. to Pesticides*, 544 F.3d at 1052.

70 Court cases that have addressed challenges to the EPA risk assessments confirm this understanding. In *Miami-Dade County v. EPA*, the 11th Circuit Court of Appeals upheld

⁶⁷ See Miami-Dade Cnty., 529 F.3d at 1069-70.

Decision makers should be mindful that courts often probe deeply into the science and reason underlying an agency's decision when a challenger asserts that a choice of methodologies or studies was unreasonable, or that the agency failed to consider a plausible alternative.⁷¹ Therefore, if a stakeholder challenges the EPA's use of a

the EPA's use of conservative risk assessment assumptions* as a means to address uncertainties. The court found these assumptions to represent a legitimate discretionary decision-making methodology because it was rational for the EPA to err on the side of overprotection when faced with data uncertainties. 529 F.3d at 1069-70 (citing West Virginia v. EPA, 362 F.3d 861, 866–67 (D.C. Cir. 2004) (explaining that "deference is due to an agency's modeling of complex phenomena, so long as 'model assumptions . . . have a 'rational relationship' to the real world"); Am. Iron & Steel Inst. v. EPA, 115 F.3d 979, 993 (D.C. Cir. 1997) (per curiam) (finding that the EPA was "reasonable" in using human health uncertainty factors in a risk assessment where the factors were created as a function of the available data. "[I]t is within EPA's discretion to decide that in the wake of uncertainty, it would be better to give the values a conservative bent rather than err on the other side."); New York v. Reilly, 969 F.2d 1147, 1152 (D.C. Cir. 1992)). In multiple decisions, courts have noted that "the law does not require selection of the single best methodology in any case, but only a study based on consideration of the relevant factors and in the construction of which there has been no clear error of judgment." Miami-Dade Cnty., 529 F.3d at 1069 (internal quotes omitted) (citing Citizens to Pres. Overland Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971), abrogated on other grounds, Califano v. Sanders, 430 U.S. 99, 99 (1977)).

* Conservative risk assumptions are those that err on the side of overstating risk under conditions of uncertainty. For example, where there is a known probability distribution, using a conservative assumption might involve selecting a risk estimate at the 95th percentile—meaning there is a 95 percent chance that the actual risk is overestimated and only a 5 percent chance that it is underestimated. See Ralph M. Perhac, Jr., Comment: Does Risk Aversion Make a Case for Conservatism?, 7 RISK: HEALTH, SAFETY & ENV'T 297 (1996), available at http://ipmall.info/risk/vol7/fall/perhac.htm.

71 See Hapner v. Tidwell, 621 F.3d 1239, 1244 (9th Cir. 2010) (citing Nw. Coal. For Alt.to Pesticides v. EPA, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008)) ("Although the ultimate scope [of our review] may be narrow, the depth must be sufficient for us to be able to comprehend the agency's handling of the evidence cited or relied upon."); Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 520 (D.C. Cir. 2009) (citations omitted) ("An agency's failure adequately to consider a relevant and significant aspect of a problem may render its rulemaking arbitrary and capricious [The] agency must examine the relevant data and articulate a satisfactory explanation for its action."); Leather Indus. of Am., Inc. v. EPA, 40 F.3d 392, 405 (D.C. Cir. 1994) (examining the EPA's risk assessment, and finding the Agency's choice of conservative exposure pathway on which to base the standard insufficiently supported); Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (1991) (invalidating asbestos rule under the Toxic Substances Control Act holding that the EPA presented insufficient evidence to justify its asbestos ban on two grounds: the failure of the Agency to consider all necessary evidence and its failure to calculate risk levels for intermediate levels of regulation); Eagle-Picher Indus., Inc. v. EPA, 759 F.2d 905, 921 (D.C. Cir. 1985) (agency must provide a full analytic defense when its model is challenged).

cumulative risk assessment methodology when making a decision to set standards "requisite to protect the public health," the Agency must be able to show that it rationally determined from the available data that it should consider cumulative risks to implement the statutory mandate effectively. The Such an interpretation of a broad public health mandate arguably would be reasonable in light of compelling scientific evidence of a cumulative adverse health effect. One could argue that where new scientific evidence indicates a different approach from the longstanding one that would better serve a statutory mandate, federal agencies should change their standard-setting methodology.

72 See AM. BAR ASS'N, supra note 1, at 378. As an example of scientific complexities that impede using cumulative risk assessment in decision making, the default assumption for cancer is that risk is additive, but that is not strictly true because different carcinogens have different modes of action. Similarly, to examine risks from multiple chemicals that have non-cancer health effects and to be able to add the exposures together it is necessary to identify chemicals with common impacts. Moreover, taking into account background levels of emissions of other pollutants from source types other than the one being analyzed, and the potential for emissions to increase up to their permitted levels, adds to the complexity and thus the uncertainty in a risk assessment, which may be a large part of the reason that the EPA would hesitate to base a decision on such a risk assessment. Although several regional cumulative risk studies for HAPs have been conducted in recent years, it would be more difficult to apply the complex methodology to a category of emission sources that are dispersed throughout multiple regions. See S. COAST AIR QUALITY MGMT DIST., FINAL REPORT: MULTIPLE AIR TOXICS EXPOSURE STUDY IN THE SOUTH COAST AIR BASIN (2008), available at http://www.aqmd.gov/prdas/matesIII/ matesIII.html; OR. DEP'T OF ENVTL. QUALITY, PORTLAND AIR TOXICS ASSESSMENT (2006), available at http://www.deq.state.or.us/aq/toxics/pata.htm.

73 See Tucson Herpetological Soc'y v. Salazar, 566 F.3d 870, 881–82 (9th Cir. 2009) (citing Marsh v. Or. Natural Res. Council, 490 U.S. 360, 378 (1989)) (noting that courts must defer to an agency's interpretation of complex scientific data, and that "[w]hen specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive"); Miami-Dade Cnty., 529 F.3d at 1063 (citations omitted) (explaining that "in the context of environmental litigation and otherwise, 'a determination of endangerment to public health is necessarily a question of policy that [must be supported by] an assessment of risks and that should not be bound by either the procedural or the substantive rigor proper for questions of fact'").

74 See FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009) (explaining that while an "agency must show that there are good reasons for a new policy . . . it need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates"); see Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 863–64 (1984) ("An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis."); see Cal. Trucking Ass'n v. Interstate Commerce Comm'n, 900 F.2d 208, 212 (9th

The remainder of this article will examine the statutory mandates in two CAA standards-setting programs to suggest how a court might analyze the Agency's interpretation of the applicable CAA provisions to permit cumulative risk decision making. We then examine the EPA's authority to assess cumulative effects in the context of deciding whether to permit a new source in an attainment area—a subject of particular currency in the environmental justice context. Note that although this article presents what we believe are legally permissible interpretations of EPA authority, using cumulative risk assessment in the contexts described here may be out of the ordinary, and could involve legal and policy interpretations that veer from longstanding interpretations of the Agency's program legislation and regulations. Broad use of cumulative risk assessment as the basis for EPA decision making will require considering a mix of scientific, political, financial, human resource, and other factors.

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SPECIFIC OPPORTUNITIES TO CONSIDER CUMULATIVE EFFECTS IN THREE EPA CLEAN AIR ACT PROGRAMS

A. The Clean Air Act: A Brief Overview

The CAA is the law that defines the EPA's responsibilities for protecting and improving the nation's air quality and the stratospheric ozone layer. The CAA directs the EPA to regulate air pollutant emissions through a combination of regulatory programs. For instance, it requires the EPA to set health-based standards for ambient (outdoor) air quality. These are known as the National Ambient Air Quality Standards (NAAQS). The CAA also requires the EPA to set

Cir. 1990) (explaining that "federal agencies have the power to 'adjust . . . policies and rulings in light of experience" (quoting Mont. Power Co. v. EPA, 608 F.2d 334, 347 (9th Cir. 1979)). In fact, cumulative risk and cumulative impacts research is currently a very active area, and the EPA has developed and implemented a screening-level cumulative risk modeling approach for prioritizing HAPs and HAP emission sources for further research. See 2005 National-Scale Air Toxics Assessment, EPA, http://www.epa.gov/nata2005/ (last updated May 21, 2012). In addition, states such as California are developing cumulative impact studies based on national research models. See CAL. ENVIL. PROT. AGENCY, CUMULATIVE IMPACTS: BUILDING A SCIENTIFIC FOUNDATION (2010), available at http://oehha.ca.gov/ej/pdf/CIReport123110.pdf.

⁷⁵ See Air and Radiation, EPA, http://www.epa.gov/air/caa/ (last updated July 16, 2012).

⁷⁶ See Clean Air Act §§ 108, 109, 42 U.S.C. §§ 7408, 7409.

national emission standards for mobile sources of air pollution, such as automobiles and their fuels. The Act also mandates emission controls for the sources of 187 hazardous pollutants embodied in the Federal National Emission Standards for Hazardous Air Pollutants (NESHAPs). The CAA establishes a comprehensive permit system for all major sources of air pollution, and requires the prevention of significant deterioration (PSD) of air quality in areas with clean air via the PSD permitting program. State, tribal, and local air agencies also play a role in CAA implementation in that the EPA authorizes state-run implementation programs that meet certain minimum requirements. Under the CAA, each state must develop a State Implementation Plan (SIP) that outlines how each state will control air pollution under the CAA. If a state fails to submit a SIP or to revise a SIP as required by the EPA, the CAA requires the EPA to create a Federal Implementation Plan (FIP) for that state.

Relevant to this article, the NAAQS provisions of the CAA require the EPA to set limits for air pollutants that endanger public health or welfare, and that are present in ambient air as a result of emissions from numerous or diverse sources. Rate and the pollutants, are particulated matter, ground-level ozone, carbon monoxide, sulfur oxides, nitrogen oxides, and lead. In contrast, the NESHAP provisions of the CAA direct the EPA to set emissions standards for specific sources that emit "hazardous air pollutants" (also known as toxic air pollutants or air toxics). The are those pollutants that cause or may cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental and ecological effects. The PSD program requires new and modified major

⁷⁷ JAMES E. MCCARTHY ET AL., CONG. RESEARCH SERV., RL30853, CLEAN AIR ACT: A SUMMARY OF THE ACT AND ITS MAJOR REQUIREMENTS 1 (2011), available at http://www.fas.org/sgp/crs/misc/RL30853.pdf.

⁷⁸ See Clean Air Act § 112, 42 U.S.C. § 7412(b)(1); *Pollutants and Sources*, EPA, http://epa.gov/ttn/atw/pollsour.html (last updated Sept. 18, 2013).

⁷⁹ See Clean Air Act § 165, 42 U.S.C. § 7475.

⁸⁰ See Clean Air Act § 110, 42 U.S.C. § 7410.

⁸¹ See id.

⁸² See id. § 7410(c)(1).

⁸³ See Clean Air Act §§ 108, 109, 42 U.S.C. §§ 7408, 7409.

⁸⁴ See What Are the Six Common Air Pollutants?, EPA, http://www.epa.gov/air/urbanair/ (last updated Apr. 20, 2012).

⁸⁵ Clean Air Act § 112, 42 U.S.C. § 7412.

⁸⁶ EPA, supra note 78.

sources of air pollution in clean air areas ("attainment areas") to apply for a PSD permit which, when granted, contains emissions limits and other specifications the permitting authority determines are necessary to prevent NAAQS violations and protect air quality.⁸⁷ The remainder of this article discusses the specific requirements of these programs, and analyzes how a reviewing court might assess the EPA's assertion of authority to consider cumulative risk in decision making under each program.

B. National Ambient Air Quality Standards (NAAQS)

The EPA must establish NAAQS for an air pollutant upon findings by the Administrator that the pollutant endangers public health or welfare, and that the pollutant's presence in ambient air results from numerous or diverse sources. ** For each such pollutant, the Agency must establish primary NAAQS that are "requisite to protect the public health" while "allowing an adequate margin of safety. ** The Agency also must set secondary NAAQS "requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. ** Effects adverse to public welfare include visibility impairment and damage to animals, crops, vegetation, and buildings. ** In the ambient and damage to animals, crops, vegetation, and buildings. ** In the ambient and damage to animals, crops, vegetation, and buildings.

1. Air Quality Criteria

To establish NAAQS for an air pollutant, the EPA must publish and revise air quality criteria, 92 which must reflect the latest scientific

⁸⁷ See Clean Air Act § 165, 42 U.S.C. § 7475; Pacific Southwest, Region 9, Air Permits, EPA, http://www.epa.gov/region9/air/permit/psd-public-part.html (last updated Aug. 6, 2013).

⁸⁸ See 42 U.S.C. §§ 7408(a), 7409(a)-(b).

⁸⁹ Id. § 7409(b)(1).

⁹⁰ Id. § 7409(b)(2).

⁹¹ Technology Transfer Network National Ambient Air Quality Standards, EPA, http://www.epa.gov/ttn/naaqs/ (last updated June 13, 2013). Welfare effects as defined in section 302(h) of the CAA (42 U.S.C. § 7602(h)), include, but are not limited to, "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and wellbeing."

^{92 42} U.S.C. § 7408(a)(2). The NAAQS are based on the air quality criteria developed by the EPA. Primary NAAQS are the "standards the attainment and maintenance of which in the judgment of the Administrator, based on [the relevant air quality] criteria and

knowledge useful in recognizing identifiable effects on public health or welfare that may be expected from that pollutant's presence in the ambient air in varying quantities.⁹³

To the extent practicable, the criteria for an air pollutant must include "variable factors (including atmospheric conditions) which of themselves or in combination . . . may alter [a pollutant's] effects on public health or welfare"; "the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare"; and "any known or anticipated adverse effects on welfare." The CAA also states, "[alll language referring to effects on welfare includes, but is not limited to, effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate . . . whether caused by transformation, conversion, or combination with other air pollutants."95 This statutory language describes the effects the EPA must consider when it sets NAAQS, and provides the EPA with authority to include cumulative effects and multimedia exposure when the Agency establishes air quality criteria for a particular air pollutant. ⁹⁶ Because a rational reading of this language demonstrates that Congress recognized a pollutant's effect on public health and welfare may be altered by other pollutants in the atmosphere, the EPA might use this provision as authority for considering cumulative effects of multiple pollutants when setting the NAAQS for an air pollutant.97

allowing an adequate margin of safety, are requisite to protect the public health." 42 U.S.C. § 7409(b)(1). Secondary NAAQS "specify a level of air quality the attainment and maintenance of which . . . is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the listed] air pollutant in the ambient air." 42 U.S.C. § 7409(b)(2).

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^{93 42} U.S.C. § 7408(a)(2). Every five years, the EPA must complete a review of air quality criteria and the NAAQS, and revise the NAAQS as appropriate. 42 U.S.C. § 7409(d)(1).

^{94 42} U.S.C. § 7408(a)(2)(A)–(C).

⁹⁵ Clean Air Act § 302, 42 U.S.C. § 7602(h).

⁹⁶ See ENVIL. LAW INST., OPPORTUNITIES FOR ADVANCING ENVIRONMENTAL JUSTICE: AN ANALYSIS OF U.S. EPA STATUTORY AUTHORITIES 107 (2001) [hereinafter ELI, OPPORTUNITIES FOR ADVANCING ENVIRONMENTAL JUSTICE], available at http://www.epa.gov/environmentaljustice/resources/reports/annual-project-reports/eli-opportunities4ej.pdf; Richard J. Lazarus & Stephanie Tai, Integrating Environmental Justice into EPA Permitting Authority, 26 ECOLOGY. L.Q. 617, 632 (1999).

⁹⁷ See ELI, OPPORTUNITIES FOR ADVANCING ENVIRONMENTAL JUSTICE, supra note 96, at 107.

Although the statutory language quoted in the preceding paragraph directs the EPA to consider how other air pollutants combine with the relevant air pollutant to effect public health and welfare, 98 it is not clear whether this instruction also provides authority for the Agency to consider the cumulative public health effects of the air pollutant with other, non-air pollutants. Nor is it clear whether these air quality criteria statutory directives permit the EPA to consider the effects arising from a combination of the effects of non-chemical stressors (e.g., poverty) and an air pollutant.

On the one hand, when setting NAAQS, the EPA must consider an air pollutant's impacts on vulnerable subpopulations, such as children and asthmatics. Therefore, the EPA arguably should consider any non-chemical stressor that exacerbates the adverse health effects of an air pollutant on these populations. Further, the air quality criteria on which NAAQS are based must include "variable factors (including atmospheric conditions) which of themselves or in combination . . . may alter [a pollutant's] effects on public health or welfare." The EPA could reasonably argue that non-air pollutants and non-chemical stressors are factors that alter a pollutant's effects.

On the other hand, one could argue that because the statutory language references cumulative effects of multiple air pollutants,

⁹⁸ Each breath of air contains a mixture of a variety of particles and gases, and these particles and gases can and do interact. As [the] EPA summarized in the recent ozone criteria document, "[h]ealth effects caused by the complex mixture are undoubtedly different (either subtly or significantly) from the additive effects of a few of the hundreds of compounds present." Deborah Behles, *Examining the Air We Breathe: EPA Should Evaluate Cumulative Impacts When It Promulgates National Ambient Air Quality Standards*, 28 PACE ENVTL. L. REV. 200, 215 (2010) (quoting EPA, AIR QUALITY CRITERIA FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS 5–65 (2006), *available at* http://cfpub.epa.gov/ ncea/cfm/recordisplay.cfm?deid=149923); see also EPA, INTEGRATED SCIENCE ASSESSMENT FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS (THIRD EXTERNAL REVIEW DRAFT) 4-17 (2012), available at http://cfpub.epa.gov/ncea/isa/ recordisplay.cfm?deid=242490.

⁹⁹ See Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 524–25 (D.C. Cir. 2009) (citing Am. Lung Ass'n v. EPA, 134 F.3d 388, 393 (D.C. Cir. 1998) (holding that "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") (remanding the EPA 2006 primary annual PM_{2.5} NAAQS because, in part, the EPA failed to explain adequately why an annual level of 15 μg/m³ is "requisite to protect the public health" while providing "an adequate margin of safety" from morbidity affecting vulnerable subpopulations)).

^{100 42} U.S.C. § 7408(a)(2)(A).

Congress meant to limit the Agency's consideration of cumulative effects to other air pollutants only. This argument might reflect application of a canon of statutory construction known as *expressio unius est exclusio alterius* ("the inclusion of one is the exclusion of others"). Essentially, this canon means that where Congress explicitly sets or excludes factors from consideration, there should be no additional exclusions or factors implied. However, Congress may provide a statutory list as examples, rather than as exclusive elements. Moreover, in analyzing statutory text, courts often are guided by the principle of reading a statute as a whole and interpreting its separate parts within the broader statutory context to further the statutory purpose. 104

As this principle relates to the CAA, Congress intended the Act "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." The preceding statement shows protection of the public health as a recurring theme throughout the CAA, and may support an argument that the EPA can use the Act "to address the health impacts of air pollution on communities that are disproportionately affected or subject to multiple sources and types of pollution." Further, the original CAA's legislative history suggests that a primary purpose of the Act is to ensure protection for those whose ability to resist the harmful effects of air pollution is compromised. The Act is to ensure protection for those whose ability to resist the harmful effects of air pollution is compromised.

¹⁰¹ YULE KIM, CONG. RESEARCH SERV., 97-589, STATUTORY INTERPRETATION: GENERAL PRINCIPLES AND RECENT TRENDS 16–17 (2008) [hereinafter CONG. RESEARCH SERV., STATUTORY INTERPRETATION], available at http://www.fas.org/sgp/crs/misc/97-589.pdf (citing Andrus v. Glover Const. Co., 446 U.S. 608, 616–17 (1980)).

¹⁰² See id.

¹⁰³ See Allied Local & Reg'l Mfrs. Caucus v. EPA, 215 F.3d 61, 78 (D.C. Cir. 2000) (interpreting a CAA statutory directive that the EPA "shall take into consideration" five listed factors as not precluding the consideration of additional factors); CONG. RESEARCH SERV., STATUTORY INTERPRETATION, *supra* note 101, at 17 (citing NationsBank v. Variable Annuity Life Ins. Co., 513 U.S. 251, 257 (1995)).

¹⁰⁴ See FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000); CONG. RESEARCH SERV., STATUTORY INTERPRETATION, *supra* note 101, at 1–3 ("The various canons of interpretation . . . are usually subordinated to interpretations that further a clearly expressed congressional purpose.").

¹⁰⁵ Clean Air Act § 101, 42 U.S.C. § 7401(b)(1).

 $^{^{106}}$ ELI, Opportunities for Advancing Environmental Justice, supra note 96, at 106.

¹⁰⁷ H.R. Rep. No. 90-728, reprinted in 1967 U.S.C.C.A.N. 1938, 1941–43 (1967).

the 1990 CAA amendments, Congress recognizes the cumulative health impacts of simultaneous exposure to multiple pollutants.

We are routinely exposed to thousands of different air pollutants emitted every day. Exposure to this mix of pollutants can produce more adverse health effects than exposure to each of the individual pollutants. These synergistic effects must be considered if we are to adequately protect public health. In addition, there are many pathways of exposure to hazardous pollutants and contaminants. Exposure to polluted outdoor and indoor air, contaminated water and soil can combine to produce greater risks than exposure through only one source. 108

This statement demonstrates explicit congressional recognition that there can be greater adverse health risks from exposure to multiple pollutants and exposure pathways than there is where human health impacts analyses consider only pollutants individually. Faced with these statements of purpose, a court should support the EPA in broadly interpreting CAA directives as permitting the Agency to develop NAAQS air quality criteria based on the cumulative risks posed by the criteria pollutant in combination with other pollutants and with non-chemical stressors that may exacerbate the adverse health effects of the criteria pollutant.

2. Requisite to Protect the Public Health with an Adequate Margin of Safety

In deciding whether a NAAQS is "requisite to protect the public health," the Supreme Court said in *Whitman v. American Trucking Association*¹⁰⁹ that the EPA may not consider implementation costs. Relying on the plain meaning of the statute, the Court concluded that public health clearly meant "the health of the public." The Court noted that Congress expressly stated the circumstances where it wished the Agency to weigh economic costs, and that to prevail in contesting the EPA's action, a challenger must show a "textual commitment of authority to the EPA to consider costs in setting NAAQS" under the applicable provision. ¹¹¹ The Court explained that

¹⁰⁸ S. REP. No. 101-228, at 2 (1989).

¹⁰⁹ Whitman v. Am. Trucking Ass'n, Inc., 531 U.S. 457, 464–71 (2001) (holding that CAA § 109(b) "unambiguously bars cost considerations from the NAAQS-setting process").

¹¹⁰ Id. at 466.

¹¹¹ Id. at 468.

an agency cannot construe a statute in a way that nullifies text designed to limit its own discretion. 112

Read narrowly, *Whitman* implies that a court would limit the EPA's interpretation of what factors the Agency may consider when setting NAAQS "requisite to protect the health." That is, because the CAA explicitly directed the EPA to consider how air pollutants may interact in addressing public health impacts, air pollutant effects are the only cumulative ones the EPA may address when setting NAAQS. Therefore, in setting NAAQS, the Supreme Court might find it impermissible for the EPA to consider the cumulative effect on the public health of pollutants or stressors that have no air-related exposure pathways.

On the other hand, the EPA must set primary NAAQS for each pollutant at levels that are "requisite to protect the public health" while "allowing an adequate margin of safety." This statutory language may be broad enough to permit addressing the impacts of non-air pollutant and nonchemical stressors if data showed that, acting with the relevant criteria pollutant, such other stressors would contribute to endangering the public health. Courts have recognized the significance of this broad public health mandate. For example, in interpreting what it means to have "an adequate margin of safety," courts have said that the EPA "has broad discretion to establish 'an adequate margin of safety' above and beyond what scientific certainty prescribes and to craft regulations that protect against unknown harms." Courts have said that the Agency must "err on the side of caution" when establishing the margin of safety, even where the "medical significance [of the effects] is a matter of disagreement."

¹¹² Id. at 485.

¹¹³ See supra text accompanying notes 108-11.

^{114 42} U.S.C. § 7409(b)(1).

¹¹⁵ Am. Lung Ass'n v. EPA, 134 F.3d 388, 393 (D.C. Cir. 1998) (citing Lead Indus. Ass'n v. EPA, 647 F.2d 1130 (D.C. Cir. 1980)).

¹¹⁶ Lead Indus. Ass'n, 647 F.2d at 1153–55; Am. Petroleum Inst. v. EPA, 684 F.3d 1342, 1350–53 (D.C. Cir. 2012) (upholding NO₂ primary NAAQS against industry challenges; holding that considering its duty to err on the side of caution, the EPA did not act unreasonably by comparing the benefits of the proposed NAAQS against not only the scenario based upon existing air quality but also upon an alternate scenario in which areas just meet the old NAAQS); Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 533 (D.C. Cir. 2009) (upholding the EPA's decision to regulate coarse PM as well as fine PM; finding that although the EPA recognizes that the evidence of danger from coarse PM is "inconclusive," the agency "need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health," where the

Another important court opinion discussing the bounds of the EPA's authority to establish NAAQS under the CAA is American Lung Association v. EPA, in which the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) explained that "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. If a pollutant adversely affects the health of those sensitive individuals, the EPA must strengthen the entire national standard."117 The court cited the CAA legislative history to support this assertion, explaining that in efforts to reduce air pollution, Congress had defined public health broadly. 118 Reading this language broadly, then, EPA arguably has authority "to protect the public health" by establishing NAAQS that are protective of populations especially vulnerable to air pollution impacts. Such a reading could support an assertion that the Agency may consider cumulative health impacts on sensitive segments of the population that experience adverse effects from simultaneous and prolonged exposure to several non-air pollutants and criteria pollutants.

In summary, although a challenger could cite the Supreme Court's *Whitman* decision to argue that the CAA should not permit the EPA to consider pollutants or stressors other than criteria air pollutants, the lower court decisions, the statutory mandate to protect public health with an adequate margin of safety, and the CAA legislative history support an assertion that the EPA has authority to consider the cumulative effects of air and non-air pollutants when setting NAAQS.

The EPA's exercise of authority is strongest when there is a specific statutory provision stating a factor or factors that the Agency must consider in a program decision. Where the Agency is relying on a broad public health mandate to support an exercise of discretion, a court could point to the general purpose statement in the CAA and agree that such a statement supports the EPA's interpretation of its

record supported the EPA's cautious decision that some protection from exposure to coarse particles is warranted in all areas) (citing *Lead Indus. Ass'n*, 647 F.2d at 1155).

¹¹⁷ Am. Lung Ass'n, 134 F.3d at 389.

¹¹⁸ Id. at 388-89.

¹¹⁹ See Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842–43 (1984) (explaining that courts "must give effect to the unambiguously expressed intent of Congress" if in the statute "Congress has directly spoken to the precise question at issue").

authority to consider unstated factors if the science in the administrative record shows that synergistic effects¹²⁰ of an air pollutant and a ubiquitous or pervasive non-air pollutant are significant and severe.¹²¹ For example, rather than following strict textual readings of statutes, the D.C. Circuit seems to make rational inferences, based on an agency's evidence in the record, that the court believes do not conflict with a statute's purpose.¹²² If the EPA were to ignore the consensus in the scientific community of severe synergistic health impacts of an air pollutant and a common non-air pollutant, a court may find that such an approach would undermine the CAA's purpose of protecting the public health.¹²³ The Agency's consideration of such scientific consensus would seem to align with Congress's intent, expressed in the legislative history of the 1990

120 Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 U. ILL. L. REV. 103, 119–120 (1996) (If the lifetime risk from exposure to one substance is added to the lifetime risk of exposure to another substance, then the total risk posed by exposure to the risks of each of these substances is additive. For example, if smoking increases the risk of contracting cancer by a factor of five, and exposure to asbestos increases the risk by a factor of ten, an additive effect would increase the lifetime risk of cancer by a factor of fifteen. If the total lifetime risk from exposure to each of several substances is greater than an additive function of the individual risks, then the lifetime risk posed by exposure to these substances is synergistic. For example, synergism between smoking and exposure to asbestos might result in a combined risk of fifty, not fifteen. An antagonistic effect results when the total risk posed by exposure to the risks of each of several substances is less than an additive function of the individual risks. Examples of antagonism are combining chemicals with toxicity levels of four and six to produce a mixture with a toxicity level of eight, or combining chemicals with toxicity levels of zero and four to produce a mixture with a toxicity level of one).

121 See Allied Local & Reg'l Mfrs. Caucus v. EPA, 215 F.3d 61, 78 (D.C. Cir. 2000) (finding reasonable the EPA's consideration of unstated factors because the statute did not preclude additional factors, citing congressional purpose and common sense as additional support for why the EPA's interpretation of its authority was reasonable) (citing George E. Warren Corp. v. EPA, 159 F.3d 616, 623–24 (D.C. Cir. 1998) (finding reasonable the EPA's consideration of factors not stated in the statute because the statute did not preclude such consideration, citing stated congressional purpose as additional support) (finding reasonable the EPA's consideration of unstated factors because the statute did not preclude additional factors, citing congressional purpose and common sense as additional support for why the EPA's interpretation of its authority was reasonable)).

122 See Sunstein, supra note 40, at 1677–79.

123 See Am. Trucking Associations, Inc. v. EPA, 175 F.3d 1027, 1051–53 (D.C. Cir. 1999), rev'd in part on other grounds, 531 U.S. 457 (2001) (holding that criteria documents, which must contain "all identifiable effects on public health or welfare which may be expected from" an air pollutant, must address any beneficial effects of air pollutants in addition to harmful effects. The court reasoned, "it seems bizarre that a statute intended to improve human health would...lock the agency into looking at only one half of a substances health effects in determining the maximum level for that substance.").

CAA amendments, that because exposure to a mix of air pollutants can produce more adverse health effects than exposure to each individual pollutant, "synergistic effects must be considered if we are to adequately protect public health." ¹²⁴

Currently, the EPA is considering the effects of nitrous oxides (NO_x) and sulfur oxides (SO_x) together when establishing NAAQS for those pollutants. However, the Agency has yet to consider the impacts or risks of interactions between criteria pollutants and other non-air pollutants when establishing NAAQS. The EPA has interpreted its NAAQS authority as "intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It is also intended to provide a reasonable degree of protection against hazards that research has not yet identified." The EPA has explained that because of these uncertainties, "the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree." The Agency explained further that in establishing

¹²⁴ S. REP. No. 101-228, at 2 (1989).

¹²⁵ See Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Sulfur, 77 Fed. Reg. 20, 218 (Apr. 3, 2012); Nitrogen Dioxide (NO₂) and Sulfur Dioxide (SO₂) Secondary Standards, EPA, http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html (last updated Sept. 20, 2013). The EPA has developed the secondary NAAQS for these pollutants together because both cause similar impacts to the environment, such as acidification. 77 Fed. Reg. at 20,222. The Clean Air Scientific Advisory Committee (CASAC), which is a CAA-required independent scientific review committee that must review the EPA's air quality criteria and NAAQS and make recommendations, has approved the development of an integrated secondary standard as a "valid, scientifically based approach." Letter from CASAC to Lisa P. Jackson, Adm'r, EPA, on Review of the Policy Assessment for the Review of the Secondary Nat'l Ambient Air Quality Standards for NO_x and SO_x: First Draft 1 (Apr. 29, 2010) (on file with the EPA), available at http://yosemite.epa.gov/sab/sabproduct.nsf/95eac6037dbee075852573a00075f732/7C35C 4501A9E0B5385257714004DBA4D/\$File/29April2010+PA+Report.pdf.

¹²⁶ Primary National Ambient Air Quality Standards for Sulfur Dioxide, 75 Fed. Reg. 35,520, 35,521 (June 22, 2010) (citing Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980), cert. denied, 449 U.S. 1042 (1980); Am. Petroleum Inst. v. Costle, 665 F.2d 1176, 1186 (D.C. Cir. 1981), cert. denied, 455 U.S. 1034 (1982)).

^{127 75} Fed. Reg. at 35,521; *see* Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 533 (D.C. Cir. 2009) (upholding the EPA's decision to regulate coarse PM as well as fine PM; finding that although the EPA recognizes that the evidence of danger from coarse PM is "inconclusive," the agency "need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health," where the

standards with an adequate margin of safety, it "considers such factors as the nature and severity of the health effects involved, the size of the at-risk population(s) and the kind and degree of uncertainties that must be addressed."128

Courts have supported the Agency's interpretation. For example, in American Trucking Associations v. EPA, 129 the D.C. Circuit upheld the PM_{2.5} and ozone NAAQS against a challenge that the EPA failed to describe the standard applied in determining the appropriate level for the NAAQS. The Agency stated that it need not determine a "safe level" of PM_{2.5} before calculating a margin of safety. 130 In upholding the NAAQS and supporting the EPA's claim that there is no threshold amount of scientific information or degree of certainty required to promulgate or revise a NAAQS, the court explained that although "the [CAA] . . . require[s] EPA [to] qualitatively . . . describe the standard governing its selection of particular NAAQS," the Agency need not "establish a measure of the risk to safety it considers adequate to protect public health every time it establishes a NAAQS."131 The court held that the CAA "requires EPA to promulgate protective primary NAAQS even where . . . the pollutant's risks cannot be quantified or precisely identified as to nature or degree." Regarding secondary NAAQS, the court explained that because "the [CAA] mandates promulgation of secondary standards requisite to protect the public welfare from any

record supported the EPA's cautious decision that some protection from exposure to coarse particles is warranted in all areas).

^{128 75} Fed. Reg. at 35,521. See also EPA, REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER: POLICY ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION: OAQPS STAFF PAPER II-2 (1996), available at http://www.epa.gov/ttn/naaqs/standards/pm/data/1996pmstaffpaper.pdf.

¹²⁹ Am. Trucking Ass'ns, Inc. v. EPA, 283 F.3d 355 (D.C. Cir. 2002) (upholding PM_{2.5} and ozone NAAQS upon remand from the Supreme Court).

¹³⁰ Id. at 368-71.

¹³¹ Id. at 369 (citing Natural Res. Def. Council, Inc. v. EPA, 902 F.2d 962, 973 (D.C. Cir. 1990), vacated in part, 921 F.2d 326 (D.C. Cir. 1991) (vacating a later part of the court's decision)); see Nat'l Envtl. Dev. Ass'n Clean Air Project v. EPA, 686 F.3d 803, 812-13 (D.C. Cir. 2012) (upholding SO₂ primary NAAQS against industry challenges that the EPA acted arbitrarily in setting the level of SO₂ emissions where the EPA concluded that it was reasonable to presume that people with more severe asthma would suffer more serious health consequences from short-term exposures to SO₂ even though the EPA did not rely on specific studies that showed this association; holding that the "EPA has discretion to set a NAAQS at a concentration level below a level that has been demonstrated to have a statistically significant association with negative health effects") (citing Am. Trucking Ass'ns, 283 F.3d at 371).

¹³² Am. Trucking Ass'ns, 283 F.3d at 369 (citations omitted).

'anticipated adverse effects associated with' regulated pollutants . . . EPA must act as soon as it has enough information (even if crude) to 'anticipate' such effects." ¹³³

The EPA's current interpretation of its NAAQS authority leaves room for the Agency to consider the cumulative effects of air and non-air pollutants if the Agency finds that the risks of these impacts adversely affect the public health, and that more stringent NAAQS would contribute to protecting the public health from these cumulative effects. Similarly, if the EPA had strong scientific evidence that a non-chemical stressor—for example, poor nutrition significantly affected a population's vulnerability to a criteria pollutant, the EPA's current interpretation of its NAAQS authority seems to allow room for the Agency to consider such evidence in deciding the level of NAAQS that will protect the public health while allowing an adequate margin of safety. Federal agencies may—and arguably should—change their standard-setting methodology where new scientific evidence indicates a different approach would better serve a statutory mandate. 134 If there is current scientific evidence to support a different determination of what constitutes "requisite to protect the public health," and the Agency rationally presents the evidence in the rulemaking process, the EPA could change the methodology by which it establishes NAAOS. 135

In assessing whether there is sufficient scientific evidence for the EPA to claim that it is reasonable to use that evidence in setting NAAQS, a court would review the Agency's action under the APA "arbitrary and capricious" standard of review. ¹³⁶ For example, a

¹³³ Id. at 380.

¹³⁴ See Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 863–64 (1984) ("An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis.").

¹³⁵ See Coal. of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 618–19 (D.C. Cir. 2010) (upholding the EPA's shift in focus, from blood levels in the original 1978 NAAQS to IQ decrements in children in the revised NAAQS, where the EPA explained in both the proposed and final rule that current scientific evidence no longer recognized a safe blood level, and that epidemiological studies of cognitive effects and lead exposure commonly use IQ scores and that the scientific literature supports the conclusion that lead exposure causes IQ loss in children).

¹³⁶ Under the CAA, courts will set aside the EPA's determination only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 7607(d)(9)(A); see also Nat'l Envtl. Dev. Ass'n Clean Air Project, 686 F.3d at 809–10

challenger opposing the EPA's consideration of a cumulative risk assessment might argue that the methodologies involve too many complex unknowns and uncertainties for the Agency to draw reasonable conclusions from the results. Recall from the Section 3.2 discussion that courts often will probe deeply into the science and reason underlying an agency's decision when a challenger asserts that the agency's choice of methodologies or studies was unreasonable or that the agency failed to consider a plausible alternative. The main lesson from these types of court challenges is that agencies must consider all relevant evidence before making a decision, and must base those choices in reason. Further, where reasonable minds could differ regarding conclusions taken from a set of evidence, courts generally will defer to agencies' expertise, particularly where the evidence and choices are in complex subject matter areas in which the agency specializes.

(citing Ethyl Corp. v. EPA, 51 F.3d 1053, 1064 (D.C. Cir. 1995) (arbitrary and capricious standard under the CAA is interpreted in "essentially the same" way as the same standard under the APA)).

137 See Hapner v. Tidwell, 621 F.3d 1239, 1244 (9th Cir. 2010) ("Although the ultimate scope of our review may be narrow, the depth must be sufficient for us to be able to comprehend the agency's handling of the evidence cited or relied upon.") (citing Nw. Coal. for Alts. to Pesticides v. EPA, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008)); Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 520 (D.C. Cir. 2009) ("An agency's failure adequately to consider a relevant and significant aspect of a problem may render its rulemaking arbitrary and capricious. [The] 'agency must examine the relevant data and articulate a satisfactory explanation for its action."") (citing Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)); Leather Indus. of Am. v. EPA, 40 F.3d 392, 405 (D.C. Cir. 1994) (examining the EPA's risk assessment, and finding the Agency's choice of conservative exposure pathway on which to base the standard insufficiently supported); Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1230 (5th Cir. 1991) (invalidating asbestos rule under the Toxic Substances Control Act holding that the EPA presented insufficient evidence to justify its asbestos ban on two grounds: the failure of the Agency to consider all necessary evidence and its failure to calculate risk levels for intermediate levels of regulation); Eagle-Picher Indus., Inc. v. EPA, 759 F.2d 905, 921 (D.C. Cir. 1985) (agency must provide a full analytic defense when its model is

138 See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (holding that a court must vacate an agency action if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise").

¹³⁹ See Natural Res. Def. Council v. U.S. EPA, 824 F.2d 1146, 1163 (D.C. Cir. 1987) (en banc); Am. Petroleum Inst. v. Costle, 665 F.2d 1176, 1184 (D.C. Cir. 1981).

In Coalition of Battery Recyclers Association v. EPA, 140 the D.C. Circuit shed light on what courts will consider sufficient scientific certainty and evidence to survive a challenge that the EPA's choice of NAAQS form and level¹⁴¹ was arbitrary. In that 2010 case, the D.C. Circuit upheld the EPA's shift in focus from blood lead levels in the original 1978 lead NAAQS to IQ decrements in children resulting from lead exposure in the revised lead NAAQS. 142 The petitioners challenging the EPA's decision contended that using IQ decrements to revise the lead NAAQS was arbitrary and capricious for three reasons. Petitioners asserted first that IQ measurements are more uncertain than blood lead level measurements, second that confounding factors such as environmental factors affect IQ scores, and third that the population significance of IQ loss is imprecise. 143 However, the court noted that in the rulemaking record, the "EPA explained that a large number of high quality studies support[ed] the inference that lead exposure causes population IQ loss, and that animal studies in which confounding factors are not present show that low levels of lead cause neurobehavioral effects."¹⁴⁴ The challengers further claimed that the EPA acknowledged the standard error of measurement for IO as between three and four IO points, and that an

¹⁴⁰ Coal. of Battery Recyclers Ass'n v. EPA, 604 F.3d 613 (D.C. Cir. 2010).

¹⁴¹ Each NAAQS has four components: the indicator, the level, the averaging time, and the form. The "indicator" defines the parameters of the substance that the EPA will measure—for example, the size or composition of the particles to which a PM standard will apply. The "level" specifies the acceptable concentration of that indicator in the air. The "averaging time" specifies the span of time across which the amount of a pollutant in the air will be averaged. For example, some NAAQS require a certain average *annual* level, while others require a certain average *daily* level. The "form" of a NAAQS describes how compliance with the level will be determined within this averaging time. A NAAQS with a daily averaging time, for example, might require that the level not be exceeded on more than one day each year. *Am. Farm Bureau Fed'n*, 559 F.3d at 516 (remanding 2006 NAAQS for fine PM to EPA; upholding 2006 NAAQS for coarse PM); *see* EPA, POLICY ASSESSMENT FOR THE REVIEW OF THE CARBON MONOXIDE NATIONAL AMBIENT AIR QUALITY STANDARDS 1-1 (2010), *available at* http://epa.gov/ttn/naaqs/standards/co/data/20101022copafinal.pdf.

¹⁴² See Coal. of Battery Recyclers Ass'n, 604 F.3d at 618–19 (upholding the EPA's shift in focus, from blood levels in the original 1978 NAAQS to IQ decrements in children in the revised NAAQS, where the EPA explained in both the proposed and final rule that current scientific evidence no longer recognized a safe blood level, that epidemiological studies of cognitive effects and lead exposure commonly use IQ scores, and that the scientific literature supports the conclusion that lead exposure causes IQ loss in children).

¹⁴³ Id. at 618.

¹⁴⁴ Id.

IQ decrement of two points was undetectable in a given individual. In rejecting this argument, the court agreed with the EPA that such an assertion confused the "critical distinction between population and individual risk," wherein a small change in IQ at the level of an individual is a substantial change at the level of a population." The *Coalition of Battery Recyclers Association* case is one example of the D.C. Circuit applying considerable deference to the EPA decisions in the scientific context.

In a 2009 decision, American Farm Bureau Federation v. EPA, 146 the D.C. Circuit rejected a challenger's objection to the EPA's methodology for setting primary annual PM_{2.5} NAAQS where the EPA declined to rely on a quantitative risk assessment prepared for the rulemaking. 147 The petitioners argued that the EPA should have relied on the risk assessment to set the PM25 NAAQS because it would result in a standard more protective than the one chosen. ¹⁴⁸ In rejecting the petitioners' argument, the court accepted as sufficiently reasonable the EPA's explanation that in leaving unresolved the question of whether there was a threshold below which PM2.5 is harmless, "the risk assessment . . . [predicted] that ever lower standards result in ever lower risks, which is not supported by statistically significant epidemiological evidence." ¹⁴⁹ The petitioners also objected to the EPA's non-reliance on the risk assessment results as arbitrary and capricious because the Agency had relied upon a risk assessment when last setting the NAAQS for PM in 1997. The court explained that it "must defer to the EPA's assessment of scientific data within its technical expertise as long as the agency has examined the data and adequately explained itself."¹⁵¹

These decisions lend support to the assertion that in revising NAAQSs, the EPA should explore fully the current state of science

¹⁴⁵ Id. at 618-19 (internal citations omitted).

¹⁴⁶ Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512 (D.C. Cir. 2009).

¹⁴⁷ Id. at 527-28.

¹⁴⁸ Id. at 527.

¹⁴⁹ Id. at 527 (internal quotation marks omitted).

¹⁵⁰ *Id*.

¹⁵¹ *Id.* (citing City of Waukesha v. EPA, 320 F.3d 228, 247 (D.C. Cir. 2003)) (internal quotation marks omitted); *see also* Am. Trucking Ass'ns, Inc. v. EPA, 283 F.3d 355 (D.C. Cir. 2002) (finding sufficient the EPA's justification for its decisions to place little faith in the quantitative results of a risk assessment prepared for the NAAQS rulemaking because the court "owe[d] deference to an agency's determination regarding the reliability of scientific evidence" and the petitioners gave "no reason to question EPA's judgment regarding the reliability of the risk assessment").

surrounding a potential revision, and that a court will uphold a challenge to the Agency's change in the methodology for setting a NAAQS if the rulemaking record adequately explains the reason for the change, and the changed methodology protects the public health. Courts generally will grant federal agencies deference to review the scientific evidence and draw inferences from it as long as they have appropriate sufficient evidence for their inferences. Therefore, even with the uncertainty inherent in cumulative risk assessments, a court may uphold the EPA's decision if the Agency provides a reasonable explanation based on all relevant scientific evidence and the EPA expertise.

C. National Emissions Standards for Hazardous Air Pollutants (NESHAPs)

Through the NESHAP program, the EPA regulates hazardous air pollutants ("HAPs," toxic air pollutants, or air toxics). HAPs are those pollutants that cause or may cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental and ecological effects. Most HAPs originate from human-made sources, including mobile sources (e.g., cars, trucks, buses), stationary sources (e.g., factories, refineries, power plants), and indoor sources (e.g., building materials and activities such as

¹⁵² See Smiley v. Citibank (S.D.), N.A., 517 U.S. 735, 742 (1996) ("Sudden and unexplained change... may be arbitrary, capricious, or an abuse of discretion. But if [this pitfall is] avoided, change is not invalidating.") (citations omitted); Coal. of Battery Recyclers Ass'n, 604 F.3d at 618–19 (upholding the EPA's change in methodology because the Agency sufficiently explained its rationale); Am. Farm Bureau Fed'n, 559 F.3d 512, 521 ("An agency's view of what is in the public interest may change, either with or without a change in circumstances.").

¹⁵³ AM. BAR ASS'N, THE LAW OF ENVIRONMENTAL JUSTICE: THEORIES AND PROCEDURES TO ADDRESS DISPROPORTIONATE RISKS, *supra* note 1, at 378.

¹⁵⁴ See Coal. of Battery Recyclers Ass'n, 604 F.3d at 618–19 (upholding the EPA's methodology against challenges of uncertainty and imprecision because the Agency explained that a large number of high quality studies supported its view to protect the population as a whole, even though precise individual effects were difficult to measure); Miami-Dade Cnty. v. EPA, 529 F.3d 1049, 1063 (11th Cir. 2008) (explaining that in the context of environmental litigation and otherwise, a determination of endangerment to public health is necessarily a question of policy that must be supported by an assessment of risks, and that should not be bound by either the procedural or the substantive rigor proper for questions of fact) (citations omitted).

¹⁵⁵ EPA, supra note 78.

cleaning). ¹⁵⁶ The CAA requires the EPA to control 187 HAPs, ¹⁵⁷ and to review the list of 187 HAPs, and add any pollutants to the list upon a finding that they "present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects . . . or adverse environmental effects." ¹⁵⁸

The CAA requires the EPA to list categories and subcategories of "major sources" and "area sources" of certain HAPs. ¹⁵⁹ For the categories and subcategories that the EPA lists, the Agency must establish initial, technology-based emissions standards (National Emissions Standards for Hazardous Air Pollutants, or NESHAPs). ¹⁶⁰ If the initial NESHAPs do not provide an ample margin of safety to protect the public health, the CAA then requires the EPA to set residual risk standards to reduce any remaining risk from sources regulated under the program. ¹⁶¹ The Agency must promulgate residual risk standards for a source category or subcategory if necessary to provide an ample margin of safety to protect the public health or to prevent an adverse environmental effect. ¹⁶²

In the NESHAP program, major sources are those sources that emit, or have the potential to emit, any single HAP at a rate of ten tons per year or more, or 25 tons per year of any combination of HAPs. For a "major source," the EPA may establish a cutoff emissions quantity of less than 10 or 25 tons per year "on the basis of the potency of the air pollutant, persistence, potential for bioaccumulation, other characteristics of the air pollutant, or other relevant factors." A statement in the Senate Report for the 1990 CAA amendments explained the purpose of this provision as follows:

The Administrator may establish quantities less than 10 tons per year for one pollutant or 25 tons per year for any combination, if the toxicity (potency) of the pollutant or pollutants or other noneconomic factors (human exposure, concentration of sources additive or synergistic effects, environmental damage or other factors) indicates that a lower threshold is appropriate. The authority to set lower thresholds as part of the "major" definition

¹⁵⁶ *Id*.

¹⁵⁷ Clean Air Act § 112, 42 U.S.C. § 7412(b)(1).

¹⁵⁸ Id. § 7412(b)(2).

¹⁵⁹ Id. § 7412(c)(1).

¹⁶⁰ *Id.* § 7412(d).

¹⁶¹ *Id.* § 7412(f).

¹⁶² Id. § 7412(f)(2).

¹⁶³ Id. § 7412(a)(1).

¹⁶⁴ Id.

may be especially useful in the control of particulate emissions including metals for some source categories. ¹⁶⁵

Congress's expressed intent indicates that standards set for major sources may address "additive or synergistic effects." This legislative history may support an assertion that in creating the HAPs regulatory structure, Congress expected the Agency to assess the cumulative risks of HAPs with other environmental pollutants. Further, in requiring the EPA to list each category or subcategory of area sources that the Agency finds "presents a threat of adverse effects to human health or the environment (by such sources individually or in the aggregate) warranting regulation," ¹⁶⁶ the CAA directs the EPA to take account of the cumulative effects of all HAPs emitters, large and small, when identifying and listing area sources of HAPs.

1. Initial NESHAPs

After listing the HAPs source categories, the EPA must establish NESHAPs for these categories, ¹⁶⁷ which require sources to meet a "maximum available control technology" (MACT) standard based on each source category's underlying industrial process. ¹⁶⁸ "The MACT standards for existing sources must be at least as stringent as the average emissions limitation achieved by the best performing 12 percent of existing sources (for which the Administrator has emissions information) or the best performing [five] sources for source categories with less than [thirty] sources." ¹⁶⁹ This level of minimum stringency is called the "MACT floor." ¹⁷⁰ For new sources, MACT standards must be at least as stringent as the control level

¹⁶⁵ S. REP. No. 101-228, at 151(1989) (emphasis added).

^{166 42} U.S.C. § 7412(c)(3).

¹⁶⁷ Id. § 7412(c)(2).

¹⁶⁸ Id. § 7412(d)(1)-(2).

¹⁶⁹ National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, 75 Fed. Reg. 32,006, 32,008 (proposed June 4, 2010); Clean Air Act § 113, 42 U.S.C. § 7413(d)(3).

¹⁷⁰ The MACT floor is the minimum control level allowed for MACT standards promulgated under the CAA, and may not be based on cost considerations. *See* National Emission Standards for Hazardous Air Pollutant Emissions: Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks; Group I Polymers and Resins; Marine Tank Vessel Loading Operations; Pharmaceuticals Production; The Printing and Publishing Industry; and Steel Pickling—HCl Process Facilities and Hydrochloric Acid Regeneration Plants, 75 Fed. Reg. 65,068, 65,071 (2010).

achieved in practice by the best-controlled similar source.¹⁷¹ In developing a NESHAP MACT standard, the EPA also must consider control options that are more stringent than the MACT floor,¹⁷² and "shall require the maximum degree of reduction in emissions of the [HAPs]" that EPA determines is achievable "taking into consideration the cost of achieving [the] emissions reduction, and *any non-air quality health and environmental impacts*[,] and energy requirements."¹⁷³

The directive for the Agency to consider non-air quality health and environmental impacts may constitute broad authority to include a wide range of these impacts in setting NESHAPs. 174 Indeed, the D.C. Circuit determined in a 2000 decision that the EPA did not comply with the CAA in setting MACT standards without showing in the administrative record whether the Agency had considered "non-airquality health and environmental impacts." A 2004 decision of this same court, Sierra Club v. EPA, let stand the EPA's interpretation of the CAA directive to consider "non-air quality health and environmental impacts," a concept not defined in the statute, as permitting analysis of any non-air impacts that may result from the required efforts to control the air quality impacts of an underlying manufacturing process. ¹⁷⁶ Under *Chevron*, where Congress does not define a term used in a statute, a court "will defer to [an agency's] construction of the ambiguous statutory language, so long as it is reasonable." In the Sierra Club case, the D.C. Circuit reasoned that the EPA's interpretation was reasonable, because "non-air quality . . . impacts" are grouped with cost and energy requirements in the CAA provision stating what the EPA must consider in establishing the MACT, and this "context strongly supports [the] EPA's interpretation of 'non-air quality . . . impacts' to mean the byproducts of the control

^{171 42} U.S.C. § 7412(d)(2).

¹⁷² *Id*.

¹⁷³ Id. (emphasis added).

 $^{^{174}}$ See ELI, OPPORTUNITIES FOR ADVANCING ENVIRONMENTAL JUSTICE, supra note 96, at 111.

¹⁷⁵ See Nat'l Lime Ass'n v. EPA, 233 F.3d 625, 634-35 (D.C. Cir. 2000).

¹⁷⁶ See Sierra Club v. EPA, 353 F.3d 976, 990 (D.C. Cir. 2004) (upholding the EPA's refusal to set "beyond-the-MACT-floor" standards where the Agency explained that the control method at issue was not predictable and consistent).

¹⁷⁷ *Id.* (citing Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842–43 (1984)).

technology—just as additional cost or energy needs are byproducts of controlling air quality impacts." ¹⁷⁸

Although the petitioner asserted that in setting the MACT standard, the statute required the EPA to consider the impacts of deposition, persistence, toxicity and bioaccumulation of HAP emissions on people, wildlife, and the environment. The court found that following the petitioner's interpretation would discredit Congress's division of the NESHAPs structure into an initial technology-based determination, followed by a risk-based determination. The Sierra Club court held that the CAA did not require the EPA to consider cumulative health risks in establishing the MACT. However, following the case reasoning, the EPA could reasonably interpret nonair quality impacts as allowing it to consider cumulative effects, because cumulative risks fit within the term "non-air quality health and environmental impacts," and especially because the EPA is currently collapsing technology (i.e., MACT standard) review with residual risk standard setting.

In another CAA provision that addresses the EPA's authority to set initial NESHAPs, the statute states that, for "pollutants for which a health threshold¹⁸¹ has been established, the Administrator may consider such threshold level, with an ample margin of safety, when

¹⁷⁸ Sierra Club, 353 F.3d at 990.

¹⁷⁹ Id.

¹⁸⁰ The Risk and Technology Review (RTR) is a combined effort to evaluate both risk and technology as required by the CAA after the application of MACT standards. The CAA directs the EPA to conduct risk assessments on each source category subject to MACT standards, and to determine if additional standards are needed to reduce residual risks. 42 U.S.C. § 7412(f)(2). Further, the CAA requires the EPA to review and revise the MACT standards, as necessary, taking into account developments in practices, processes and control technologies. 42 U.S.C. § 7412(f)(2). The RTR review combines these two required efforts. See Risk and Technology Review, EPA, http://www.epa.gov/ttn/atw/rrisk/rtrpg.html (last updated May 31, 2013).

¹⁸¹ A health threshold for a pollutant is a threshold below which no observable effects occur. See National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, 75 Fed. Reg. 32,006, 32,030 (proposed June 4, 2010) (citing S. REP. No. 101-228, at 171-72 (1989)); Human Health Toxicity Assessment, EPA, http://www2.epa.gov/region8/human-health-toxicity-assessment (last updated April 22, 2013). (For non-cancer effects, "[t]he threshold dose is typically estimated from toxicological data (derived from studies of humans and/or animals) by determining the highest dose that does not produce an observable adverse effect and the lowest does which does product an effect." For cancer effects, it is typically assumed that there is no health threshold, i.e., "there is no dose other than zero that does not increase the risk of cancer.").

establishing [NESHAPs]."¹⁸² In a 2010–2011 rulemaking on setting initial NESHAPs for boiler sources, the EPA explained that this provision "is intended to allow [the] EPA to establish emission standards other than conventional MACT standards, in cases where a less stringent emission standard will still ensure that the health threshold will not be exceeded, with an ample margin of safety."¹⁸³ In this rulemaking, the EPA interpreted the health threshold provision to allow it "to weigh additional factors, beyond any established health threshold, in making a judgment whether to set a standard for a specific pollutant based on the threshold, or instead follow the traditional path of developing a MACT standard after determining a MACT floor."¹⁸⁴ The EPA gave a representative list of such additional factors, including the following:¹⁸⁵

- The potential for cumulative adverse health effects because of concurrent exposure to other HAPs with similar biological endpoints, from either the same or other source categories, where the concentration of the threshold pollutant emitted from the given source category is below the threshold.
- The potential impacts on ecosystems of releases of the pollutant.
- Reductions in criteria pollutant emissions and other co-benefits that would be achieved via the MACT standard.

In justifying its interpretation, the Agency explained that, "[e]ach of these factors is directly relevant to the health and environmental outcomes at which [the NESHAP provisions] of the [CAA are] fundamentally aimed." In this boiler MACT rulemaking, the EPA concluded that it lacked the information to calculate a sufficiently protective health-based emissions standard, because the Agency lacked information to assess the toxicity of the relevant HAP (in this case, hydrogen chloride [HCl], as a surrogate for acid gas HAPs) with other respiratory irritants, and to meaningfully evaluate other air pollutant sources near boilers emitting hydrogen chloride. In this

^{182 42} U.S.C. § 7412(d)(4).

¹⁸³ National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, 75 Fed. Reg. at 32,030.

¹⁸⁴ Id.

¹⁸⁵ *Id*.

¹⁸⁶ *Id*.

¹⁸⁷ National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, 76 Fed. Reg. 15,608, 15,642–44 (Mar. 21, 2011); National Emission Standards for Hazardous Air

rulemaking, the EPA asserted authority to consider cumulative risks from other pollutants affecting the same health endpoint (i.e., respiratory irritants) under a NESHAP provision that did not mention cumulative risks. Using the same rationale, i.e., by referencing the underlying purposes of the statutory provisions at issue, the EPA could similarly interpret other broad CAA authorities.

2. Residual Risk NESHAPs

In the second stage of HAPs regulation, the EPA must review any residual health risks that have not been eliminated by the initial technology-based standards. The EPA must promulgate residual risk NESHAPs "if promulgation of such standards is required in order to provide an ample margin of safety to protect public health . . . or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect." ¹⁸⁹

In its current residual risk determinations, the EPA considers cumulative effects, at least in a narrow sense. The EPA has explained in recent residual risk rulemakings that the 1990 CAA Amendments authorized the Agency's use of a two-step process for developing standards to address residual risk, and preserved its interpretation of "ample margin of safety" developed in the 1989 Benzene NESHAP 190

Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, 75 Fed. Reg. at 32,030–32.

¹⁸⁸ 42 U.S.C. § 7412(f); *see* Clean Air Act Amendments of 1990, Pub. L. 101-549, 104 Stat. 2399 (Nov. 15, 1990).

189 42 U.S.C. § 7412(f)(2)(A). "Adverse environmental effect" is defined as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life or natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental qualities over broad areas." 42 U.S.C. § 7412(a)(7).

190 E.g., NESHAP for Secondary Aluminum Production, 77 Fed. Reg. 8,576, 8,578 (proposed Feb. 14, 2012); see NESHAP for Benzene Emissions, 54 Fed. Reg. 38,044 (Sept. 14, 1989) (codified at 40 CFR pt. 61). The EPA asserts that CAA Section 112(f)(2)(B), 42 U.S.C. § 7412(f)(2)(B), preserves the interpretation set out in the Benzene NESHAP, and that the D.C. Circuit concluded that the EPA's interpretation of Section 112(f)(2)(B) is a reasonable one. NESHAP for Secondary Aluminum Production, 77 Fed. Reg. at 8,578–79; see Natural Res. Def. Council v. EPA, 529 F.3d 1077, 1083 (D.C. Cir. 2008) (stating that "subsection 112(f)(2)(B) expressly incorporates the EPA's interpretation of the Clean Air Act from the Benzene standard, complete with a citation to the Federal Register").

The first step in this process is the determination of acceptable risk. "The second step provides for an ample margin of safety to protect public health, which is the level at which the standards are set (unless a more stringent standard is required to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect)." ¹⁹¹

The EPA has explained that it does not define rigid lines of acceptability, but weighs rather broad objectives by applying a series of other health measures and factors. ¹⁹² For example, in setting a cancer risk presumption for the 1989 Benzene NESHAP, the EPA explained:

[R]ather than a rigid line for acceptability, the Agency intends to weigh it with a series of other health measures and factors. These include the overall incidence of cancer or other serious health effects within the exposed population, the numbers of persons exposed within each individual lifetime risk range and associated incidence within, typically a 50 [kilometer] exposure radius around facilities, the science policy assumptions and estimation uncertainties associated with the risk measures, weight of the scientific evidence for human health effects, other quantified or unquantified health effects, effects due to co-location of facilities, and co-emission of pollutants. ¹⁹³

In this statement, the EPA apparently recognizes Agency discretion to consider cumulative effects when assessing the need for residual risk amendments to the NESHAPs. The EPA has noted in recent residual risk rulemakings that these health measures and factors taken together may provide a more realistic description of the magnitude of

¹⁹¹ NESHAP for Secondary Aluminum Production, 77 Fed. Reg. at 8,578; NESHAP for Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks and Related Sources, 75 Fed. Reg. 65,068, 65,071–72 (proposed Oct. 21, 2010). The EPA explained in the *Benzene* NESHAP that an overall objective in protecting the public health with an adequate margin of safety was to provide maximum feasible protection against risks to health from HAPs by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1-in-1 million (1 x 10⁻⁶); and (2) limiting to no higher than approximately 1-in-10,000 (1 x 10⁻⁴) (i.e., 100-in-1 million) the estimated risk that a person living near a facility would have if he or she was exposed to the maximum pollutant concentrations for seventy years. *See* NESHAP for Benzene Emissions, 54 Fed. Reg. at 38,044–45.

¹⁹² NESHAP for Secondary Aluminum Production, 77 Fed. Reg. 8,576, 8,579; NESHAP: Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks and Related Sources, 75 Fed. Reg. 65,068, 65,072; EPA, RESIDUAL RISK REPORT TO CONGRESS ES-11 (1999), available at http://www.epa.gov/ttn/caaa/t3/reports/risk_rep.pdf.

¹⁹³ NESHAP for Benzene Emissions, 54 Fed. Reg. 38,045 (emphasis added).

risk in the exposed population than that provided by maximum individual lifetime cancer risk alone. The EPA asserts that in the 2008 case *Natural Resources Defense Council v. EPA (NRDC)*, the D.C. Circuit approved this approach to establishing health-based residual risk standards as reasonable when the court stated that the statutory approach to establishing residual risk standards "expressly incorporates [the] EPA's interpretation of the [CAA] from the *Benzene* standard." ¹⁹⁵

Unlike the NAAQS and MACT standard setting authorities, the residual risk standard setting directives of the CAA do specifically mention risk. For HAPs that are known, probable, or possible human carcinogens, if the initial NESHAP standard does not, "reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than 1-in-1 million," the EPA must promulgate residual risk standards for the source category as necessary, "to provide an ample margin of safety to protect public health." A risk level of 1-in-1 million implies a likelihood that up to one person, out of one million equally exposed people, would contract cancer if exposed continuously (24 hours per day) to the specific concentration over seventy years (an assumed lifetime)." This would be in addition to those cancer cases that would normally occur in an unexposed population of one million people.

Note that the statutory directive to promulgate residual risk standards for carcinogens obligates the Agency to establish standards that provide an adequate margin of safety, but does not require that the EPA establish standards such that the lifetime cancer risk is

¹⁹⁴ See, e.g., NESHAP for Secondary Aluminum Production, 77 Fed. Reg. 8,576, 8,579; NESHAP: Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks and Related Sources, 75 Fed. Reg. 65,068, 65,072.

¹⁹⁵ Natural Res. Def. Council v. EPA, 529 F.3d 1077, 1083 (D.C. Cir. 2008).

^{196 42} U.S.C. § 7412(f)(2)(A).

¹⁹⁷ Glossary of Key Terms, EPA, http://www.epa.gov/ttn/atw/natamain/gloss1.html (last updated Feb. 11, 2011); see also Ind. Dep't of Envtl. Mgmt., Risk Assessment, IN.GOV, http://www.in.gov/idem/4144.htm (last visited Oct. 29, 2013) ("The risk associated with the potential to develop cancer after exposure to [a pollutant] is often expressed as a probability or a fraction in a range from zero to one (0.0–1.0). A zero chance would mean there is no chance of developing cancer and a one chance would mean there is absolute certainty that one will develop cancer. Usually the numbers are very small and shown in fractions of one million or fractions of one hundred thousand."

¹⁹⁸ EPA, supra note 197.

reduced to below 1-in-1 million; rather, 1-in-1 million is the risk benchmark at which the EPA must promulgate health-based standards for carcinogenic HAPs. As the D.C. Circuit observed in NRDC, the statute "says nothing about the substantive content of [the residual risk] standards." In *NDRC*, the court rejected the petitioner's argument that the EPA must set the residual risk standard for carcinogenic HAPs to reduce the risk below 1-in-1 million.²⁰⁰ The EPA declined to set residual risk standards for the HAP at issue because the Agency determined that "no individual would face an excess lifetime cancer risk of greater than 100-in-one million, which [the] EPA regard[ed] as the 'presumptively acceptable' [risk] level under its precedents."²⁰¹ Because the risk of 1-in-1 million is the procedural trigger for when the EPA must set residual risk standards, and not an expression of the risk those standards must protect against, the court found that the "EPA's interpretation of [the CAA residual risk standard provision], although not an inevitable one, certainly is, at least, a reasonable construction of the statute."202 This decision indicates that the EPA likely has wide latitude to reasonably interpret what level of residual risk standards are necessary, "to provide an ample margin of safety to protect the public health,"²⁰³ and that courts will view such Agency determination with a great degree of deference as falling within the Agency's technical expertise.²⁰⁴

Were the EPA to add the cumulative effects of background pollutants to a residual risk assessment, such an analytical method would be different from what the Agency does now for residual risk HAPs determinations. However, the EPA's stated approach to determining required emissions levels for providing "an ample margin of safety to protect public health" appears to leave room for the Agency to consider a broad range of cumulative effects, including the cumulative risks posed by non-chemical stressors. Factors such as poverty and lack of health care could impact a population's sensitivity

¹⁹⁹ Natural Res. Def. Council v. EPA, 529 F.3d 1077, 1081-83 (D.C. Cir. 2008).

²⁰⁰ Id. at 1081.

²⁰¹ Id. at 1080.

²⁰² Id. at 1083.

^{203 42} U.S.C. § 7412(f)(2)(A).

²⁰⁴ See City of Waukesha v. EPA, 320 F.3d 228, 247 (D.C. Cir. 2004) (explaining that courts "will give an extreme degree of deference to the agency when it 'is evaluating scientific data within its technical expertise") (quoting Huls Am., Inc. v. Browner, 83 F.3d 445, 452 (D.C. Cir. 1996)).

^{205 42} U.S.C. § 7412(f)(2)(A).

to a HAP source, especially if there are many sources located near a population impacted by such non-chemical stressors. As discussed above, Federal agencies can change their standard-setting methodology if the current scientific evidence supports the revised methodology and the agency explains its new reasoning in the rulemaking process. Therefore, if the EPA can demonstrate that reliable scientific evidence shows substantial cumulative health risks of a particular HAP, when combined with other relevant stressors near major sources (either chemical or non-chemical), it appears likely that a court would uphold a residual risk decision that considered such cumulative risks.

D. Prevention of Significant Deterioration (PSD) Permits

The CAA establishes several permit programs to control the amount and type of air emissions from certain sources. The statute requires states and the EPA to designate geographic areas (e.g., counties or metropolitan statistical areas) as "attainment" or "nonattainment" based on whether the air quality in that area meets the NAAQS for a given criteria pollutant. In an attainment area, before construction of a major new source or modification of an existing source that will emit the pollutant for which the area is in attainment, a permitting authority must conduct preconstruction review and approve the construction or modification. The program for review and approval is the PSD (prevention of significant deterioration) permitting program.

Under the CAA, each state must develop a SIP that outlines how the state will control air pollution under the Act, ²⁰⁹ including how the

²⁰⁶ See Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 863–64 (1984) ("An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis."); see also Cal. Trucking Ass'n v. Interstate Commerce Comm'n, 900 F.2d 208, 212 (9th Cir. 1990) (explaining that "federal agencies have the power to adjust policies and rulings in light of experience") (internal citations omitted).

²⁰⁷ See Clean Air Act § 107, 42 U.S.C. § 7407(d)(1)(A)(i)–(ii).

^{208 42} U.S.C. §§ 7475, 7479(2)(c), 7411(a)(4) ("Preconstruction requirements"), 7479(2)(C) (defining construction to include the modification of any source or facility), 7411(a)(4) (defining modification).

²⁰⁹ Clean Air Act § 110, 42 U.S.C. § 7410. (A state implement plan (SIP) is a collection of the regulations, programs, and policies that a state will use to meet the EPA standards

state will implement the PSD program.²¹⁰ The EPA must approve state SIPs and serves as the permitting authority for states without an approved SIP or states improperly implementing the program.²¹¹ Although there are other CAA permit programs, this analysis addresses PSD permits, which frequently are the subject of challenges and of administrative review decisions that address CAA authority to review and issue PSD permits.

The PSD permit program requires an owner or operator to obtain a permit for a new or modified major source with the potential to emit a criteria pollutant in an attainment area for that pollutant and, consequently, contribute to concentrations of the pollutant in the area. In attainment or PSD areas, a source must apply Best Available Control Technology (BACT). The CAA requires that the permitting authority take into account energy, environmental, and economic impacts and other costs in weighing BACT options.

To obtain a PSD permit, an applicant must show that emissions from the source would "not cause, *or contribute to*, air pollution in excess of any [emissions limitation for each pollutant subject to PSD regulation], [NAAQS], or any other applicable emission standard of performance under this chapter,"²¹⁵ by demonstrating that emissions will not cause or contribute to air pollution that exceeds an area's

and clean up polluted areas. *Understanding the Clean Air Act*, EPA, http://www.epa.gov/air/peg/understand.html (last update Mar. 6, 2012).

²¹⁰ See 42 U.S.C. § 7410(a)(2)(C).

²¹¹ See 42 U.S.C. § 7410(c)(1) (directing the EPA to create a Federal Implementation Plan (FIP) for a State if a State fails to submit a SIP or to revise a SIP as required by the EPA).

²¹² 42 U.S.C. § 7475; 40 C.F.R. § 51.165(b); see also Pacific Southwest, Region 9, Air Permits, EPA, http://www.epa.gov/region9/air/permit/psd-public-part.html (last updated Aug. 6, 2013).

^{213 42} U.S.C. § 7475(a)(4).

^{214 42} U.S.C. § 7479(3) (defining best available control technology as "an emission limitation based on the maximum degree of reduction of each pollutant subject to regulation under this chapter emitted from or which results from any major emitting facility, which the permitting authority, on a case-by-case basis, taking into account energy, environmental, and economic impacts and other costs, determines is available for such a facility through application of production processes and achievable methods, systems, and techniques, including fuel cleaning, clean fuels, or treatment or innovative fuel combustion techniques for control of each such pollutant. In no event shall application of 'best available control technology' result in emissions of any pollutants which will exceed the emissions allowed by any applicable [NAAQS or NESHAP]."); 40 C.F.R. § 51.165(a)(xl) (requiring state plans to have a specific definition for BACT, which incorporates the statutory definition).

^{215 42} U.S.C. § 7475(a)(3) (emphasis added); see also 42 U.S.C. § 7475(d).

maximum allowable increase over baseline concentration (ambient air increment, or PSD increment).²¹⁶ The baseline concentration is defined for each pollutant and, in general, is the ambient concentration existing at the time that the first complete PSD permit application affecting an area is submitted.²¹⁷ "Significant deterioration" occurs at the point where the amount of criteria pollution from the proposed source would exceed the applicable PSD increment.²¹⁸ PSD increments prevent the air quality in attainment areas from deteriorating to or below the level set by the NAAQS. The Environmental Appeals Board (EAB or Board), an EPA administrative tribunal that adjudicates appeals of permit decisions made by states and local districts with delegated Federal authority, is the primary adjudicator of challenges to decisions of PSD permitting authorities.²¹⁹

On several occasions, the EAB has addressed environmental justice issues in connection with PSD permit appeals.²²⁰ Environmental justice issues usually arise in the context of claims that the permitting authority failed to consider the combined impact of constructing or modifying a source and the cumulative effects of other pollution sources on minority or low-income communities near the relevant permit area. In the context of a PSD permit review, a cumulative effects analysis and an environmental justice analysis are analogous in that each could reasonably be part of the initial permit review and approval process, although the applicable statutory provisions mention neither as factors in the PSD program.

The EAB has stated in numerous decisions that even without formal Agency rules or guidance on environmental justice, the EPA may address environmental justice issues in PSD permitting

²¹⁶ See 40 C.F.R. § 52.21(k); see also 40 C.F.R. § 52.21(c) (ambient air increments).

 $^{^{217}}$ Prevention of Significant Deterioration (PSD) Basic Information, EPA, http://www.epa.gov/NSR/psd.html (last updated July 22, 2011).

²¹⁸ *Id*.

²¹⁹ See Memorandum from Gary S. Guzy, EPA General Counsel, to EPA Assistant Administrators on EPA Statutory and Regulatory Authorities Under Which Environmental. Justice Issues May Be Addressed in Permitting 12 (Dec. 1, 2000) [hereinafter EPA OGC Memorandum] (on file with the EPA), available at http://www.epa.gov/compliance/ej/resources/policy/ej_permitting_authorities_memo_120 100.pdf; see also Environmental Appeals Board, EPA, http://yosemite.epa.gov/oa/EAB Web Docket.nsf (last visited Oct. 29, 2013).

²²⁰ See EPA OGC Memorandum, supra note 218.

decisions.²²¹ In a 1999 decision, *In re Knauf Fiber Glass*, the EAB remanded a PSD permit to the delegated permitting authority citing the failure to provide an environmental justice analysis in the administrative record in response to comments raising the issue.²²² More recently, the EAB affirmed that a delegated permitting authority must consider environmental justice issues in reviewing whether to issue a PSD permit, based on Executive Order 12898²²³ directing executive branch agencies to consider environmental justice in Federal actions.²²⁴ However, it appears that the EAB will find an environmental justice analysis sufficient upon a showing that the proposed source will not cause or contribute to a NAAQS violation.²²⁵

221 See EcoElectrica, L.P., PSD Appeal Nos. 96-8 and 96-13, 1997 EPA App. LEXIS 5, *27-32 (1997); P.R. Elec. Power Auth. (Cambalanche Combustion Turbine Project), PSD Appeal No. 95-2, 6 E.A.D. 253, 255-58 (1995); EPA, note 16, at 13-17; see also EPA OGC Memorandum, supra note 218, at 12. (Noting that the EAB first addressed environmental justice issues under the CAA in 1993 in the decision Power Station Limited Partnership, 4 E.A.D. 832 (1993). In that decision, the EAB stated that the CAA did not allow for consideration of environmental justice and siting issues in air permitting decisions. In response, the EPA's Office of General Counsel (EPA OGC) filed a motion for clarification on behalf of the Office of Air and Radiation and Region V. EPA, supra note 16, at 13; EPA OGC Memorandum, supra note 217, at 12. Among other things, the EPA OGC asserted that the CAA requirement to consider alternatives to the proposed source, and the broad statutory definition of BACT, provided ample opportunity for considering environmental justice in PSD permitting; see 42 U.S.C. § 7475(a)(2) (requiring a public hearing where the EPA and interested persons have the opportunity to submit presentations on the air quality impact of the applicant source, alternatives to the applicant source, control technology requirements, and other appropriate considerations)); EPA, supra note 16, at 13-14; EPA OGC Memorandum, supra note 218, at 12. In an amended opinion and order (October 1993), the EAB deleted the controversial language without affirmative stating whether it is permissible to address environmental justice concerns under the PSD program. Gennesee Power Station Ltd. P'ship, 4 E.A.D. 832 (1993).

²²² Knauf Fiber Glass, 8 E.A.D. 121, 124–27 (1999); *see* EPA, *supra* note 16, at 14; EPA OGC Memorandum, *supra* note 216, at 12.

223 Exec. Order. No. 12,898, 59 Fed. Reg. 7,629 (Feb. 16, 1994).

224 Shell Gulf of Mex., Inc. & Shell Offshore, Inc., (Frontier Discovery Drilling Unit), 2010 EPA App. LEXIS 49, at *111–12 (2010) (citing Prairie State Generating Co., 13 E.A.D. 1, 123 (EAB 2006), aff'd sub nom. Sierra Club v. EPA, 499 F.3d 653 (7th Cir. 2007); AES P.R., L.P., 8 E.A.D. 324, 351 (EAB 1999), aff'd sub nom. Sur Contra La Contaminacion v. EPA, 202 F.3d 443 (1st Cir. 2000); Knauf Fiber Glass GmbH, 8 E.A.D. 121, 174–75 (EAB 1999); EcoElectrica, L.P., 7 E.A.D. 56, 67–69 (EAB 1997)).

225 See Shell Gulf of Mex., Inc. & Shell Offshore, Inc., (Frontier Discovery Drilling Unit), 2010 EPA App. LEXIS 49, at *124 (noting that in the context of PSD permit challenges, EAB has accepted compliance with the NAAQS as sufficient to demonstrate that emissions from a proposed facility will not have disproportionately high and adverse human health or environmental effects on a minority or low-income population) (citing Knauf II, 9 E.A.D. at 15–17; Sutter Power Plans, 8 E.A.D. 680, 692 (EAB 1999)); see also Avenal Power Ctr., LLC, 2011 EPA App. LEXIS 26, at *44 (finding that a "substantive

Nevertheless, the EAB has recognized that a permitting authority has discretion under PSD program regulations to establish permit conditions based on environmental justice considerations.²²⁶

Under the CAA, a PSD permit decision must address whether emissions from the applicant source *cause or contribute to* violations of air emissions concentrations or increment limits.²²⁷ Thus, when issuing a PSD permit, the permit-issuing authority appears to have broad discretion to consider how a source interacts with other sources to produce the ambient air mix in an attainment area. In upholding the EPA discretion to address environmental justice even without formal Agency rules or guidance, the EAB decisions referenced above support this interpretation.

As with environmental justice factors, the EPA has no formal rules or guidance addressing cumulative effects in the PSD review process. However, as with addressing environmental justice factors, a reasonable consideration in determining whether emissions cause or contribute to air quality violations is the cumulative effects of adding pollution from a new or modified source to a community already overburdened with other chemical and non-chemical stressors.

Note that the EAB has addressed cumulative effects only in the context of visibility as an air quality-related value. In a 1992 decision, *In re Old Dominion*, a petitioner challenged a PSD permit asserting that by showing that all currently proposed sources collectively would adversely impact the affected land areas, the permitting authority could demonstrate that the emissions from the proposed source would have, "an adverse impact on the air quality-related values (including visibility)" on affected land. ²²⁹ The EAB disagreed, stating, "PSD permit determinations are made individually under the [CAA] on a case-by-case basis, and the State is not required to withhold or deny a permit application for a qualified source based on the supposition that

environmental justice analysis that endeavors to include and analyze data that is germane to the environmental justice issue raised during the comment period" may comply with the Executive Order even if it does not reach a definitive conclusion, if "the permit issuer demonstrates that it exercised its considered judgment when determining that it could not reach a determinative conclusion due to the insufficiency of available valid data").

²²⁶ EPA, *supra* note 16, at 16 (quoting AES P.R., L.P., 8 E.A.D. 324, 351 (EAB 1999)). ²²⁷ 42 U.S.C. § 7475(a)(3).

^{228 42} U.S.C. § 7475(d)(2)(C)(ii).

²²⁹ Old Dominion Elec. Coop., 3 E.A.D. 779; 1992 EPA App. LEXIS 37, at *20 (1992).

there might be an adverse impact on visibility in an area if other pending applications are subsequently approved."²³⁰ However, although EAB did not require the permitting authority in that case to consider cumulative effects in evaluating visibility values, the Board suggested that there could be circumstances where it would be prudent "to consider the collective potential impacts on visibility from all prospective sources that have not yet received final permits."²³¹ Therefore, the *In re Old Dominion* decision suggests that it is permissible for a PSD permitting authority to focus on cumulative air quality impacts, at least in evaluating the air quality value of visibility.

Existing PSD program guidance appears to endorse at least a narrow consideration of cumulative effects in permitting decisions. For example, in PSD program guidance on modeling procedures for demonstrating compliance with the PM_{2.5} NAAQS, the EPA states "Secondary formation of PM_{2.5} from emissions of NO_x, SO_x and other compounds from sources across a large domain . . . may be the dominant source of ambient PM_{2.5} in some cases."²³² Agency guidance further states, "[I]f the facility emits significant quantities of PM_{2.5} precursors, some assessment of their potential contribution to cumulative impacts as secondary PM_{2.5} may be necessary."²³³ On the other hand, the statutory "cause or contribute to" language could be viewed as limiting the considerations in a PSD permit process to air impacts, as opposed to considering the cumulative risks posed by air pollution, other media stressors, and non-chemical stressors. Still, there are environmental justice communities in many attainment areas where adding a new or modified source might raise serious public health issues because of the potential adverse cumulative effects of

^{230 1992} EPA App. LEXIS at *20.

²³¹ Old Dominon Elec. Coop., 3 E.A.D. 779 at 20 n.24, ("While it may be prudent in such circumstances for a State to consider the collective potential impacts on visibility from all prospective sources that have not yet received final permits, nothing cited by Petitioners requires this type of planning."). The EAB decision referred to existing EPA policy that, in determining whether a proposed source will cause an adverse impact on visibility, the cumulative visibility impacts of the pending PSD permit applicant and all PSD-permitted sources, including those not yet constructed, must be assessed against background visibility conditions. *Id.*

 $^{^{232}}$ Memorandum from Stephen D. Page, Director, Office of Air Quality Planning & Standards, on Modeling Procedures for Demonstrating Compliance with PM $_{2.5}$ NAAQS 3 (Mar. 23, 2010), $available\ at\ http://www.epa.gov/region07/air/nsr/nsrmemos/pm25 memo.pdf.$

²³³ Id. at 9.

multiple facilities. In such instances, based on EAB decisions, the PSD permitting authority has discretion to consider cumulative risk and impacts in decision making as part of an environmental justice analysis.

To some extent, the EPA already does consider cumulative air pollutant impacts in PSD permitting decisions. Regarding the subject of cumulative effects of multiple air pollutants, in several places in its "Guideline on Air Quality Models," the EPA addresses background concentrations of air pollutants and background air quality data as inputs to air quality models.²³⁴ Additionally, a currently available 1990 Draft New Source Review Workshop Manual applicable to the same subject indicates that the Agency requires a full ambient air impact analysis to include the emissions from the proposed source itself, "the estimation of background pollutant concentrations resulting from existing sources," and emissions from "residential, commercial, and industrial growth that accompanies the new activity at the new source or modification."²³⁵ This manual states, however, that if a preliminary analysis shows the emissions from a proposed source as having only minimal impacts on ambient air quality, the permitting authority may allow an applicant to forego a full ambient air analysis. 236

In summary, the EAB decisions discussed above appear to support the EPA's authority to establish permit conditions on the basis of cumulative effects or cumulative risk considerations, at least in terms of cumulative criteria pollutant impacts from all relevant exposure pathways in the relevant permit area. Because the CAA specifies that PSD permit decisions must ensure that emissions from the applicant source would "not cause, or contribute to, *air pollution* in excess of any [emissions limitation for each pollutant subject to PSD regulation], [NAAQS], or any other applicable emission . . . standard of performance,"²³⁷ it is not clear the considerations of cumulative risks could encompass non-criteria air pollutants or nonchemical stressors that might increase a population's vulnerability to certain air

^{234 40} C.F.R. § 51, (2013) ("Guideline on Air Quality Models").

²³⁵ See EPA, New Source Review Workshop Manual: Draft C-24 to C-25 (1990), available at hhttp://www.epa.gov/region07/air/nsr/nsrmemos/1990wman.pdf.

²³⁶ Id.

^{237 42} U.S.C. § 7475(a)(3) (emphasis added).

pollution effects. 238 However, the stated purpose of the PSD program is "to protect public health and welfare from any actual or potential adverse effect . . . from air pollution or from exposures to pollutants in other media . . . notwithstanding attainment and maintenance of all [NAAQS]."239 The EPA could cite this statement of congressional purpose to interpret the PSD provisions as permitting a broad consideration of cumulative effects on overburdened communities (including consideration of non-air background health effects and non-chemical stressors) as a means of furthering the purpose of the PSD program and CAA. 240

IV

ADDRESSING POTENTIAL COUNTER-ARGUMENTS TO THE EPA'S CLAIM OF AUTHORITY TO CONSIDER CUMULATIVE EFFECTS UNDER CLEAN AIR ACT PROGRAMS

If the EPA were to consider a cumulative risk assessment in implementing one of its broad CAA directives to protect the public health with an "ample margin of safety" (NAAQS and residual risk NESHAPs), consider "non-air quality health and environmental impacts" (NESHAPs), or issue permits that would, "not cause, or contribute to, air pollution in excess of any [emissions limitation or NAAQS]" (PSD program); such a decision might be opposed by stakeholders that believe the EPA has exceeded its CAA authority. These challengers would likely make at least two major arguments. First, a challenger would argue that based on the overall legislative structure for protecting human health and environmental resource areas, Congress implicitly prohibited considering cumulative effects outside of the specific pollutants or resource areas addressed by a particular statute. Second, a challenger would argue that the recent D.C. Circuit cases vacating the EPA's rules attempting to implement the CAA "good neighbor" provision signal a strict construction of the

²³⁸ Note that the EPA has recently asserted its position that, when establishing BACT for a source (i.e., PSD permit conditions) to control criteria pollutants, the Agency could consider a technology's ability to control emissions of other pollutants. EPA, *supra* note 16, at 17. This position suggests that a permitting authority could consider the cumulative effect of a proposed source's emissions when combined with other HAPs sources in the relevant geographical area.

²³⁹ Clean Air Act, § 160, 42 U.S.C. § 7470(1).

²⁴⁰ See EPA, supra note 16, at 13 (stating that, "[t]he ability to condition a permit due to environmental justice considerations would further the purpose of [the PSD program] 'to protect public health and welfare'").

CAA. The analysis below explains why these arguments would not be fatal to the EPA considering the results from a cumulative risk assessment in making decisions under these CAA programs.

A. The Overall Legislative Structure Does Not Mandate Regulation by Individual Media

A stakeholder challenging the EPA's interpretation of the Agency's statutory authority to consider the results of a cumulative risk assessment might argue that such a statutory interpretation is impermissible because the overall legislative structure for protecting human health and environmental resources prohibits considering stressors outside of the pollutants Congress addressed in a given statute. In other words, Congress has addressed environmental pollutants and problems on a piecemeal basis, or pollutant-by-pollutant. Therefore, the argument would continue, when establishing standards for protecting the nation's waters, for example, Congress did not intend a statute that addresses water pollutants to provide the EPA with authority to consider the combined health impacts of air pollutants and water pollutants.

A challenger making this argument would likely cite *Food and Drug Administration v. Brown & Williamson Tobacco Corp.* (*FDA v. Brown*). In that case, the Supreme Court refused to find that the Food and Drug Administration (FDA) had authority to regulate tobacco products under the Food, Drug, and Cosmetic Act (FDCA), reasoning that authority to regulate those products under the statute would require banning them from the market, based on FDA's findings regarding the significant health risks posed by tobacco products. The Court concluded that such a ban would contradict Congress's clear intent as expressed in recent tobacco-specific legislation to allow the continuing sale of tobacco products in the

²⁴¹ See Pamela Hill, Emerging Policy and Legal Directions at EPA, 33 NEW ENG. L. REV. 625, 626–27 (1999) (noting that Congress has structured environmental statutes on media-specific bases, which has made it difficult to comprehensively protect environmentally significant places or to consider important factors such as sensitive populations and cumulative risk).

²⁴² FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

²⁴³ *Id.* at 135–37, 160–61.

United States.²⁴⁴ The Court refused to defer to FDA's expansive construction of its statute, explaining:

"the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," and "fit, if possible, all parts into a harmonious whole." Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. In addition, [the reviewing court] must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. ²⁴⁵

Applying the Supreme Court's reasoning in *FDA v. Brown*, one could argue that because Congress addressed different pollutants and the protection of different media under different statutory schemes, it did not intend for the EPA to consider the cumulative effects of all pollutants when determining how stringently to limit one type of pollutant.

On the other hand, in *Massachusetts v. EPA*, the Supreme Court found that the EPA could find carbon dioxide to be an air pollutant under the CAA based on that pollutant's contribution to global climate change, although the EPA argued the CAA did not contemplate the regulation of substances that contribute to climate change. In various CAA provisions, Congress has given the EPA undefined directives to do what is necessary to protect the public health with an ample margin of safety, presumably to allow the statute to remain flexible over time so that the Agency could decide whether to restrict pollutants based on the latest scientific advancements affecting the EPA's understanding of health effects. Indeed, in *Massachusetts v. EPA*, the Supreme Court explained that although:

[T]he Congresses that drafted the [1970 Clean Air Act] might not have appreciated the possibility that burning fossil fuels could lead to global warming, they did understand that without regulatory flexibility, changing circumstances and scientific developments would soon render the Clean Air Act obsolete. The broad language [directing EPA to prescribe standards for any air pollutants that 'cause, or contribute to, air pollution which may reasonably be

²⁴⁴ Id. at 137-39.

²⁴⁵ Id. at 133 (citations omitted).

²⁴⁶ Massachusetts v. EPA, 549 U.S. 497, 528 (2007).

²⁴⁷ See id. at 532.

anticipated to endanger public health or welfare'] reflects an intentional effort to confer the flexibility necessary to forestall such obsolescence." ²⁴⁸

Therefore, one reading of *Massachusetts v. EPA* is that Congress purposefully writes statutes broadly so that the EPA can implement them more effectively over time. This reading lends support to the argument that the EPA could interpret its various broad CAA authorities as permitting it to consider cumulative risks, if the Agency reasonably determined that the consideration of such evidence was necessary to carry out its statutory mandate effectively.²⁴⁹

B. Recent "Good Neighbor" Provision Court Cases Do Not Signal a Strict Construction of the Clean Air Act

A challenger also might cite *EME Homer City Generation v. EPA* (*EME*)²⁵⁰ and *North Carolina v. EPA* (*North Carolina*),²⁵¹ to support an assertion that a CAA provision does not give the EPA discretion to consider the results of a cumulative risk assessment because in those cases, the D.C. Circuit rejected the Agency's broad interpretation of its CAA authority. In *EME* and *North Carolina*, the D.C. Circuit rejected the EPA's interpretations of the CAA provision that requires each SIP to ensure the prevention of "any . . . type of emissions activity" that "contribute[s] significantly to nonattainment in, or interfere[s] with maintenance by, any other State with respect to any [NAAQS]"²⁵² (known as the "good neighbor" provision). In *North Carolina*, the D.C. Circuit found that the Agency went beyond its statutory authority when it established a regional interstate emissions trading program in an attempt to implement the "good neighbor" provision.²⁵³ In *EME* (2012), the D.C. Circuit vacated an EPA rule

²⁴⁸ *Id.* at 532, 549 (citing Pa. Dep't of Corr. v. Yeskey, 524 U.S. 206, 212 (1998) ("[T]he fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.") (internal quotation marks omitted).

²⁴⁹ See id. at 529-32.

²⁵⁰ EME Homer City Generation, L.P. v. EPA, 696 F.3d 7 (D.C. Cir. 2012).

²⁵¹ North Carolina v. EPA, 531 F.3d 896 (D.C. Cir. 2008).

^{252 42} U.S.C. § 7410(a)(2)(D)(i).

²⁵³ North Carolina, 531 F.3d at 907–22 (vacating the EPA's Clean Air Interstate Rule because the "good neighbor" provision requires the elimination of emissions from sources contributing to nonattainment in downwind states and the emissions trading program established by the Clean Air Interstate Rule would not ensure this occurred because its

developed in response to the court's *North Carolina* ruling that attempted to implement the "good neighbor" provision by defining emissions reduction responsibilities for upwind states based on those states' contribution to downwind states' air quality problems.²⁵⁴ In both cases, the court vacated the EPA's rules, determining that the Agency had exceeded its "good neighbor" statutory authority. *EME* and *North Carolina* indicate that the D.C. Circuit reads the "good neighbor" provision as permitting the EPA to establish a program requiring each state to eliminate its own significant contribution to downwind pollution, or that achieves something measurable towards that goal, but that the EPA could not require anything more.²⁵⁵

Some might argue that the D.C. Circuit's analyses and narrow interpretations of the CAAin *EME* and *North Carolina* signal the D.C. Circuit's hesitance to permit broad interpretations of the CAA. ²⁵⁶ Others might argue that the cases imply the court's willingness to check what might be seen as excessive EPA action, and to require congressional action to change existing programs significantly. ²⁵⁷ However, the EPA statutory interpretation under review in *EME* and *North Carolina* was distinguishable from the statutory interpretations suggested in this Article.

In *EME* and *North Carolina*, the court vacated the EPA rules at issue most notably for this discussion, because the "good neighbor" provision provides a very specific instruction rather than containing broad statutory mandates to protect the public health with an ample margin of safety.²⁵⁸ The specific instruction in the "good neighbor" provision that each SIP must ensure the prevention of "any . . . type of emissions activity" that "contributes significantly to nonattainment in, or interferes with maintenance by, any other State with respect to any

trading programs would only guarantee that emissions would be reduced on a regional basis).

²⁵⁴ EME Homer City Generation, 696 F.3d 11–12 (vacating the EPA's Cross-State Air Pollution rule because the "good neighbor" provision grants the Agency authority to require upwind States to reduce only their own significant contributions to a downwind state's nonattainment, but the Cross-State Air Pollution Rule could require upwind states to reduce emissions by more than their own significant contributions to a downwind state's nonattainment).

²⁵⁵ See id. at 17–18, 44–45; North Carolina, 531 F.3d at 916–21.

²⁵⁶ See Elizabeth Kruse, Case Comment: North Carolina v. EPA, 33 HARV. ENVTL. L. REV. 283, 294–95 (2009).

²⁵⁷ See id. at 294.

 $^{^{258}}$ See EME Homer City Generation, 696 F.3d at 14–15, 23–24; North Carolina, 531 F.3d at 907–22.

[NAAQS]"²⁵⁹ contrasts with the broad statutory mandates to protect the public health we are addressing in this article, e.g., to establish standards "requisite to protect the public health" while "allowing an adequate margin of safety" (the NAAQS standard setting authority). Because a specific instruction is more limiting than a broad grant of authority, *EME* and *North Carolina* do not preclude the D.C. Circuit from upholding the EPA's interpretation of its authority to consider any information or analyses the Agency reasonably determines is necessary to decide the level at which standards are protective of the public health.

CONCLUSIONS

In 2009, the NRC recommended that the EPA take account of cumulative risks in Agency risk assessments. However, the CAA does not direct the EPA as a regulator, or designated permitting authorities in the PSD program to evaluate cumulative risks of non-air pollutants or non-chemical stressors. Acknowledging the ambiguity regarding discretion to consider cumulative effects in CAA decision making, the authors conclude, based on the analysis in this article, that some of the CAA's broad statutory directives to protect the public health allow room for the EPA to consider such cumulative effects.

In *Chevron*, the Supreme Court created a two-part framework for reviewing agency interpretations of statutes it implements. At *Chevron* Step One, a reviewing court examines statutory language to determine whether Congress has spoken directly to the issue. The CAA directs the EPA to take actions necessary to protect the public health with an "ample margin of safety" (NAAQS and residual risk NESHAPs), to consider "non-air quality health and environmental impacts" (NESHAPs), and to issue permits that would "not cause, or contribute to, air pollution in excess of any [emissions limitation or NAAQS]" (PSD program). One of these or related CAA

²⁵⁹ Clean Air Act § 110, 42 U.S.C. § 7410(a)(2)(D)(i).

²⁶⁰ Clean Air Act § 109, 42 U.S.C. § 7409(b)(1).

²⁶¹ See NAT'L RES. COUNS., ADVANCING RISK ASSESSMENT, supra note 3.

²⁶² Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837 (1984).

²⁶³ Id. at 842-43.

²⁶⁴ Clean Air Act § 112(2), §§ 164(a)(2)(B); see id. § 165.

provisions speak directly to how these decisions are made or whether they provide discretion to consider cumulative risks in making decisions under these programs. A court reviewing a challenge to the EPA's assertion of discretion to assess cumulative risks likely would find these CAA provisions ambiguous under *Chevron* Step One, and turn to a review of whether the EPA's interpretation of its authority is reasonable under *Chevron* Step Two. 265 *Chevron* suggests that if an agency makes a regulatory decision rationally based on some factor or analysis that the applicable Federal statute did not specifically prohibit the agency from considering, a court would not overturn the decision simply because of reliance on the unstated factor or analysis.

Given the argument that a CAA provision allows the EPA discretion to use a cumulative risk assessment to support decision making under a CAA program, there remains the question of whether the EPA's use of cumulative risk assessment in a particular circumstance can withstand arbitrary or capricious review under the APA. Whether a particular cumulative risk analysis is appropriate for consideration in an Agency policy or regulatory decision is a fact-driven inquiry requiring case-by-case judicial examination. A reviewing court's inquiry into the reasonableness of a cumulative risk assessment likely would examine whether the data and assumptions used in the assessment were rational, based on the available information, and whether the Agency's conclusions were reasonable based on the analysis. If data and assumptions are sufficient for a court to decide "whether the agency's conclusions are rationally supported," the court must affirm. 266

In many current circumstances, making reasonable quantitative estimates of impacts using cumulative risk assessments would require

²⁶⁵ Chevron, U.S.A., 467 U.S. at 842-43.

²⁶⁶ Nw. Coal. for Alt. to Pesticides v. EPA, 544 F.3d 1043, 1057 n.7 (D.C. Cir. 2008) (quoting Ctr. for Auto Safety v. Peck, 751 F.2d 1336, 1373 (D.C. Cir. 1985) (Wright, J., dissenting)) ("Although the ultimate scope may be narrow, the depth must be sufficient for us to be able to comprehend the agency's handling of the evidence cited or relied upon. The purpose of this in-depth review is to educate ourselves so that we can properly perform our reviewing function: determining whether the agency's conclusions are 'rationally supported.' For, although data interpretation and analysis are functions that often lie within an agency's realm of expertise, it is our duty to review those functions to ascertain whether the agency's actions were complete, reasoned, and adequately explained. The mere fact that an agency is operating in a field of its expertise does not excuse us from our customary review responsibilities. And, where the agency's reasoning, although complex, is rational, clear, and complete, we must affirm. Contrarily, where the agency's reasoning is irrational, unclear, or not supported by the data it purports to interpret, we must disapprove the agency's action.") (citations omitted).

access to data that currently are nonexistent or insufficient. Recently, potential users in the scientific community have suggested the necessity and value of having the following cumulative effects data and tools: larger emissions inventories, air quality monitoring networks, modeling software, and pollution inventories expanded to unregulated operations. The authors believe that the EPA and the scientific community should focus on developing the necessary data and tools to provide a sound, cumulative risk assessment framework. The Agency then should develop guidelines for a cumulative risk assessment methodology, including guidance for evaluating qualitative cumulative effects.

267 See NAT'L ENVIL. JUSTICE ADVISORY COUNS., ENSURING RISK REDUCTION IN COMMUNITIES WITH MULTIPLE STRESSORS: ENVIRONMENTAL. JUSTICE AND CUMULATIVE RISKS/IMPACTS 47–48 (2004), available at http://www.epa.gov/environ mentaljustice/resources/publications/nejac/nejac-cum-risk-rpt-122104.pdf; JUSTICE ADVISORY COUNS. TO THE N.J. DEPT. OF ENVIL. PROTECTION, CUMULATIVE IMPACTS SUBCOMMITTEE, STRATEGIES FOR ADDRESSING CUMULATIVE IMPACTS IN ENVIRONMENTAL JUSTICE COMMUNITIES 26 (2009), available at http://www.state.nj.us/ dep/ej/docs/ejac impacts report200903.pdf; MINN. POLLUTION CONTROL AGENCY, PROCESS FOR CUMULATIVE LEVELS AND EFFECTS ANALYSIS FOR MINN. STAT. § 116.07, SUBD. 4A, available at http://www.cumulativeimpacts.org/documents/ProcessDocument 5 10.pdf; N.Y. STATE DEPT. OF ENVIL. CONSERVATION & N.Y. STATE DEPT. OF HEALTH, REPORT OF THE HEALTH OUTCOME DATA WORK GROUP (2006), available at http://www.dec.ny.gov/docs/permits_ej_operations_pdf/hodreport.pdf; N.Y. STATE DEPT. OF ENVIL. CONSERVATION DISPROPORTIONATE ADVERSE ENVIRONMENTAL IMPACT ANALYSIS WORK GROUP, FINAL REPORT OF THE N.Y. STATE DEPT. OF ENVIL. CONSERVATION DISPROPORTIONATE ADVERSE ENVIRONMENTAL IMPACT ANALYSIS WORK GROUP (2004), available at http://www.dec.ny.gov/docs/permits ej operations pdf/daeireport.pdf.