Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process (June 4, 2020)
("Proposed Benefit-Cost Analysis Rule") EPA–HQ–OAR-2020-00044

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Comments of American Chemistry Council; American Petroleum Institute; National Association of Manufacturers; U.S. Chamber of Commerce

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I. Executive Summary

The United States Environmental Protection Agency (EPA or Agency) has proposed to provide consistency and greater transparency in analyzing the benefits and costs of rules proposed and finalized under the Clean Air Act. Ensuring that EPA's rulemaking process uses consistent procedures and clear data that transparently shows how the Agency develops proposed rules will benefit all stakeholders. The past decade is proof that we can achieve environmental progress and economic growth at the same time. Under improved Clean Air Act regulatory provisions, we can build on these achievements with continued innovation and improved technologies.

These are the comments of the Associations[1] on that proposal. The Associations conclude:

- This rule is needed to improve consistency and transparency in how EPA assesses risk and arrives at estimates of benefits and costs; EPA has a history of inconsistent approaches to such estimates.

- EPA has ample authority under the Clean Air Act to issue this rule and the final rule will be binding upon the Agency.

- The Associations support the use of scientific, engineering, and economic best practices as the basis for developing the analyses. The Agency should provide detail as to the best practices in the preamble of the final rulemaking, and the Agency should adequately describe the best practices in the regulatory text.

- EPA should perform and fully consider benefit-cost analyses (BCAs) in making regulatory decisions under the Clean Air Act unless the courts have ruled that a specific statutory provision clearly prohibits such consideration.

- The final rule should require EPA to undertake a non-binding determination of whether the benefits of the statutory objective of the regulatory provision justify the costs as part of the BCA. This determination would help inform policymakers and the public regarding whether the benefits of the proposed regulation, based on the statutory objective, justify the costs. While the Administrator would be required to consider the findings of this determination, he or she would still retain full flexibility to issue a standard that does not meet this net targeted benefits determination described in these comments, when appropriately described and justified.

- EPA should promulgate language that ensures that all underlying risk assessments

[1] These comments are submitted by the American Chemistry Council, American Petroleum Institute, National Association of Manufacturers, and U.S. Chamber of Commerce.

supporting significant Clean Air Act regulation, including those that provide key inputs to the development of EPA's health benefit estimates in BCAs, are consistent with best practices. Furthermore, the rule should require EPA to assess the direct, indirect, explicit, and implicit costs of significant regulatory actions and their alternatives when feasible.

- EPA should present BCAs in a manner consistent with reasoned economic and scientific judgments about uncertainties. In addition, the net benefits of each Clean Air Act rule should be presented based on the targeted pollutant without ancillary and criteria pollutant health co-benefits, before presenting the net benefits including the ancillary benefits and the criteria pollutant health co-benefits.

II. Introduction

The Associations and their member companies are committed to reducing emissions as necessary, consistent with the requirements of the Clean Air Act (CAA), to provide air quality protective of public health and welfare, while continuing to expand equitable economic opportunity in the United States. We have worked for many years with the Agency, states, tribal, and local authorities to reduce air pollution. As a result, between 1970 and 2019, air quality improved, while both the U.S. gross domestic product and population grew steadily. In just the last two years (from 2017 to 2019), According to EPA, combined emissions from the six Clean Air Act criteria pollutants declined by 7 percent.[2] From 2018 to 2019, the number of days listed as unhealthy for sensitive groups dropped by 40 percent as the amount of criteria pollutants in our air continued to fall. Americans are breathing the cleanest air in decades as the combined emissions of criteria and precursor pollutants were reduced by 77 percent between 1970 and 2019.[3]

We support this proposal to provide consistency and greater transparency in analyzing the benefits and costs of EPA rules. Ensuring that EPA's rulemaking process uses clear and consistent procedures and data that transparently show how the Agency develops proposed rules will benefit all stakeholders. The past decade is proof that we can achieve environmental progress and economic growth at the same time. Under improved Clean Air Act regulatory provisions, we can build on these achievements with continued innovation and improved technologies.

III. General Comments

A. This rule is needed to improve consistency and transparency in how EPA assesses risk and estimates benefits and costs; EPA has a history of inconsistent approaches to such estimates.

Rulemakings under the Clean Air Act have historically used inconsistent approaches to BCA review. The rule proposes to establish procedures that will improve the objectivity and transparency of BCA and its presentation. The rulemaking will also assure its consistent application.

[2] *See* www.epa.gov/criteria-air-pollutants.
[3] *Id.*

B. EPA has ample authority under the Clean Air Act (CAA) to issue this rule.

In the proposed rule, the Agency states that it proposes to take this action under Section 301(a)(1) of the CAA, which explicitly authorizes the Administrator "to prescribe such regulations as are necessary to carry out his [or her] functions" under the CAA. Although we agree that Section 301(a)(1) is an important source of authority for this action, it is certainly not the only one. As discussed below, there are many sections of the CAA that require EPA to consider benefits and costs, as well as ones that call for consideration of scientific information, and EPA has authority to implement those sections by issuing regulations to govern how it will do so. Section 301(a)(1) simply enhances and clarifies this authority by explicitly stating that the Administrator may issue regulations "necessary to carry out his [or her] functions" under other parts of the statute.

Even without explicit statutory authority, government agencies have inherent authority to develop procedures, practices, and criteria for decision making and to establish them by regulation, as long as they are not inconsistent with applicable statutory requirements and are not arbitrary and capricious. As law school professor Elizabeth Magill has noted, "self-regulation" by administrative agencies is "a ubiquitous phenomenon":

> That is, they limit their options when no source of authority requires them to do so. They *voluntarily* constrain their discretion. They adopt rules, guidelines, and interpretations that substantively limit their options—limiting either the range of outcomes they can reach or the rationales that can be used to defend their choices. They also limit their procedural freedom by committing to afford additional procedures, such as hearings, notices, and appeals, that are not required by any source of authority.[4]

As courts and legal scholars have long recognized, even where Congress has granted an agency broad discretion, the agency can place limits on that discretion through rulemaking. Thomas W. Merrill, *The Accardi Principle*, 74 Geo. Wash. L. Rev. 569, 596 (2006). *See, e.g.*, Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979); Batterton v. Francis, 432 U.S. 416, 425 n.9 (1977); Gen. Elec. Co. v. EPA, 290 F.3d 377, 380 (D.C. Cir. 2002); Appalachian Power Co. v. EPA, 208 F.3d 1015, 1020 (D.C. Cir. 2000); Syncor Int'l Corp. v. Shalala, 127 F.3d 90, 96 (D.C. Cir. 1997). Indeed, prominent legal scholars have argued that, as a matter of public policy, agencies should exercise their authority to do so. HENRY J. FRIENDLY, THE FEDERAL ADMINISTRATIVE AGENCIES 142–47 (1962). KENNETH CULP DAVIS, DISCRETIONARY JUSTICE 52–161 (1969); *See also* Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 533 (2003) ("[A]gencies must supply the standards that discipline their discretion under delegating statutes, and it does not matter for legitimacy purposes whether they do so under 'ordinary' administrative law or 'constitutional' administrative law.").

In the final rule, EPA should make it clear that it has other sources of explicit statutory authority for this rule besides section 301(a)(1). Section 301(a)(1) does not authorize EPA to issue any regulations it might choose; rather, it is limited to those that are needed for the Agency "to carry

[4] Elizabeth Magill, Agency Self-Regulation, 77 GEO.WASH. L.REV. 859 (2009).

out [its] functions" under the Act. Under many CAA programs, EPA is required to make regulatory decisions based on statutory factors that are related to health impacts of pollutants (and therefore the benefits of reducing them) and the cost of measures that might be used to regulate them. The statutory provisions that establish and govern these programs are an additional source of authority for the proposed rule, especially in conjunction with Section 301(a)(1).[5]

In addition to general authority to consider costs, in many cases, the Agency is directed to consider both the costs and the benefits of potential regulatory actions. For example, in section 111, if EPA finds that industrial facilities in a particular source category "cause, or contribute significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare," the Agency must establish performance standards for new sources in that source category and, in some cases, provide guidance that states can use to establish performance standards for existing sources in the category. Under Section 111(a)(1), for both new and existing sources, these standards must be based on "the best system of emission reduction which (taking into account the cost of achieving such reduction and any non-air quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated." Even without Section 301(a)(1), Section 111 would authorize EPA to establish procedures and practices that would govern the Agency's approach for assessing both costs and benefits when it comes to setting standards of performance. Section 301(a)(1) only

[5] In public statements some individuals have argued that two recent decisions by the United States Court of Appeals for the District of Columbia Circuit (*Merck v. HHS, No.* 19-5222 (D.C. Cir. June 16, 2020) and *New York Stock Exchange (NYSE) v. SEC*, No. 19-1043 (D.C. Cir. June 16, 2020)) conflict with EPA's reliance on Section 301 of the Clean Air Act as the basis for the current proposal. Contrary to these assertions, these decisions do not undermine EPA's reliance on Section 301. In contrast to the instant case, where the Agency is addressing issues that are within its purview -- how to address costs and quality of scientific studies when undertaking substantive rulemakings -- the rules at issue in those cases directly lacked any such clear nexus with the agency's statutory dictate. In *Merck*, the D.C. Circuit held that the Department of Health and Human Services (HHS) could not use its rulemaking authority to promulgate a rule requiring drug makers to disclose their wholesale prices because HHS had failed to "demonstrate an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs." Slip op at 12. The court noted "the further a regulation strays from truly facilitating the "administration" of the Secretary's duties, the less likely it is to fall within the statutory grant of authority." *Id.* at 13.

In contrast, the rule at issue here is directly tied to how the Agency will administer its statutory duties when risk and cost issues are implicated. Thus, the Agency has not only shown a "discernible nexus," it has shown a direct nexus. *NYSE* is similarly inapplicable. In that case, the court faulted the SEC for exceeding its statutory authority when the SEC invoked a general rulemaking authority provision and argued that it had implied authority to promulgated substantive requirements on third parties so that it could determine if there was a substantive issue that the SEC then might address using its substantive rulemaking authority. The court held that the act provided no such delegation of authority to conduct such a rulemaking without analysis tying the rule to the Act's statutory dictates. But here the Agency is not acting without authority; nor is it imposing costly requirements that are potentially inconsistent with statutory requirements on third parties. . Rather, here EPA is using general rulemaking authority to help structure its subsequent substantive decision making with respect to costs and how it will evaluate scientific uncertainty, and it is doing so with a host of statutory provisions at issue which require that the Agency consider such issues. Nothing in those provisions require or prevent EPA from adopting regulations that improve the rulemaking process by providing consistent rules for how the Agency will evaluate relevant information.

enhances this authority by authorizing the Agency "to prescribe such regulations as are necessary to carry out [its] functions" under Section 111.

Another example that has received much attention in recent years is Section 112(n)(1)(a), which directed EPA to perform a study of the risks to public health of power plants emissions of hazardous air pollutants (HAPS) that would remain after the implementation of other CAA programs. Based on this study, the Agency was required to determine whether it was "appropriate and necessary" to regulate power plants under Section 112. EPA was authorized (and required) to issue such regulations only if it made a formal finding that they were "appropriate and necessary."

After conducting the required study, EPA found that it was "appropriate" to regulate coal- and oil-fired power plants under Section 112 because their emissions continued to pose risks to public health and the environment and because controls capable of reducing these emissions were available. It found regulation "necessary" because the imposition of other CAA provisions did not eliminate those risks. But the Agency explicitly stated that it did not (and did not need to) take the costs of such regulation into account in making this "necessary and appropriate determination," even though the Agency projected that the cost would be approximately $9.6 billion a year -- the most expensive regulation in EPA'S history. Having considered the issue in a challenge to the regulation, the Supreme Court held that the Agency's refusal to take cost into account was unlawful:

> The Agency must consider cost -- including, most importantly, cost of compliance -- before deciding whether regulation is appropriate and necessary. We need not and do not hold that the law unambiguously required the Agency, when making this preliminary estimate, to conduct a formal cost-benefit analysis in which each advantage and disadvantage is assigned a monetary value. It will be up to the Agency to decide (as always, within the limits of reasonable interpretation) how to account for cost.

Michigan v. EPA, 135 S.Ct. 2699 (2015).[6] Although the Supreme Court noted that Section 112(n)(1)(a) does not "unambiguously require[]" EPA "to conduct a formal cost-benefit analysis in which each advantage and disadvantage is assigned a monetary value," it signaled very clearly that this would be an acceptable way of doing it. In the proposed rule, EPA is not only proposing to commit itself to conducting a formal CBA (under Section 112(n)(1)(a) and elsewhere in the CAA) but is also fleshing out important details as to how it must be conducted. Although Section 112(n)(1)(a) does not compel this rule, it certainly provides statutory authority for it, either standing alone or in conjunction with Section 301(a)(1), as do the additional statutory provisions discussed below.

[6] On remand, the Agency initially determined that, even considering costs, it was appropriate and necessary to regulate coal- and oil-fired power plants under Section 112. But before the courts could review that decision, the Agency changed its mind based on a different approach for weighing costs and benefits – and this decision is now in litigation. Regardless of how this decision ultimately comes out, it will be based on EPA's approach for evaluating costs and benefits.

Indeed, Section 301(a)(1) authorizes the Agency "to prescribe such regulations as are necessary to carry out his [or her] functions" under any CAA program that requires or allows EPA to make decisions by taking costs and/or benefits into account. There are many such programs where these are relevant decision criteria, including the following:

- Under Section 169 of the CAA, permitting authorities must include emission limits in permits covered by the "prevention of significant deterioration" (PSD) program. These "best available technology" (BACT) emission limits must be based on "the maximum degree of reduction of each pollutant subject to regulation . . . which the permitting authority, on a case-by-case basis, *taking into account energy, environmental, and economic impacts and other costs,* determines is achievable for such facility" (emphasis added).

- Under Section 169A, when a state (or the Administrator) is called upon to determine best available retrofit technology for purposes of addressing visibility impairing pollutants, they are required to take into account "consideration of cost of compliance" (emphasis added).

- Under Section 112(d)(2), when EPA chooses to regulate "area sources" of hazardous air pollutants (HAPS), or where it decides to set major source standards that "go beyond the floor", it is required to set "emissions standards" for both new and existing sources that reflect "the maximum degree of reduction in emissions of [HAPs] that the Administrator, *taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements,* determines is achievable for new or existing sources in the category or subcategory" (emphasis added). This same standard applies when EPA chooses to establish any emission limits that "go beyond the MACT floor."

- Under Section 183(e), EPA is required to set limits on the use of "volatile organic compounds" in certain consumer and commercial products, including paints and other coatings. These limits must reflect "the degree of emissions reduction that the Administrator determines, *on the basis of technological and economic feasibility, health, environmental, and energy impacts,* is achievable through the application of the most effective equipment, measures, processes, methods, systems or techniques...." (emphasis added).

- Title II of the CAA requires EPA to set emission limits for virtually all types of "mobile sources," including cars, all sizes of trucks and buses, and all manner of other heavy duty on- and off-road vehicles, portable generators, lawn mowers, and other types of lawn and garden equipment. Although there is some variation in the precise wording of the approach that EPA must use in developing standards for different types of mobile source, most of them require the Agency to take both benefits and costs into account.

    - For example, Section 202(a)(3)(B), a key provision added under 1990 Clean Air Act Amendments, provides: "[o]n the basis of information available to the Administrator *concerning the effects of air pollutants* emitted from heavy-duty

> vehicles or engines and from other sources of mobile source related pollutants *on the public health and welfare, and taking costs into account*, the Administrator may promulgate regulations under paragraph (1) of this subsection revising any standard promulgated [before 1990]" (emphasis added).

In other cases, even when costs are not spelled out as a specific consideration, the statute nonetheless authorizes consideration of costs. Indeed, except where statutory language or context dictate otherwise, the Agency may (or must) take costs into account. *NRDC v. EPA*, 824 F.2d 1146 (D.C. Cir. 1987). These provisions include:

- Section 112(d)(6) of the CAA requires EPA to conduct a technology review of existing MACT standards at least every 8 years. In conducting these reviews, EPA considers the cost of achieving the reductions.

- Section 112(f)(2) of the CAA requires that EPA conduct a one-time residual risk review of source categories regulated by MACT standards. When determining if a standard provides for an "ample margin of safety" EPA has reasonably interpreted the statute to allow for consideration of "*cost and economic impacts*." *NRDC v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir 2008) (upholding EPA's interpretation of 112(f)(2)).

- Title I Parts C and D of the CAA, related to preconstruction review, also require EPA in promulgating regulations implementing the preconstruction review provisions to the Act to balance costs and benefits of regulation. *See Chevron v. NRDC*, 104 S.Ct. 2778, 2786 (1984) ("[I]in the permit program Congress sought to accommodate the conflict between the economic interest in permitting capital improvements to continue and the environmental interest in improving air quality.")

In some cases, the statute requires EPA to consider factors other than benefits and costs -- factors such as "energy impacts" and "technical feasibility." Under the proposed rule, these factors would likely be included in the consideration of costs, but the Agency should nevertheless address these factors explicitly where Congress has singled them out for attention.

There appear to be only three CAA programs where courts have determined that the Agency cannot make decisions by weighing benefits and costs when conducting rulemakings or limited such considerations -- (1) when setting national ambient air quality standards (NAAQS) under section 109[7]; (2) when approving State Implementation Plans[8]; and (3) when calculating the "MACT floor" under Section 112(d).[9] Importantly, however, even though EPA does not take

[7] *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 464-71 (2001). The Court did not, however, preclude all consideration of costs and benefits in determining if revision of a standards was appropriate. *Id.* 494("§ 109 [of the Act] does not require the EPA to eliminate every health risk, however slight, at any economic cost, however great, to the point of hurtling industry over the brink of ruin or even forcing deindustrialization.") (Breyer, J., concurring in part and concurring in the judgment) (internal quotations omitted). *See also Lead Indus. Ass'n v. EPA*, 647 F.2d 1130 (D.C. Cir 1980).

[8] *Union Elec. Co. v. EPA*, 427 U.S. 426 (1976).

[9] *Lime Ass'n v. EPA*, 233 F.3d 625, 640 (D.C. Cir. 2000). We note that under certain circumstances it may be possible for the Agency to take cost into account in decisions that might ultimately effect the stringency of the MACT standard. For example such factors could play into a decision in establishing a category or source category.

compliance cost into account when setting the NAAQS, it must still conduct a risk assessment for each criteria pollutant to determine the level of the standard that is "requisite to protect public health with an adequate margin of safety."[10] Thus, the Agency would still be required to follow the rule's requirements for using best available scientific information and best practices from the physical and biological sciences. Accordingly, Section 109 should also be identified as a source of limited authority when the proposed rule is finalized.

In the proposal, EPA takes comment on if and how it should incorporate BCA into regulatory decision making. In order to improve regulatory decision making, and to ensure that it is making reasoned decisions, the Agency should take the opportunity to correct past practices that do not provide for adequate consideration of costs and benefits. Indeed, the Agency recently came to the conclusion that past practices were insufficient when it finalized the Agency's reconsideration of the appropriate and necessary finding in the EGU MACT, and it should take the opportunity to incorporate these approaches into its consideration of costs more generally.[11] EPA's past approaches have often not conducted this type of weighing at all. Indeed, early analyses of cost under the Act often largely turned on whether the costs were exorbitant. For example, in the context of Section 111 the D.C. Circuit stated: "[a]n adequately demonstrated system is one which has been shown to be reasonably reliable, reasonably efficient, and which can reasonably be expected to serve the interests of pollution control without becoming exorbitantly costly in an economic or environmental way." *Essex Chemical Corp. v. EPA*, 486 F.2d 375, 433–34 (D.C. Cir. 1973).

More recently, EPA has determined whether the costs of a rule are reasonable by looking to see if the cost per ton of pollution reduction are in the range of cost per ton that it had required in other rules. See, e.g., Standards of Performance for Portland Cement Plants; Proposed Rule 73 Fed. Reg. 34,072, 34,077 (June 16, 2008) ("The estimated emission reduction over the baseline would be 44 tpy for the model kiln and the cost per ton of additional PM control is $3,969. This cost appears to be reasonable to EPA, given that it is well within the range of cost effectiveness for total PM control accepted as reasonable for other stationary sources."). While the provisions noted above do not "unambiguously require" that EPA "conduct a formal cost-benefit analysis in which each advantage and disadvantage is assigned a monetary value," the U.S. Supreme Court has signaled very clearly that this would be an acceptable way of doing it. *Michigan vs. EPA.* Indeed, both the Majority and dissenting opinions in *Michigan* agreed that "cost is almost always a relevant -- and usually a highly important -- factor in regulation" and that failing to weigh cost and benefits in regulating can lead to irrational decision making. *Id.* at 2717 (Kagan, J. dissenting) (agreeing with the majority that the regulation of power plants would be unreasonable if the Agency failed to account for costs and benefits but faulting the majority for requiring that such considerations be addressed in the decision to list power plants for regulation as opposed to the content of the regulation). Indeed, the Supreme Court has long recognized that such balancing is both appropriate, and often necessary, to ensure that agencies act reasonably --

[10] Similarly, under 112(f) the Agency must evaluate risk to determine if additional standards are required to be promulgated. Accordingly, it should also be cited as an additional source of authority with respect to risk evaluations.

[11] EPA's National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units – Reconsideration of Supplemental Finding and Residual Risk and Technology Review, 85 Fed. Reg. 31286 (May 22, 2020).

"'in an age of limited resources available to deal with grave environmental problems, where too much wasteful expenditure devoted to one problem may well mean considerably fewer resources available to deal effectively with other (perhaps more serious) problems. '" *Id.* at 2708 (majority opinion), 2717 (Kagan, J. dissenting) *(quoting Entergy Corp. v. Riverkeepers*, 556 U.S. 208, 234 (2009) (Breyer, J. concurring in part, dissenting in part)).

The Agency's past practices for considering costs do not always conform with this direction from the Court. For example, the "range-based" look alone is insufficient; as the fact that another party has been required to bear a similar cost in the past does nothing to support a conclusion that costs do not significantly outweigh the benefits or that limited resources are being appropriately directed to address "other (perhaps more serious) problems." *Entergy Corp.*, 556 U.S. at 234 (2009) (Breyer, J. concurring in part, dissenting in part)). As EPA recently observed, these cost reasonableness metrics "focus only on whether costs could be absorbed, rather than on whether they should be absorbed" and thus do not meet the Supreme Court's direction in *Michigan* that reasonable regulation requires an agency to fully consider both "the advantages and disadvantages" of a decision. 85 Fed. Reg. 31266, 31294 (May 22, 2020) (quoting 135 S.Ct. at 2707).

C. The final rule will be binding on the Agency.

There is a long line of cases, dating back to *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 265-68, 74 S.Ct. 499, 98 L.Ed. 681 (1954), that stand for the proposition that an agency must follow its own regulations, regardless of whether they are substantive or procedural, if they are issued through notice-and-comment rulemaking. When it comes to interpretative rules and rules of decision embodied in agency precedents, the case law is not entirely clear on whether they are always binding. But "[l]egislative rules are universally acknowledged as 'binding' on the agency" that issued them. Thomas Merrill, Thomas W. Merrill, *The Accardi Principle*, 74 Geo. Wash. L. Rev. 569, 596 (2006). *See also Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979); *Batterton v. Francis*, 432 U.S. 416, 425 n.9 (1977); *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000); *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 96 (D.C. Cir. 1997). Thus, "even if the applicable statutes confer complete discretion on agency actors, if those actors have the authority to constrain their discretion by promulgating legislative rules, and they choose to do so, they have created law that can serve as the basis for judicial review." Merrill, *supra*, at 605.

EPA has suggested here that the rule is a procedural rule that would not regulate any person or entity outside EPA and would not affect the rights or obligations of outside parties. Although it is true that the rule would not regulate any parties other than EPA, it certainly would affect the rights of outside parties because it would give them a right to challenge any EPA rule that does not comply with the requirements of the rule. The Administrator has publicly stated that this is one of the main purposes of the rule -- to provide a measure of self-discipline on EPA by creating an enforcement mechanism that outside parties can use to assure that EPA actually follows its own requirements.

In reality, the rule is certainly more than just procedural. It would create substantive decision criteria that require the Agency to consider the results of a properly conducted BCA when

making decisions. Although conducting BCA as described in the rule will provide important information to the public regarding the benefits and cost of a rule, as well as the uncertainties surrounding the underlying science, the Agency must nonetheless make it clear in the final rule that it will integrate this information into its substantive CAA decision making. As discussed above, risks and costs are statutory criteria that need to be evaluated throughout the Act.

We take note of the Agency's statement that the rule is merely procedural. However, referring to the rule as merely procedural creates potential problems under Section 307(d)(8) of the CAA, which provides that, "[i]n reviewing alleged procedural errors, the court may invalidate the rule only if the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made."

Thus, insisting that the rule is solely procedural creates an unnecessary and presumably unintended hurdle for parties seeking to enforce the requirements of the rule. To avoid these problems, the final rule must:

- Clearly state EPA's intention for the rule to be binding and enforceable on the Agency;

- Explain that the rule includes important substantive requirements as well as procedural requirements;

- Make it clear that even the procedural elements are of "central relevance" to the outcome of regulatory actions under the Act and that failure to fully and properly evaluate them is likely to lead to a difference in the outcome of such actions; and

- Explicitly recognize that the Agency is committed to fully and properly considering costs and benefits where permitted, and making decisions based on a proper scientific evaluation (even when costs cannot be considered) in accordance with the requirements of the rule.

D. The final BCA rule should require EPA to use scientific, engineering, and economic best practices as the basis for developing the analyses supporting final rules. The Agency should provide detail as to the best practices in the preamble of the final rulemaking, and adequately describe the best practices in the regulatory text.

The final BCA rule should require scientific, engineering, and economic best practices as the basis for developing the analyses supporting proposed and final rules. The Agency should provide additional detail regarding the best practices in the preamble of the final rule and adequately describe the best practices in the regulatory text.

The best practices should drive greater transparency and consistency in the BCA and standardize important elements of the analysis. The recommended practices should include more systematic reviews of existing studies and models; more complete and accurate accounting of risks, costs, and benefits; greater acknowledgement of scientific (i.e., non-statistical forms of) uncertainties;

better analysis of the need for the regulation; and analysis of a standardized set of regulatory alternatives. Including these best practices will enhance public accountability and understanding of how EPA assesses risks, benefits, and costs.

Because best practices will continue to evolve as more advanced analytic techniques are developed, the Agency should create a process in the final rule that would allow the Agency to periodically update the required best practices. Any proposed updates to the best practices included in the final rule should go through a notice-and-comment rulemaking process to ensure the public has the opportunity to provide important input.

E. EPA should perform and fully consider benefit-cost analyses in making regulatory decisions under the CAA unless the specific statutory provision clearly prohibits such consideration.

The Agency solicits comment on how it should take into account the "results of a benefit-cost analysis in future rulemakings under specific provision of the CAA" and "under what circumstances EPA could or should determine that a future significant CAA regulation be promulgated only when the benefits of the intended action justify its cost."[12]

The Associations believe that EPA should fully consider the results of the BCA in making regulatory decisions under the CAA unless the specific statutory provision clearly prohibits such consideration. As discussed at length in the preamble and above, the Agency has broad latitude to consider costs under most CAA provisions, even when the underlying provision is silent. Failure to consider costs and benefits could result in a misallocation of both public and private resources and regulations that may be both inefficient and unlawful given the *Michigan v. EPA* holdings. For these reasons, the final rule should require EPA to consider the results of the BCA in making regulatory decisions unless it is clearly prohibited.

F. The final rule should require EPA to undertake a non-binding determination of whether the benefits of the rule, in terms of achieving the statutory objective under which the rule is issued, justify the costs as part of the BCA. This determination would help inform decision makers and the public of whether the benefits of the regulation, based on the statutory objective, justify the costs. While the Administrator would be required to consider the findings of this determination, he or she would still retain full flexibility to issue a standard that does not meet this net targeted benefits determination described above, when appropriately described and justified.

a. EPA's BCA should focus on the benefits in terms of achieving the statutory objective; ancillary benefits should be estimated and considered separately.

As currently drafted, the proposed rule would require EPA to present the results of its BCA in a transparent way that would allow the public to understand the benefits that are

[12] *Id*. at 35,623.

attributable to the pollution reductions targeted by the statutory provisions that authorize EPA's regulatory action and the "ancillary benefits" (sometimes referred to as "co-benefits") that are attributable to reductions in other pollutants. Likewise, the proposal would require EPA, to the extent feasible, to present a summary of the costs disaggregated into all relevant cost categories. The Associations support this general approach with the following specific recommendations set out in these comments.

The proposal also states that, when it comes to co-benefits, "[EPA may] explore whether there may be more efficient, lawful and defensible, or otherwise appropriate ways of obtaining ancillary benefits" because they may "be the primary target of an alternative regulation that may more efficiently address such pollutants, through a more flexible regulatory mechanism, better geographic focus, or other factors. The proposal explains that "[t]his may be relevant when certain benefits are the result of changes in pollutants that EPA regulates under a different section of the CAA or under another statute."

EPA's proposal describes how and why it may be appropriate to make a distinction between targeted benefits and ancillary benefits. The Associations believe that this issue must be further fleshed out in the final rule. At the very least, the final rule should require EPA to consider whether the regulation is justified based on the specific statutory authority being invoked and describe if there are other statutory authorities through which the claimed ancillary benefits could be achieved.

The Agency also solicits comment on how it should take into account the results of a BCA in future rulemakings under specific provision of the CAA, and under what circumstances EPA could or should determine that a future significant CAA regulation be promulgated only when the benefits or the intended action justify its cost. For reasons described later in these comments, there are many circumstances where costs considerations are permitted or required and such a balancing is appropriate. In conducting such analyses, EPA should constrain itself to considering only the direct (non-ancillary) benefits in determining if a rule is justified since to do otherwise would be inconsistent with the statutory scheme and, in many cases, allow the Agency to do indirectly what it may not be able to do directly.

EPA should not rely on ancillary, co-benefits as the primary basis for issuing a regulation. By relying on co-benefits as the primary basis for regulation, EPA disregards the target of the underlying statutory provision that is designed to regulate a specific pollutant, and inappropriately regulates the co-benefits (most often criteria pollutants) outside the statutory provisions/safeguards established by Congress to regulate those pollutants.

Some CAA regulatory programs, like MACT standards under section 112 and NSPS under Section 111, are very prescriptive and provide little or no flexibility with respect to standard setting – even if compliance options ultimately give the source flexibility. Within an industry category or subcategory, they require all sources[13] throughout the country to meet the same standard, even though the benefits may vary considerably from place to place and cost-effectiveness may vary considerably from facility to facility.

[13] MACT standards with apply to both new and existing sources while NSPS only cover new or modified sources.

There will often be more flexible regulatory mechanisms that would allow the "ancillary benefits" of one regulation to be obtained more efficiently by another regulatory or non-regulatory approach. At the very least, EPA must explicitly consider these issues and discuss them in its regulatory analysis.

In some cases, it appears that BCA has been used not to inform regulatory decisions but to justify decisions made for reasons unrelated to the purpose of the regulation and then to promote the regulation by touting the idea that the regulation is "a bargain for society" because the benefits exceed the costs. But the purpose of BCA is not simply to decide whether, for a particular regulation or Agency action, the benefits would exceed the cost. Such analysis must also consider efficiency and cost-effectiveness. Once EPA identifies ancillary benefits that could potentially be achieved through a particular regulation, it must consider whether those benefits could be achieved more efficiently through a program whose design and purpose is to achieve those benefits.

As with the previously discussed constraints on considering costs for certain CAA programs, the statutory structure of the CAA also suggests there are further constraints on EPA's ability to make regulatory decisions by taking certain benefits into account. In Sections 109 and 110, Congress created a comprehensive and detailed statutory scheme for regulating emissions of criteria pollutants and their precursors. Under this scheme, Congress carefully delineated the distinct roles of EPA and the States. EPA is required to set the National Ambient Air Quality Standards (NAAQS) for criteria pollutants, and states are given the responsibility for meeting those standards. Importantly, states are also given almost complete discretion in deciding how to meet them. *See Union Electric v. EPA*, 247 US 426 (1976). When it comes to criteria pollutants, it is states that determine which existing sources to regulate and how to regulate them. EPA may take over this role *only if* a state is unwilling or unable to adopt a set of regulations (in the form of a state implementation plan, or "SIP") that will bring a state into attainment and address that state's contribution to non-attainment in other states.

To be sure, EPA has both the authority and the responsibility to issue regulations to limit emissions of criteria pollutants (and their precursors) from new mobile sources and certain types of new stationary sources. But when it comes to regulating criteria pollutants from *existing* sources, states have almost exclusive authority to regulate the sources within their borders unless EPA makes a formal determination that a state has not satisfied its obligation to develop a SIP that will bring the state into attainment and ensure that its emissions do not significantly contribute to nonattainment in other states.[14] EPA may not circumvent this limitation by using regulatory programs for HAPs, for example, as a way to reduce emissions of criteria pollutants (or their precursors) from existing sources. Doing so undermines the cooperative federalism system established by Congress to address NAAQS pollutants.

[14] In the absence of such a finding EPA has limited direct authority to address emissions from upwind sources when petitioned by a downwind state to find that a source, or group of sources, cause or contribute significantly to no attainment in the petitioning state. *See* CAA § 126(b).

Moreover, for EPA to take such incidental benefits into account in deciding to regulate circumvents important constraints on EPA's authority when it is authorized to regulate. One important constraint on EPA's authority to consider ancillary benefits comes from the NAAQS themselves. EPA is required to undertake a robust scientific review to set the NAAQS at a level requisite to protect public health with an adequate margin of safety. Even if EPA believes that there are benefits from reducing concentrations of a criteria pollutant below this level, it may not compel a state or an industry or a company to do so. The Supreme Court made this clear in *EPA v. EME Homer City Generation*, 134 S.Ct. 1584 (2014), which involved a challenge to EPA's Cross-State Air Pollution Rule (CSAPR).

In CSAPR, EPA set state-specific "budgets" that required power plants in 28 states to reduce their emissions of SO2 and NOx. EPA developed and issued the rule under section 110(a)(2)(d) of the CAA (the so-called "Good Neighbor Provision"), which requires states to ensure that emissions from within their borders do not "contribute significantly" to nonattainment in other states. If EPA finds that a state has failed to do so, it has an obligation to issue a federal implementation plan (or FIP) to directly regulate existing sources in that state to enforce the Good Neighbor Provision.

In *Homer City*, the Court upheld virtually every aspect of CSAPR, including EPA's approach for setting state budgets for SO2 and NOx, which was based entirely on EPA's analysis of the emission reductions that could be achieved cost-effectively. The Court acknowledged, however, that such an approach could lead to "over control" in some states – emission reduction requirements that went beyond what was necessary to ensure that sources in a particular state did not significantly contribute to nonattainment in other states. This, the Court held, is unlawful. EPA does not have authority to require a state, or sources within a state, to reduce emissions beyond what was necessary to prevent "significant contribution." In other words, EPA has no authority to require reductions in emissions of criteria pollutants below the level necessary to achieve the NAAQS. Although the normal deadline for challenging the CSAPR rule had long since passed, the Court went out of its way to say that states and companies regulated under CSAPR could bring new lawsuits to challenge their CSAPR emission budgets – if they could show that EPA had required them to go beyond what was necessary to meet the NAAQS.
Given this limitation on EPA's authority, in the programs designed to address NAAQS pollutants, the Agency cannot use ancillary benefits associated with reductions in NAAQS pollutants to justify regulatory requirements for HAPs or other non-criteria pollutants that are more stringent than required under the statute, if the justification for doing so is based on ancillary benefits of reducing a criteria pollutant below the level of the NAAQS.

b. The BCA should include a determination of whether the statutory objective benefits justify the costs.

In addition to being required to consider the results of the BCA, the Associations recommend that the final rule also require EPA to undertake a non-binding determination of whether the benefits of the statutory objective of the regulatory provision justify the costs as part of the BCA.

This determination would help inform decision makers and the public whether the benefits of the proposed regulation, based on the statutory objective, justify the costs. While the Administrator would be required to consider the findings of this determination, he or she would still retain full flexibility to issue a standard that does not meet this net targeted benefits determination, when appropriately described and justified.

In addition, as discussed in more detail in these comments, in presenting summary information of the results of the benefits and costs analysis, EPA should also include in the preamble and in the BCA the results of its determination of whether the statutory-objective benefits justify the costs of the recommended option. If the Agency selects an option where those benefits fail to justify the costs, EPA should include in the preamble and the BCA summary the reasons why EPA elected to select an option with higher costs than benefits.

We note that in the proposed rule, EPA does not propose that a "hard" test be required whereby the benefits of the intended action addressing the targeted pollutant outweigh its cost. The Associations agree that a hard, absolute test is not needed and that the Administrator should retain flexibility in specific circumstances. That said, EPA should seek to ensure, using the BCA, that the benefits of addressing the targeted pollutant justify the costs.

In determining whether the statutory objective benefits justify the costs, the Associations also recommend that the analysis comply with OMB Circular A-4 by focusing on the benefits and costs to residents and citizens of the United States. Global and "private" benefits should continue to be reported separately. We further elucidate these points below.

These straightforward steps would enhance transparency and better inform the public with regard to the statutory constraints that may be compelling costly and inefficient regulations.

G. EPA should promulgate language that ensures that all underlying risk assessments supporting significant CAA regulation, including those that provide key inputs to the development of EPA's health benefit estimates in BCAs, are consistent with best practices. Furthermore, the rule should require EPA to assess the direct, indirect, explicit, and implicit costs of proposed significant regulatory actions and their alternatives when feasible.

a. The final rule should clarify that it applies to all risk and hazard assessments and their inputs used to support significant CAA rulemakings.

BCAs conducted by EPA will not be consistent unless the rule is clear that it applies to all underlying risk assessments as key inputs to the BCA -- including components of them such as the hazard assessment and hazard values. EPA's 2010 Guidelines for Preparing Economic Analyses make this clear, stating that "[b]ecause economists rely on risk assessment outcomes as key inputs into benefits analysis, it is important that risk assessments and economic valuation studies be undertaken together." Notably, although the 2010 Economic Analysis Guidelines do cite some EPA risk assessment guidelines, many more exist. Additionally, there are inconsistencies within the Agency regarding how these guidelines are interpreted that could

result in inconsistencies in BCAs (e.g., using linear extrapolation versus a threshold approach for health effects relevant to certain endpoints).

In addition to inconsistencies in BCA, inconsistency in methodologies among the risk assessments used to support benefit estimates and the risk/hazard assessments used to support regulatory decisions would create inefficiencies and be confusing for decision makers and the public. Ensuring that the final rule is clear that it includes all underlying risk assessments (inclusive of both hazard and exposure) and best practices will promote consistency and transparency and improve scientific rigor. This is also important because it is likely that the BCA and risk assessment methodologies utilized pursuant to the final rule will be influential throughout the Agency, given EPA recognition that multiple statutes "…implicitly direct the EPA to consider costs, alone or in conjunction with benefits and other factors."[15]

EPA should also ensure that risk assessments that provide key inputs to the development of EPA's health benefit estimates in a BCA are consistent with certain additional best practices. The final rule should include language that outlines and incorporates the following best practices for improving the consistency and clarity of risk assessments. Specific recommendations in response to EPA's proposed rule text are included further below.

Identification and Evaluation of Studies and Information Used in Risk Assessments

EPA should ensure that risk assessments underlying a BCA use best practices for transparent and consistent identification, evaluation, and integration of evidence. Literature search strategies used for identifying applicable information and selecting pertinent studies should be clearly and transparently described, with an opportunity for public comment. Clear criteria should be in place to define how studies are selected for inclusion and exclusion.

Additionally, risk assessments should employ uniform evaluation methods to determine the quality, relevance, and reliability of the various types of studies and information used in the assessment, which can include epidemiologic, toxicologic, and mechanistic information. Results of individual study evaluations, based on the application of consistent criteria, should be made available to the public for review. The criteria should consist of clear and transparent principles for evaluating the quality and relevance of studies used to address the whether the identified studies are of sufficient quality and are applicable to the risk assessment. Criteria for evaluation of study quality and relevance should be provided in enough detail to allow for replication. All relevant information of sufficient quality should be used in the risk assessments, including both positive and negative results.

Weight-of-Evidence Frameworks

The final rule should ensure that underlying risk assessments weigh the study results in the context of relevant assumptions and uncertainties and integrate the evidence accordingly, utilizing a transparent framework for integrating study results based on a weight-of-evidence (WOE) approach to establish cause and effect. WOE relies on evaluation and integration of

[15] *Id.* at 35,613.

evidence and to formulate conclusions based on inferences.[16] Therefore, selection of hazard and mechanistic data, analysis of the data for quality, relevance, and reliability, and integration of the data using clearly delineated objective criteria are critical to a WOE assessment.[17,18] Risk assessments must be based on a framework that takes into account and integrates all relevant studies, while giving the greatest weight to information from the most relevant and highest quality studies.

Multiple frameworks have been published in the scientific literature representing best practices. Rhomberg, et al. (2013), reviewed approximately 50 WOE frameworks and identified four minimum elements of WOE assessments, including: 1) defining the causal question and developing criteria for study selection, 2) developing and applying criteria for review of individual studies, 3) evaluating and integrating evidence and 4) drawing conclusions based on inferences. [19] An example of a well-established WOE framework meeting the above criteria is the mode-of-action/human relevance framework developed by WHO/IPCS and the International Life Sciences Institute. The final rule should adopt a WOE framework that includes these minimum elements, taking into account all relevant studies.

Mode of Action

The final rule should ensure that the WOE framework used in the underlying risk assessment incorporates modern knowledge of mode of action (MOA) to determine potential risks to humans at environmentally relevant exposures. Determination of the likely operative MOA is central to the assessment of human relevance and selection of dose-response extrapolation methods for quantifying risks at environmentally relevant levels of exposure.[20]

In accordance with established best practices for systematic, evidence-based reviews, the BCA should ensure that a consistent WOE framework was applied, based on specific hypothesized MOAs to permit data from laboratory experiments, epidemiological investigations, and mechanistic research to be integrated in a manner that provides a robust understanding of the MOA and the potential hazards and risks that exposures to a substance could pose to humans. In addition to the WHO framework mentioned above, adverse outcome pathways (AOPs) can also

[16] Boobis, AR, et al, (2006). IPCS Framework for Analyzing the Relevance of a Cancer Mode of Action for Humans. Crit. Rev. Toxicol., 36:10, 781-792, doi: 10.1080/10408440600977677; Boobis AR; Doe JE; Heinrich-Hirsche B; Meek ME; Munn S; Ruchirawat M; Schlatter J; Seed J; Vickers C. (2008); IPCS framework for analyzing the relevance of a non-cancer mode of action for humans. Crit. Rev. Toxicol. 38:87–96. Sonich-Mullin C, Fielder R, Wiltse J, et al., IPCS conceptual framework for evaluating a mode of action for chemical carcinogenesis. Regul Toxicol Pharmacol. 2001;34(2):146-152. doi:10.1006/rtph.2001.1493; Meek, ME, et al, (2014). New developments in the evolution and application of the WHO/IPCS framework on mode of action/species concordance analysis. J. Appl. Toxicol, 34(1): 1-18. http://dx.doi.org/10.1002/jat.2949.

[17] Fenner-Crisp PA, Dellarco VL. Key Elements for Judging the Quality of a Risk Assessment. *Environ Health Perspect*. 2016;124(8):1127-1135. doi:10.1289/ehp.1510483

[18] Linkov, I., Massey, O., Keisler, J., Rusyn, I. and Hartung, T. (2015) "From 'weight of evidence' to quantitative data integration using multicriteria decision analysis and Bayesian methods", *ALTEX - Alternatives to animal experimentation*, 32(1), pp. 3-8. doi: 10.14573/altex.1412231.

[19] Rhomberg LR, Goodman JE, Bailey LA, et al., A survey of frameworks for best practices in weight-of-evidence analyses. Crit Rev Toxicol. 2013;43(9):753-784. doi:10.3109/10408444.2013.832727

[20] Becker RA, Dellarco V, Seed J, et al., Quantitative weight of evidence to assess confidence in potential modes of action. Regul Toxicol Pharmacol. 2017;86:205-220. doi:10.1016/j.yrtph.2017.02.017

be used to organize potential mechanisms into models that describe how exposure might cause cancer (e.g., using the approach of the OECD Adverse Outcome Pathway (AOP) methodology).[21]

Threshold vs Linear Approaches

The final rule should also incorporate all appropriate alternative approaches for dose-response modeling that have sufficient biological support in the risk assessment. Specifically, nonlinear extrapolations which have a significant biological support should be clearly presented and discussed in addition to any linear approach being presented. Failure of a chemical risk assessment's dose-response extrapolation to appropriately consider and incorporate scientifically robust information may result in significantly overestimating health and environmental risks.

EPA must provide a robust, objective scientific rationale if it elects to use a no-threshold model since there is significant body of evidence that homeostatic mechanisms act at the molecular, cellular and tissue level to prevent adverse responses to low level exposures.[22] This is true not only for systemic and local effects of non-carcinogens, but also for both genotoxic and non-genotoxic carcinogens.[23]

Exposure Assessment

The final rule should ensure that the regulatory decision and the BCA supporting them incorporate a transparent and structured process to identify, evaluate and integrate scientific evidence for both the hazard and exposure assessments. This should also include an evaluation of the criteria used to determine if data are acceptable or unacceptable for use in the exposure assessment. The final rule should require exposure assessments to provide objective and realistic estimates of likely exposure based on the best available knowledge regarding toxicity and anticipated exposure.

Endogenous Exposures

Risk assessments for exogenous chemicals with endogenous exposures should systematically account and consider endogenous or background levels of chemicals. Farland, et al. (2019), address this and note that it is important to encourage the development of data and models to put exogenous exposures to endogenous or background chemicals in context as an integral part of

[21] https://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm

[22] Rhomberg et a., 2011. Linear low-dose extrapolation for noncancer health effects is the exception, not the rule, Crit Rev Toxicol. 41: 1–19; Zhang, et al., 2014. Molecular signaling network motifs provide a mechanistic basis for cellular threshold responses. Environ Health Perspect. 122: 1261–1270.

[23] Thresholds of Genotoxic Carcinogens: From Mechanisms to Regulation (edited by Takehiko Nohmi and Shoji Fukushima) 2016. Academic Press https://doi.org/10.1016/C2013-0-19100-3; Clewell, et al., 2019. Dose-dependence of chemical carcinogenicity: Biological mechanisms for thresholds and implications for risk assessment. Chemico-Biological Interactions 301: 112-127; Wolf, et al., 2019. Chemical Carcinogenicity Revisited 1: A Unified Theory of Carcinogenicity Based on Modern Knowledge Reg. Tox. Pharm. 103: 86-92; Cohen, et al., 2019. Chemical carcinogenicity revisited 3: Risk assessment of carcinogenic potential based on the current state of knowledge of carcinogenesis in humans Reg. Tox. Pharm 103: 100-105.

risk assessment, and to review endogenous or background chemicals with exogenous exposures in a systematic manner.[24]

Uncertainty Analysis (including variability; integrated uncertainty analysis; and sensitivity analysis)

As discussed further below, characterizing the confidence in and uncertainty with the risk assessment is critically important to support the underlying regulatory decision. To more accurately reflect scientific certainties and uncertainties, the BCA should ensure that risk assessment information includes an evaluation of the sensitivity of derived estimates to model assumptions and the effect of uncertainty on the estimates. Providing a sense of the magnitude and uncertainty of potential risks estimates will allow the information to be utilized more appropriately.[25] Chemical-Specific Adjustment Factors (CSAFs) or Data-Derived Uncertainty Factors (DDEFs) should be considered instead of default uncertainty factors whenever possible.

Model Utility and Application

All models utilized should be fit for purpose, provide an accurate representation of the toxicity or exposure related information and be based on realistic and reasonable inputs. Decisions based on model information must be employed in a manner consistent with the best available science and most accurate information. The Agency must ensure that any decisions are based on the most up-to-date, representative models that exist and also strive to utilize available and reliable empirical data in lieu of default models or assumptions. Also, scientifically robust models such as physiologically-based pharmacokinetic (PBPK) models should be considered for replacing defaults used to calculate human equivalent doses.

Establish a Clear Preference for Data in Lieu of Default Assumptions

In assessing risk and when extrapolating risk from high exposures to relevant public exposure, EPA should establish a clear preference for relying on representative, measured data in lieu of modeled results or default assumptions. If gaps exist in the measured data, then modeled results can be used to draw inferences for those gaps. This is a widely accepted principle in risk assessment and has been generally adopted by the Agency. EPA's staff paper *Risk Assessment Principles and Practices* embraces the preference for data and recognizes that the default values should only be used as a last resort:

> EPA's current practice is to examine all relevant and available data first when performing a risk assessment. When the chemical-and/or site specific data are unavailable (that is, when there are data gaps) or insufficient to estimate parameters or resolve paradigms, EPA uses a default assumption in order to continue with the risk assessment. Under this

[24] Farland WH, Lynch A, Erraguntla NK, Pottenger LH. Improving risk assessment approaches for chemicals with both endogenous and exogenous exposures. Regul Toxicol Pharmacol. 2019;103:210-215. doi:10.1016/j.yrtph.2019.01.029

[25] It is important that underlying hazard and risk assessments catalogue and communicate the uncertainties in the assumptions and mathematical manipulation of the data relied on to derive both the exposure and the hazard/dose-response inputs. This is critical for giving risk managers the range of scientifically supportable, allowable, and safe exposure levels.

> practice EPA invokes defaults only after the data are determined to be not usable at that point in the risk assessment – this is a different approach from choosing defaults first and then using data to depart from them.[26]

A data-first preference is also apparent in EPA's posted procedures for conducting a human health risk assessment. The Hazard Identification phase begins by examining sources of data, starting in order of preference with human clinical data followed by epidemiology data. When data from human studies are unavailable, EPA then turns to animal data and models based on the data to draw inferences about risks to human health. In each case, EPA begins by thoroughly reviewing existing data.[27]

Establishing a preference for measured data in the final rule would achieve greater clarity and encourage the production of measured data to address data gaps that would otherwise trigger the use of defaults. While consideration of data quality and reliability is a critical step in the evaluation process, the use of data, including the use of data from well-designed laboratory studies, is preferred over explicit and implicit assumptions that can significantly alter the results of the risk assessment in ways that may not always be apparent.

Explain the Basis for Significant Judgments, Data, Models and Inference

When selecting and quantifying health endpoints in a benefit-cost analysis, the proposed rule would require EPA to: (1) explain the basis for significant judgments, assumptions, data, models, and inferences used or relied upon in the assessment or decision; and (2) describe the sources, extent and magnitude of significant uncertainties associated with the assessment. The Associations support this common-sense approach.

EPA's current principles for risk characterization instruct risk assessors to "articulate major assumptions and uncertainties" and to "identify reasonable alternative interpretations, and separate scientific conclusions from policy judgments."[28] EPA's risk characterization policy further requires EPA to "explicitly disclose the risk assessment methods, default assumptions, logic, rationale, extrapolations, uncertainties, and overall strength of each step in the assessment."[29] The proposed rule's requirements -- to explain the basis for significant judgments, assumptions, data, models, and inferences used and to describe the sources, extent and magnitude of significant uncertainties -- are consistent with EPA's current procedures and should be required in risk assessments supporting significant regulatory actions under the CAA.

To provide further information on the role of key assumptions in risk assessment, EPA should list the major assumptions used to characterize/estimate exposure and to derive toxicity values and their potential impact on the final risk estimates using quantitative ranges.[30] This can be illustrated with the use of data displays such as tables.

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[26] EPA, *Risk Assessment Principles and Practices* (EPA2004a), p51.
[27] EPA, Conducting a Human Health Risk Assessment, Hazard Identification, at https://www.epa.gov/risk/conducting-human-health-risk-assessment
[28] EPA, Risk Characterization, Step 4 of Conducting a Human Health Risk Assessment.
[29] *Id.*

b. The final rule should also incorporate the following specific recommendations on the proposed risk-related rule text.

The proposed rule's study-selection criteria for concentration-response functions (CRFs) is an important element of the rule that should be strengthened.

In selecting concentration-response functions for purposes of risk assessment, the proposed rule would require EPA to select from studies that meet the following three specific criteria: (1) the study was externally and independently peer-reviewed consistent with federal guidance; (2) the pollutant analyzed in the study matches the pollutant of interest in the regulation; and (3) the concentration-response functions must be parameterized from scientifically robust studies.

EPA also solicits comments on whether additional requirements within the study selection criteria are necessary to ensure a high-quality and appropriately reliable characterization of air quality and risk.

The Associations appreciate and support EPA's focus on this important step in the risk assessment process. The selection of studies for the purpose of identifying concentration-response functions can dictate the outcome of risk assessments and benefit analyses. The Associations recommend amendments to the proposed criteria and the insertion of additional criteria to ensure that the Agency relies on studies that reflect the best available evidence while encompassing the range of potential scientific uncertainties.

As an initial matter, when finalizing the rule, EPA should clarify that the term "concentration" as set out at in the proposal at Section 83.3 (a)(9)(iii) encompasses both dose and concentration response functions found in animal/toxicology studies, human clinical studies and epidemiology studies. This will ensure that the criteria apply broadly to study selection, regardless of whether the studies are based on animal or human data.

The Associations support the criteria proposed in Section 83.3(a)(9)(iii)(A)-(B) but recommends the deletion of the criterion in Section 83.3(a)(9)(iii)(C) that states "concentration-response functions must be parameterized from scientifically robust studies." As currently drafted, this criterion conveys no specific meaning and would not effectively help the Agency discriminate among studies.

Alternatively, EPA should include criteria that assure the Agency is capturing the full range of model and shape uncertainties reflected in well-conducted epidemiology studies. At this point in the risk assessment process, the objective should not be the elimination of uncertainties but rather the full investigation of the many potential scientific uncertainties affecting model selection and the shape of the concentration response function.

The Associations recommend that EPA include the following criteria to guide EPA in selecting studies. Specifically, EPA should give preference to studies that:

- Make available the results of all models referenced in the study, and the models

and data necessary for replicating the study in a manner that protects confidential business and personal information in accordance with current law.

- Have published protocols a priori on sites accessible to the public.[31]

- Have adequate statistical power considering Type I and Type II errors.[32]

- Assess the influence of covariates.

- Present the results of all statistical analyses along with a discussion of the reason a method was used, any assumptions made in the analysis, identification of any outliers and their disposition, and the validity of the conclusions.

- Explore a broad range of alternative models, including models with alternative shapes, exposure windows and lag times, nonparametric models that incorporate fewer assumptions, and various threshold models across the dose or exposure range.

- Investigate factors that might account for spatial heterogeneity.

Section 83.3(a)(9)(iii)(D) of the proposed rule correctly recognizes that additional criteria may be needed for selecting epidemiology studies for purposes of identifying concentration-response functions. When an epidemiological study is used, the proposal would require EPA to consider the following additional three criteria: (1) the study must assess the influence of confounders; (2) the study location must be appropriately matched to the analysis; and (3) the study population characteristics must be sufficiently similar to those of the analysis. The Associations support the proposed criteria with the following modifications: the first criterion above should be clarified to include covariates as well as confounders, and the second and third criteria should be retained, with clarification that preference be given to studies of United States populations.

In addition to these study selection criteria, the Associations support addition of a requirement that EPA give preference to epidemiology studies that:

- Explored which of its model specifications may have predictive validity;

- Conducted a quantitative bias assessment**;**

- Evaluated the potential for exposure misclassification and its impact; and

- Have taken steps to reduce this potential.

[31] See PRISMA, Transparent Reporting of Systematic Reviews and Meta-analysis.
[32] Type I errors are also known as false positives while Type II errors are also known as false negatives.

c. The final rule's provisions regarding the characterization of concentration response functions should focus on identifying the range of scientific uncertainties rather than arbitrarily reducing them.

Section 83.3(a)(9)(iv) states that if multiple studies meet EPA's selection criteria, the Agency must "characterize multiple concentration-response functions, and, if appropriate, combine them as a means of providing a broader representation of the effect estimate." In the preamble, EPA provides further detail by stating the Agency would quantify risks using separate concentration-response relationship and, if appropriate, pool, or combine, the results (e.g., in a meta-analysis) as means of providing a broader representation of the effects estimate.

Concentration-response functions should be combined only in limited circumstances after a full assessment of the similarities and differences of the underlying studies and data, and an opportunity for public comment. Before combining data or concentration response functions, the final rule should require EPA to publish for public comment the criteria for when studies or data will be combined. Publishing the criteria before beginning the analysis will allow for increased transparency and provide independent researchers the opportunity to identify and comment on potential issues with regard to combining the data or concentrations response functions.

As a general matter, data and concentration response functions from toxicology studies of different species should not be combined. In addition, combining data from the same species should be done with care after a detailed analysis. The results of any combined analysis should then be compared with the results of individual concentration-response functions from the source studies.

Combining epidemiology data or concentration response functions derived from epidemiology data should also not be done without a full assessment of the similarities and differences in the study design and population. Combining studies using meta-analysis or pooling techniques is often scientifically inappropriate due to heterogeneity in study designs, populations, and results -- especially with regard to epidemiological studies. Pooling or combining heterogeneous data can also mask evidence of scientific uncertainty rather than allow its exploration. These caveats support the contention that combining data from different studies requires an awareness of these limitations and a heightened degree of care.

For similar reasons, using meta-analysis to combine concentration-response functions from multiple epidemiology studies for the purpose of developing a narrower if not single concentration-response function should be employed only with a requisite amount of care due to: (1) likely differences in study design that are common among epidemiology studies (such as differences in models, parameters, and exposure windows); and (2) differences in the underlying health and genetic predispositions of the study population, unassessed/unmonitored co-pollutant exposures and unassessed socio-economic conditions. It is possible that even studies that are limited to the U.S. population may not be defensibly combined using meta-analysis because of likely differences in how the study participants are selected. Very few studies select participants using truly random-selection measures.

If concentration-response functions are combined after a full assessment of the individual study and population differences, each concentration response function (including the maximum and minimum concentration-response function values from the selected studies) should still be qualitatively evaluated separately for its strengths and weaknesses and its potential predictive power as a reality check. The fundamental objective of risk assessment is to develop a tool that will assist EPA in predicting how changes in emissions will affect future risks. Therefore, each concentration-response function and model on which it is based should be qualitatively evaluated for purposes of its potential strengths and weaknesses as a predictive tool and compared to any combined concentration-response function. This analysis should go well beyond the role of using concentration-response estimates to identify existence of a hazard to the need to substantiate a concentration-response relationship.

EPA should also recognize that the full range of concentration-response functions in the selected studies is unlikely to represent all of the uncertainties present. Even when including the full range of concentration-response functions from the selected studies, risk assessors must recognize that the selected studies may not include all relevant study designs or models, thereby limiting EPA's ability to assess concentration-response functions that have not been evaluated or included. The selected concentration response functions may also be based on similar models giving a false impression of greater robustness even though they may fail to include the model/study design with the greatest predictive power. These, and other limitations of CRFs, should be described when EPA characterizes their strengths and limitations.

The concentration-response models selected for a risk assessment may also reflect assumptions that are odds with the Administrator's own subjective judgments regarding risks. For instance, in setting NAAQS, EPA has repeatedly selected concentrations levels that reflect judgments regarding increasing levels of uncertainty of obtaining public health benefits at lower concentrations levels. Despite these repeated judgments, criteria pollutant risk assessments by EPA have typically still relied on models and concentration-response functions that assume a continued certainty in the dose-response relationship even at very low levels of exposure. In many instances, these studies are making assumptions about risk without sufficient biological support for a mode of action for effects at these extremely low concentrations.

To address this issue, Cox (2018) uses air quality monitoring data from Los Angeles to simulate the shapes of estimated concentration-response curves for $PM_{2.5}$ when the true functions are assumed to be step functions with well-defined response thresholds.[33] The resulting estimated concentration-response functions, however, continue to show risk a linear decline in risk, well below the response threshold and incorrectly predicting risk at these low levels. The author concludes that ignored estimation errors can obscure the shapes of the true concentration-response curves and lead to unrealistic predictions of changes in risk. Other researchers, including Goldman, et al., (2011), have found that measurement error resulted in reduced statistical significance for risk ratio estimates, with the average attenuation ranging from 18 to 92 percent.[34] The final rule should require that the risk analysis address these significant sources of

[33] Cox, L.T. "Effects of exposure estimation errors on estimated exposure-response relations for $PM_{2.5}$" Environmental Research, Vol. 164, July 2018, pp 636-646.

[34] Goldman, et al., (2011), "Impact of exposure measurement error in air pollution epidemiology: effect of error type in time-series studies."

scientific uncertainty that may not be fully reflected in the range of the selected concentration response functions.

Given these considerations Section 83.3(a)(9)(iv) of the proposed rule should be amended to require EPA to address uncertainties that may not be adequately represented in the selected functions.

d. EPA should select concentration-response functions that represent the full range of scientific uncertainty in studies meeting the study-selection criteria.

Section 83.3(a)(9)(v) and (vi) of the proposed rule would require EPA to*:*

i. base decisions about the choice of the number of alternatives quantified for each endpoint on the extent to which it is technically feasible to quantify alternative CRF relationships given the available data and resources.

ii. select and clearly identify CRFs with the strongest scientific evidence, as well as evidence necessary to demonstrate the sensitivity of the choice of the concentration-response function on the magnitude and the uncertainty associated with air pollution-attributable effects (emphasis added).

The Associations support selecting alternative concentration-response functions from the selected studies that reflect the full range of alternative plausible models, including threshold and non-threshold models, and alternative concentration-response function shapes. The selected concentration-response functions should be supported by mode of action data, particularly at low concentrations, and should include the minimum and maximum values as well as functions that are based on significantly different models in order to ensure the risk assessment appropriately evaluates all major sources of uncertainty relating to the concentration-response functions found in the literature. EPA should demonstrate the sensitivity of the choice of the concentration response function on the magnitude of estimated risk and on the general uncertainty associated with air pollution-attributable effects. In evaluating the risk, EPA should also carefully assess the full distribution of exposure values to determine the role of outliers on the results.

Which concentration-response function gets more weight within this range is a subjective judgment that may only be made by the Administrator in the final analysis. To assist the Administrator in weighing the uncertainties, EPA should include a discussion of the relative strengths and weaknesses of each concentration response function included, recognizing that all studies taken together as a whole reflect model uncertainty that should be accounted for in the risk assessment.[35]

As noted above, in selecting CRFs that represent the full range found in the selected studies, EPA must continue to recognize and discuss the significant possibility that all of the functions represented may still be wrong if they represent associations that do not have predictive validity. EPA should accommodate and address this core uncertainty in its risk estimates, namely how

[35] This should qualitative and quantitative assessment of the concentration-response relationship to provide for estimates of a range of plausible risk estimates and/or safe levels of exposure.

likely it is that the relationship may not be causal and have no effect, or have significantly different effects due to inability of the association-based models to detect the true CRF shape, or to have used the correct causal measure of exposure (e.g., due to time window uncertainties, or differential potencies of different constituents of the pollutant mass).

e. EPA's required analysis for evaluating the selected concentration-response function should include the following recommendations.

Once EPA has identified the CRFs to use for quantifying the selected health endpoints, Section 83.3(a)(9)(vii) of the proposed rule would require EPA to characterize:

(A) the variability in the CRFs across studies and models, including plausible alternatives;
(B) the assumptions, defaults, and uncertainties, their rationale, and their influence on the resulting estimates;
(C) the extent to which scientific literature suggests that the nature of the effect may vary across demographic or health characteristics;
(D) the potential variability of the concentration-response function over the range in concentrations of interest for the given policy;
(E) the influence of potential confounders on the reported risk coefficient;
(F) the likelihood that the parameters of the concentration-response differ based on geographic location; and
(G) attributes that affect the suitability of the study or model for informing a risk assessment, including the age of the air quality data, and the generalizability of the study population.

It is important that the proposed rule identify and require the specific steps the Agency will take in characterizing issues associated with risk estimates based on the selected concentration-response functions. This analysis is a central piece of the risk assessment process and it is pivotal to ensuring that the full uncertainties present in the selected CRF are explicitly explored. The Associations offer the following specific comments on the proposed criteria.

- EPA should clarify that "characterization" means to perform a risk analysis of the full range of CRFs included in the selected studies based on the study-selection criteria, including evaluating quantitatively, when possible, or qualitatively the elements in (A) through (G). As discussed above, EPA should avoid characterizations based on a single CRF or a narrow range resulting from a statistical combining of several functions.

- As noted earlier, the selected CRFs should include the minimum and maximum values as well as concentration-response functions that address alternative models and shapes.

- In characterizing the selected CRF, EPA should again recognize in the characterization that the full range of the selected CRFs may not address all important sources of scientific uncertainties, including the potential for an undetected threshold. EPA should address qualitatively, if not quantitatively, the potential implications of these missing uncertainties.

The Associations therefore recommend the following changes Section 83.3(a)(9)(vii) to provide greater clarity:

> *a. Required Analysis for Quantification with Selected CRF -- Once EPA has identified the concentration-response functions to use for quantifying the selected health endpoints, the Proposal would require EPA to perform its risk characterization by evaluating qualitatively and quantitatively when possible:*
>
> *i. the range in the CRFs across studies and models, including plausible alternatives and the potential for no or low effects;*
> *ii. the assumptions, defaults, and uncertainties, their rationale, and their influence on the resulting estimates;*
> *iii. the extent to which scientific literature suggests that the nature of the effect may vary across demographic or health characteristics;*
> *iv. the potential range of the concentration-response functions over the range in exposure concentrations of interest for the given policy;*
> *v. the influence of potential confounders on the reported risk coefficient;*
> *vi. the likelihood that the parameters of the concentration-response and the resulting potential risk differ based on geographic location; and*
> vii. *attributes that affect the suitability of the study or model for informing a risk assessment, including the age of the air quality data, and the generalizability of the study population.*
>
> f. Risk assessments should seek to develop probability distributions that reflect the range of scientific uncertainties.

Section 83.3(a)(9)(viii) of the proposed rule would correctly require EPA, when feasible, to use a probability distribution of risk when determining expected benefits. The proposed rule goes on to state, however, that when it is infeasible to estimate a distribution, EPA must use measures of the central tendency of risk. It also notes that upper-bound risk estimates must not be used unless they are presented in conjunction with lower bound and central tendency estimates.

The final rule should require the use of probability distributions to reflect the significant uncertainties present in risk estimates, but we also note that such probability distributions can only be developed through subjective informed judgment about the alternative risk assessment input assumptions. The proposed rule also correctly requires the distribution to include lower bound and central estimates of risk with upper-bound risk estimates. These minimum requirements are important and sensible in ensuring that the distribution embraces the full range of uncertainties present in the data.

As a practical matter, however, the proposed rule is incorrect in requiring the Agency to rely on central tendency measures of risk when it is infeasible to estimate a probability distribution. Central tendency estimates, such as the mean and median are, by definition, based on a probability distribution. It is impossible to arrive at a mean or median estimate without first estimating a distribution. For these reasons, the final rule should omit the requirement for central tendency estimates if a distribution is infeasible, and instead should require that the full range of

estimates be provided with explicit acknowledgment that a "central" or "best" estimate is infeasible to estimate.

Probability distributions can be used to: (1) characterize the variation in the estimated slopes of the concentration-response functions reported in the selected studies -- a majority of which are likely to be linear-no-threshold models that differ only in terms of their slope; or (2) characterize scientific uncertainties that remain with the available set of statistically-estimated concentration response functions.[36] Of the two potential approaches for characterizing uncertainty in risks, applying the first alone would omit major sources of uncertainty and would likely misinform decision makers and the public more than simply presenting the minimum and maximum risk estimates from the set of selected studies. The second approach to estimating a risk probability distribution is likely to be far more important for analysis and consideration, and thus is the focus of the following comments.

The second probability distribution approach should focus on the possibility that none of the selected concentration-response functions reflects the correct predictive model. This possibility cannot be eliminated by statistical means, as many different measures of historical exposures to ambient concentrations are highly correlated with each other, and thus may be equally well associated (as a matter of statistical significance) with the health endpoint. The alternative associations, however, will differ in the magnitude of risk that they predict. Since only one of the wide range of alternative measures of past exposures can be the causal one, there is significant scientific uncertainty about which CRF's risk predictions are correct, and statistical tests alone cannot readily resolve this question. Further, it is quite possible that none of the CRFs have used the right causal measure, which makes it impossible to be confident that the correct risk estimate lies within the range of CRFs reported in the literature.

Exposure measurement error (for any window of exposure that one wishes to use) and limited data at very low exposures also contribute to scientific uncertainty regarding the shape or continued existence of a concentration-response relationship at lower exposures levels in the study and at levels below the lowest measured levels in the study, and if so, what the mode of action may be. In the case of $PM_{2.5}$, another important scientific uncertainty that should be accounted for in a thorough probability distribution on risk would be the relative toxicity of $PM_{2.5}$ constituents.

These important forms of scientific uncertainty may not be represented by the range of concentration-response functions from the selected studies but can significantly alter the risk and benefit estimates. Judgments need to be made about the relative likelihood of each of these uncertainties if a proper probability distribution on risk is to be calculated. If EPA is not prepared to make the requisite subjective judgments, substantial insight about the role of these uncertainties for decision making can be obtained by thorough quantitative sensitivity analyses, including joint sensitivity analyses in which two or more uncertain input assumptions to the risk estimation formula are considered in various combinations across their individual possible ranges.

[36] Examination of the uncertainty and assumptions underlying reference concentrations (RfCs) leads to a range of plausible RfC values for setting safe levels of air concentrations.

One example of how a thorough sensitivity analysis can provide information on the impact of uncertainty on the shape of the concentration-response curve at low levels is found in a 2015 paper by Smith and Gans.[37] The authors present a quantitative sensitivity analysis of possible health risk thresholds for $PM_{2.5}$ in a manner that does not require the analyst to make a judgment about potential threshold levels. Instead the authors perform a series of alternative risk calculations across the full spectrum of possible threshold assumptions, including levels that many may personally consider implausible. The resulting figure (Fig. 3 below) shows the change in the risk estimate as the threshold assumption is increased from 0 micrograms per cubic meter (ug/m3).

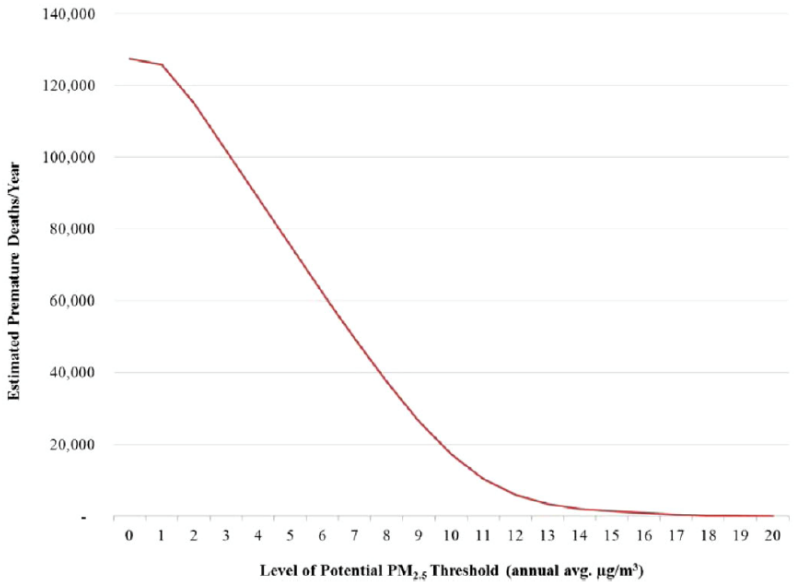


Fig. 3. Sensitivity of estimated mortality risk associated with $PM_{2.5}$ to alternative threshold assumptions (national annual premature deaths).

This relatively simple analysis could be expanded to use different concentration response functions that reflect the full range of studies selected as a starting point for the risk analysis. By plotting the sensitivity curves for each alternative CRF, a range of potential risk estimates at each potential threshold level could replace the single curve shown in the figure. This range will be wide at the left side of the chart (where no threshold is assumed) reflecting the range of slope estimates across the various available linear-no-threshold CRFs. However, the range will become narrower as higher thresholds are assumed (i.e., moving to the right of the figure), eventually collapsing to zero for assumed thresholds that exceed baseline pollutant levels anywhere in the geographic region over which risk is being analyzed. Such a graph would provide EPA and the public with valuable information of how the potential risks vary across the full range of concentration-response functions from the selected studies and the full range of uncertainties regarding different threshold values. Producing a figure such as this does not require any subjective probabilities: it leaves each person reviewing the benefits analysis free to make his or her own judgment about the portions of the chart that are most likely, and to thus understand the implications of their personal views on the quantitative

[37] Smith, A.E. and Gans, W. "Enhancing the Characterization of Epistemic Uncertainties in PM2.5 Risk Analyses" *Risk Analysis*, Vol 35, No 3, 2015, pp. 361-378.

estimate of health risks (and associated benefits). Such a chart can be useful to EPA in its role as a policy maker (as in the case of setting a NAAQS) as the Agency considers the strengths and weaknesses of the scientific evidence to draw policy conclusions. However, once that judgment has been made, estimation of a range of co-benefits estimates for a BCA of a later non-NAAQS regulation should be informed (and consistent with) the regulatory determination about the most appropriate risk input assumptions.

EPA could also consider a second approach to addressing key uncertainties that EPA used in its 1997 $PM_{2.5}$ risk assessment and which is discussed at length in A Smith's 2018 paper on incorporating subjective uncertainty in quantitative risk assessments for National Ambient Air Quality Standards.[38] This approach to evaluating threshold uncertainty did use probability distributions, but to avoid having to take a specific subjective position, the risk analysis applied three alternative probability distributions ("cases") over potential threshold levels when conducting its risk analysis. In each of the three cases, the risk assessors assigned specific probabilities to the existence of a threshold at various levels, using four discrete levels (9, 12.5, 15 and 18 $\mu g/m^3$) as a condensed summary of the full range of potential levels. (These distributions are shown in the table below. For example, in Case I, the assessors assigned a 55 percent probability that the threshold existed at 9 $\mu g/m^3$.) Each probability distribution "case" could be viewed as an alternative possible subjective view on this uncertainty, although not attributed to any specific individuals. This allowed a probabilistic analysis of uncertainties to proceed as a form of sensitivity analysis -- in this case the sensitivity being explored was sensitivity to different possible points of view about the likelihood and level of an effects threshold.

Cut-point Weighting Schemes

	Case I	Case II	Case III
9 $\mu g/m^3$	0.55	0.35	0.10
12.5 $\mu g/m^3$	0.20	0.35	0.20
15 $\mu g/m^3$	0.15	0.20	0.40
18 $\mu g/m^3$	0.10	0.10	0.30

As noted by A. Smith, the preamble to the 1997 $PM_{2.5}$ NAAQS rule highlights the importance of the insights generated from this sensitivity analysis:

> Based on the results from the sensitivity analyses of the key uncertainties and the integrated uncertainty analysis, the single most important factor influencing the uncertainty associated with the risk estimates is whether or not a threshold concentration exists below which PM-associated health risks are not likely to occur.[39]

Future risk assessments for $PM_{2.5}$ or ozone that ignore uncertainties surrounding the potential existence of a threshold will fail to include and characterize the very important subjective judgments that the Administrator makes in setting the NAAQS (which can be inferred from each NAAQS rationale). The judgments made by the Administrator when setting each

[38] Smith, Anne E "Setting Air Quality Standards for PM2.5: A Role for Subjective Uncertainty in NAAQS Quantitative Risk Assessments?" *Risk Analysis*, Vol. 38, No. 11, 2018, pp. 2318-2339.
[39] 62 Fed. Reg. at 38565.

NAAQS should be reflected consistently in any characterization of the ranges of uncertainty in the risks and/or benefits from reductions of those criteria pollutants. If this is not required, the public and others reviewing the BCA will be unable to evaluate whether the Agency's final decision appropriately reflects the available science and existing uncertainties.

The Associations therefore recommend the following regulatory text for Section 83.3(a)(9)(viii):

> *When feasible, the Proposal would require EPA to use a probability distribution of risk to reflect the full range of scientific uncertainties in the concentration-response functions as well as significant scientific uncertainties that may not be addressed in the functions when determining expected benefits. When it is infeasible to estimate a distribution, the full range of estimates must be provided without an estimate of central tendency. Upper-bound risk estimates must not be used unless they are presented in conjunction with lower bound and central tendency estimates.*

g. The final rule should adopt the following best practices when analyzing benefits and costs.

Limit the estimation and monetization of health endpoints to those that are likely causal or causal. Section 83.3(a)(7) proposes to quantify benefits if the "scientific evidence indicates there is a "clear causal or likely causal relationship between pollutant exposure and effect" and there is an anticipated change in that effect in response to the regulation under analysis. The Associations agree as a general matter to this minimum criterion for quantification. The quantification of claimed benefits with less support than "likely causal" determinations, such as "suggestive causal," would give undue credence to the existence of highly uncertain benefits and would result in spurious estimates. This has the potential to further confuse decision makers and the public.

To provide greater clarity and consistency, the final rule should include clear definitions for "causal" and "likely causal." The Associations recommend the following definitions:

- *Causal* – the evidence is sufficient to conclude that there is a causal relationship between the relevant pollutant exposure and the outcome. Causality is supported when an association has been observed between the pollutant and the outcome in studies in which chance, bias, and confounding could be ruled out with reasonable confidence, and when the animal and mechanistic evidence from studies in exposed humans is consistent with (i.e., not contradicted by) the epidemiologic evidence.

- *Likely Casual* – the weight of evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists, and the association cannot readily be explained by plausible non-causal alternatives (e.g., chance, bias, or confounding).

The definition of "likely causal" recommended in these comments is based on the Institute of Medicine's (IOM) thorough, evidenced-based analysis of causality.[40] After a detailed analysis of what is meant by "cause" in contrast to statistical association,[41] and an examination of quantitative and qualitative approaches for integrating epidemiological, laboratory and other evidence to reach conclusions,[42] the IOM recommends, based on this foundational work, a "systematic" review of the evidence to determine the strength of the evidence using the following four categories:

- *Sufficient*: The evidence is sufficient to conclude that a causal relationship exists.
- *Equipoise and Above*: The evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists.
- *Below Equipoise*: The evidence is not sufficient to conclude that a causal relationship is at least as likely as not, or is not sufficient to make a scientifically informed judgment.
- *Against*: The evidence suggests the lack of a causal relationship.[43]

The "likely causal" definition recommended above is based on the IOM's second category "Equipoise and Above." Adopting this definition would limit quantification to those health endpoints for which the weight of evidence is *at least* as likely as not to be causal and the apparent association cannot readily be explained by plausible non-causal alternatives. This would prevent the estimation and tabulation of benefits in categories that are far too uncertain to be justified. Quantifying benefits below this 50 percent confidence level would mislead the public into believing the benefits are "real" simply because they are quantifiable. Having one or two studies that allow quantification does not mean that quantification is correct and necessary, especially if the weight of the evidence suggests that the effect is not as least as likely as not.

For these reasons and to ensure consistency, EPA should provide additional clarification in the final rule at Section 83.3(a)(7)-(8), which provides that EPA must quantify effects for endpoints which scientific evidence is robust enough to support such quantification; and that EPA must, to the extent supported by scientific literature as well as practicable in a given rulemaking, i) quantify *all* benefits; ii) monetize *all* the benefits by following well-defined economic principles using well-established economic methods; and iii) qualitatively characterize benefits that cannot be quantified or monetized.

Without further amendment, these provisions could be interpreted as free-standing criteria that could conflict with causal framework criteria for determining which health endpoints should be quantified. Similarly, in response to EPA's request for comment on an alternative approach that

[40] Institute of Medicine "Improving the Presumptive Disability Decision-making Process for Veterans" National Academies Press, 2008.
[41] *Id.,* Chapter 7 "Scientific Evidence for Causation in the Population" p 150+
[42] *Id.* at Chapter 8 "Synthesizing the Evidence for Causation" p175+
[43] *Id.* at 189.

would "select all endpoints for which there is a positive willingness to pay (WTP) condition on the available scientific literature" the Associations recommend that EPA delete this provision or clarify that the same minimum quality/confidence standards for existence of an underlying causal physical relationship would apply before including any benefits estimate for an endpoint based on such a WTP finding.

The approach set out in the proposed rule, to require a full analysis of the uncertainties underlying the estimation of both the benefit and cost estimates, is appropriate.

Section 83.3(a)(10) (i)-(iv) of the proposed rule would require EPA to identify uncertainties underlying the estimation of both benefits and costs and, to the extent feasible:

- Quantitatively analyze those that are most influential;
- Present benefits and cost estimates in ways that convey their uncertainty;
- Provide a reasoned explanation for the scope and specific quantitative or qualitative methods chosen to analyze uncertainties;
- Use quantitative methods to analyze uncertainties that have the largest potential effect on benefits or cost estimates;
- Characterize, preferably quantitatively, sources of uncertainty in the assessment of costs, changes in air quality, assessment of likely changes in health and welfare endpoints, and the valuation of those changes;
- Consider, and transparently acknowledge, the extent to which qualitatively-assessed costs or benefits are characterized by uncertainty.

The Associations strongly support EPA's proposed requirements for the identification and analysis of key sources of uncertainty in the BCA, including the specific criteria proposed in Section 83.3(a)(10) (i)-(iv). As discussed above, this analysis must include the full range of concentration-response functions as well as the significant uncertainties that may not be included in those functions, such as the presence of a threshold, pollutant constituents and/or exposure window uncertainty.

To the extent uncertainties affecting potential costs, and causal or likely causal benefits cannot be quantified, the final rule should require qualitative assessments of these uncertainties as proposed in (iv). In furtherance of this goal, EPA should consider applying contingency tables (where sensitivities are evaluated one-by-one) or qualitative ranking tools or tables that assign percent ranges of the magnitude of the likely uncertainty level present in a non-quantifiable benefit. If percent ranges cannot be assigned, EPA should consider descriptors of the direction and magnitude of uncertainty using words or symbols. Specifically, words or an ordinal scale describing how much a source of uncertainty affects the assessment or its conclusion should be provided (e.g., low, medium or high uncertainty; conservative, very conservative or non-conservative; unlikely, likely or very likely; or symbols indicating the direction and magnitude of

uncertainty: —, –, -, +, ++, +++).

The Associations therefore recommend that Section 83.3(a)(10) be amended as follows:

> *The Agency must identify uncertainties underlying the estimation of both benefits and costs and, to the extent feasible, quantitatively analyze using sensitivity analyses those that are most influential; and must present benefit and cost estimates in ways that convey their uncertainty. The Agency must provide a reasoned explanation for the scope and specific quantitative or qualitative methods chosen to identify and analyze significant uncertainties.*

The final rule should require combining probability distributions that characterize significant sources of uncertainty to the extent they can be feasibly and credibly combined.

Where probability distributions for relevant input assumptions are available based on subjective judgments that characterize significant sources of uncertainty in the assessment, and can be feasibly and credibly combined, Section 83.3(a)(10) (v) of the proposed rule would require EPA to characterize how the probability distributions of the relevant input assumption uncertainty would impact the resulting distribution of benefit and cost estimates. Section 83(a)(10)(vi) would further require EPA to provide expected-value estimates of benefits and costs as well as distributions surrounding each of the estimates. In cases where estimates based on expected values are not feasible, the proposed rule would require the Agency to present a plausible range of benefits and costs.

As proposed, the final rule should require the Agency to combine uncertainties, including probability distributions based on subjective judgments, to assess risk, uncertainties and potential net benefits when possible. Evaluating uncertainties individually limits the ability of the public to understand the cumulative implications of their potential impact on the likelihood that the rule will yield net benefits. This requirement will also force EPA to focus on developing an array of tools necessary to combine uncertainties, including probability distributions of uncertainty.

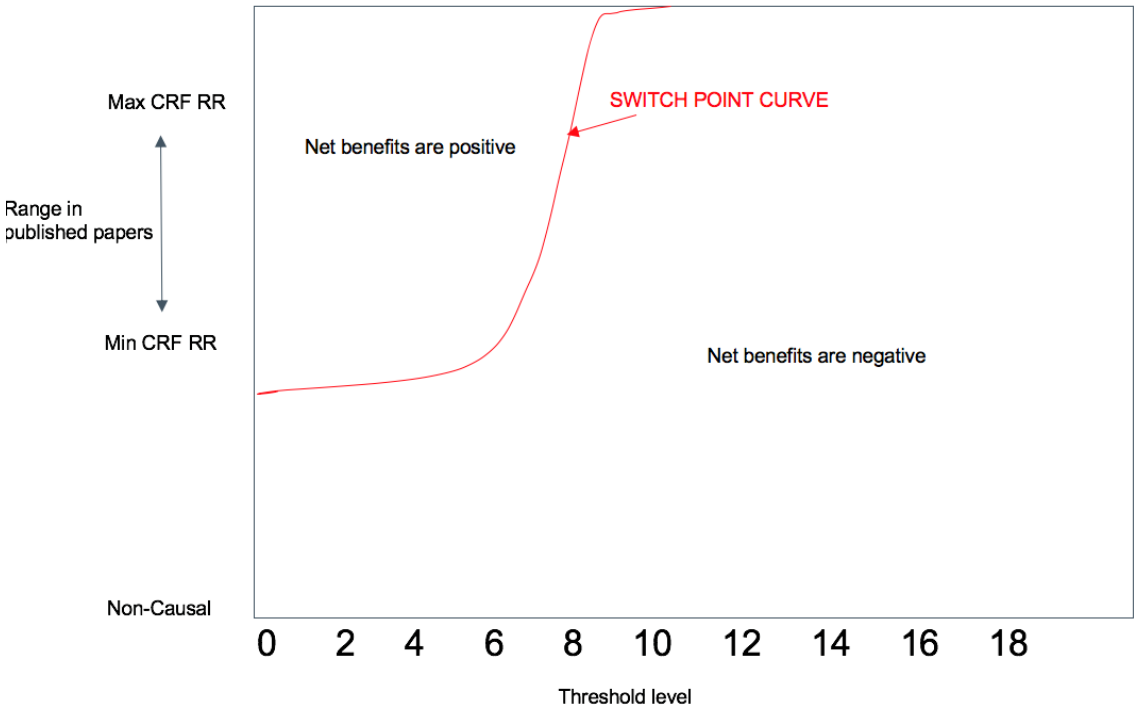
One of the tools EPA can apply in combining major sources of uncertainty builds on the concept of "switch points" discussed in EPA's 2020 Draft Economic Guidelines.[44] According to the Guidelines, switch points are defined as those conditions under which the economic analysis would recommend a different policy decision. They typically reflect the input parameter value where the estimated net benefits changes sign. As the Guidelines further note, switch points for key input parameters can be very informative and can help decision-makers understand how robust the analytic conclusions are.[45]

To be more helpful in situations involving more than one important uncertainty, the concept of switch points can be extended to "breakeven frontier" graphs that depict the sensitivity of the net benefits switch point to various combinations of two major uncertain BCA input assumptions. The resulting switch curve would represent the combinations of the uncertain variables (X and Y) that result in net benefits going from negative to positive. If additional major sources of

[44] EPA, Draft Economic Guidelines, pp. 5-21.
[45] *Id.*

uncertainty exist, EPA could create additional "breakeven frontier" graphs to depict the effects of those additional combinations of uncertainties.

The breakeven curves provide a way of demonstrating how two major sources uncertainties may combine to affect whether the proposed option in question will result in net benefits. In the following purely illustrative diagram, the two major hypothetical uncertainties used in this example (and discussed at length above) are the slope of the concentration-response function found in the literature and the existence and location of an undetected threshold.



In this diagram, the Y-axis reflects the uncertainty regarding the magnitude of the estimated concentration-response function in epidemiology studies, while the X-axis reflects the uncertainty regarding potential threshold levels. The curve shows the combinations of the two uncertain values that result in exactly zero net benefits, and thus defines the ranges of combinations of the uncertain input assumptions that would produce positive and negative net benefits. In this example, no probabilities are needed, but it can be seen what specific conditions can produce a positive BCA result, and readers can assess for themselves whether those are highly likely combinations or not. The likelihood of achieving positive net benefits would be directly quantified if EPA were to also identify its subjective judgments regarding the presence of a threshold and the concentration-response function, but this is not essential for a figure, such as this to shed greater transparency on the role of key uncertainties in determining the potential for the regulation be net beneficial. It provides decision makers with a clear framework to assess what conditions have to be true to decide if the regulation would be net beneficial.

The final rule should clarify that reduced-form models, such as benefits-per-ton estimates, that mask uncertainties should be rarely, if ever, used in significant CAA actions.

The major focus of the proposed rule, and these comments in support, is the proposed rule's emphasis on increasing transparency and exploring the uncertainties affecting the risk, benefit, and cost estimates. Use of reduced-form tools, such as benefits-per-ton, are back-of-the-envelope simplifications of benefit estimation that should rarely, if ever, be used in the context of BCA because they do little to explore uncertainties and can provide a misleading picture of benefits and their certainty. Benefit-per-ton estimates rely on only one or two concentration-response functions -- and do not address uncertainties regarding threshold, exposure misclassification or pollutant constituents to name just a few. Similar to the inappropriate use of meta-analysis discussed above, these summary measures conflict with the transparency goals of this rulemaking, in particular because their use prevents any sensitivity or uncertainty analysis to be conducted on key scientific uncertainties associated with the concentration-response relationship. The final rule should clarify that these tools are not permissible in assessing the benefits of significant proposed actions under the CAA.[46]

Describe qualitatively benefits that cannot be quantified if they are causal or likely causal.

Section 83.3(a)(8) of the proposed rule is correct in requiring the Agency to qualitatively characterize benefits that cannot be quantified or monetized. In qualitatively characterizing benefits, the final rule should require EPA to note in the characterization the causal classification of these potential benefits, including whether they are suggestive, likely causal or causal. This will help decision makers and the public understand the potential significance of the nonquantifiable benefits.

Report Value of Statistical Life (VSL) and the Value of a Statistical Life Year (VSLY) when monetizing benefits.

OMB Circular A-4 encourages agencies to monetize benefits using both VSL and VSLY based on the fact that the value of statistical life is not likely to be a single number relevant for all situations. According to Circular A-4, there may be significant differences between the effect on life expectancy for the population affected by a particular health risk and the populations studied. Use of VSLY can better reflect those differences.

By failing to report VSLY, EPA lags other agencies in providing more complete information on the risks and expected benefits of regulation. For instance, the U.S. Department of Health and Human Services (HHS) has routinely adopted VSL and VSLY in assessing the potential benefits of proposed regulations.[47] The federal Food and Drug Administration and Department of Transportation have also reported benefits using VSLY.[48]

[46] This is to be distinguished from costs-per-ton, which can be a useful metric with an appropriate role to address other considerations.

[47] U.S. Department of Health and Human Services, "Analytical Framework for Evaluating Anti-Bacterial Productions" 4/15/2014 at https://aspe.hhs.gov/report/analytical-framework-examining-value-antibacterial-products/364-value-statistical-life-vsl; *see also* U.S. Department of Health and Human Services Rule on Organ Procurement and Transportation Network, 63 Fed. Reg. 16296 (April 2, 1998)

[48] Use of Materials Derived From Cattle in Human Food and Cosmetics, 53 Fed. Reg. 14718 (March 16, 2016).

Kip Viscusi in his 2018 book "Guideposts for a Safer Society" addresses concerns that using VSLY could lead to lower valuations. According to Mr. Viscusi, using VSLY is likely to do just the opposite:

> Any concerns about the use of the VSLY leading to a devaluation of policies generating small life-expectancy gains are misplaced. The adoption of VSLY in the United States has boosted the assessed benefits of health-related policies associated with relatively small increases in life expectancy.[49]

The rationale for using both VSL and VSLY was cogently presented in 2004 by Cass Sunstein five years before he became OIRA Administrator:

> My simplest claim in this Essay is that in terms of welfare, it is fully appropriate to focus on life-years, not merely lives, and that both academic and public criticisms of the life years approach are misconceived. The reasons for this conclusion are simple. No program literally "saves" lives; life-extension is always what is at issue.[50]

In this same article, Sunstein goes on to suggest that, when "willingness to pay" is used as part of a BCA, "primary attention should be paid to VSLY rather than VSL."[51] The Associations concur and recommend that EPA use both VSL and VSLY in monetizing health benefits.

<u>EPA should report "private" benefits separately.</u>

In recent years, several economists working in the field of BCA have raised alarms over the government's growing tendency to count benefits that appear to assume that consumers' and firms' contrary choices are irrational or that the government can make better choices than firms and consumers. This issue affects the BCA of many EPA regulations.

The BCA of pollution control regulations that count individual or firm economic and product savings as societal benefits may assume that consumers and firms are not making rational decisions and that the objectives of government regulatory policy, to the exclusion of other objectives, are preferred. As Ted Gayer from Brookings explains regulatory "[s]tandards provide a valuable case study of how agencies can be blinded by parochial interests to assume not only that their mandate trumps all other concerns but also that economic actors outside of the agency are completely incapable of making sound decisions."

In many instances, consumer preferences that do not fully embrace the objectives of regulatory policies could in fact represent rational considerations, such as a higher discount rate, a different perspective on the perceived benefits, concerns over the loss of performance, and the potential for higher maintenance costs, to name just a few of the many factors affecting consumer and business decisions.

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[49] W. Kip Viscusi, Guideposts for a Safer Environment, (2018).
[50] Cass R. Sunstein, "Lives, Life Years, and Willingness to Pay," *Columbia Law Review*, vol. 104 (January 2004), pp. 205-252.
[51] *Id.* at 211.

While EPA can still report the societal benefits that may result from the rulemaking, such as benefits that result from the reduced pollution, the Agency should not count potential savings to the consumer or firm as public benefits if the government is mandating outcomes that are contrary to the firms' or individuals' preferences. By including these 'private" consumer or firm savings as a public or societal benefit, the BCA may end up counting as a public benefit what may actually be a loss to the firm or the individual. As Mr. Gayer explains: "a benefit-cost analysis that mistakenly assumes consumers (or producers) are systematically making irrational decisions will sacrifice welfare gains, too, as it will ignore valid, informed preferences of consumers (or producers); the resulting regulations could restrict and homogenize market choices and therefore harm the people involved."

For these reasons, EPA should adopt a policy that omits the calculation of private benefits that are premised on the irrationality of firms or consumer behavior. At a minimum, the Agency should report any such private "benefits" separately and note when reporting such benefits that the actions could result in losses to the consumer or firm.

The BCA should focus on benefits to people in the United States.

The proposed rule seeks comment on whether non-domestic benefits and costs of regulations, when examined, should be reported separately from domestic benefits and costs of such regulations, similar to how the proposed rule would provide for a separate presentation of benefits limited to those targeted by the relevant statutory provision or provisions. The Associations support the separate presentation of non-domestic benefits and costs from the domestic benefits and costs.

Separating domestic from the non-domestic benefits and costs helps ensure that any comparisons of benefits and costs are made on an equivalent basis. Moreover, only domestic benefits should be included in the net benefits tables. If non-domestic estimates are included, they should be presented separately. This will ensure that the U.S. public, which will bear the direct compliance costs of the policy, understands the benefits and costs that accrue to them alone.

Much of the policy regarding the reporting of domestic and non-domestic benefits and costs is well-established in a series of executive orders and agency guidance. For example, Executive Order 12866 makes clear that "the American people deserve a regulatory system that works for them, not against them." The Executive Order further explains in the "regulatory philosophy and principles" section that "[f]ederal agencies should promulgate only such regulations as are required by law…to protect or improve the health and safety of the public, the environment, or the well-being of the American people" (emphasis added). The focus of federal agency regulatory analysis should accordingly be U.S. citizens and residents. Separately presenting the domestic and non-domestic benefits and costs will thus further assist EPA in implementing its BCAs consistent with EO 12866.

Circular A-4 also emphasizes that agencies should focus on domestic effects. The Circular states, "[the agency's] analysis should focus on benefits and costs that accrue to citizens and residents of the United States" (emphasis added). The Circular goes further to explain to agencies that, for

"regulation that is likely to have effects beyond the borders of the United States…effects should be reported separately."

Several decades of executive orders and guidance explain the philosophy and need for federal agencies to focus on domestic costs and benefits. While the focus of regulatory policy in these government-wide policy documents is on the impacts to American citizens, the centralized government-wide guidance issued by OMB also instructs agencies to separately report the domestic from the non-domestic benefits and costs.

h. The rule should also include the following best practices to ensure a full and objective accounting of regulatory costs.

Specifically, the final rule should require EPA to assess the direct, indirect, explicit, and implicit costs of proposed significant regulatory actions and their alternatives when feasible consistent with the recommendations below.

Compliance Costs

The proposed definition of "social cost," while accurate, does not provide sufficient information or steps to assure that EPA's benefit-cost analysis includes all the necessary cost elements. To ensure a comprehensive and clear analysis of costs, EPA should include following definitions in the final rule that are based on EPA's 2010 Economic Guidelines.[52]

Explicit Costs are those costs for which an explicit monetary payment is made, or for which it is straightforward to infer a value.

Implicit Costs are those costs that include the value of current and future lost output, the lost value of product variety, time costs of searching for substitutes, and reduced flexibility in responding to changes in market conditions.

Direct Costs are those costs that fall directly on regulated entities as the result of the imposition of a regulation. They include all explicit and implicit costs that regulated entities will bear.

Indirect Costs are the costs incurred by entities with direct market ties to the regulated entities, or experienced by sectors, consumers or government agencies not under the direct scope of the regulation.

The final rule should also include requirements that specify the specific cost factors that should be examined. For example, while EPA typically includes capital and operational costs associated with control technologies on existing systems, facilities often face additional costs that should be evaluated. These may include engineering, design, and installation costs associated with required technologies, as well as transitional costs associated with training workers to operate equipment and systems, and costs associated with production outages during the transitional period. While

[52] Guidelines for Preparing Economic Analysis, EE-0568, U.S. Environmental Protection Agency, (2010, revised 2014).

estimating such costs can be challenging due to variations in site-specific circumstances, the final rule should require the Agency to undertake efforts to develop a reasonable range of estimates that reflects these activities.

Executive orders and various statutes support the inclusion of these costs estimates in EPA's BCA. EO 12866 specifies that an assessment of the costs of a regulation should include "any adverse effects on the efficient functioning of the economy and private sector (including productivity, employment, and competitiveness)" in addition to compliance costs.[53] The Unfunded Mandates Reform Act of 1995 requires that cost estimates take into account both indirect and implicit costs on state and local governments. The Congressional Review Act places an emphasis on agency analysis to determine whether there is "a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions….".

In addition to the potential for CAA regulations to impose indirect costs on state and local governments, there may be implicit costs imposed on regulated entities due to output lost when shifting limited resources. This shift in resources means that it could cost more money to produce the same unit of output and may reduce the value of product variety as a result of restrictions on the production of certain goods. It may also increase product research and development costs while regulated entities the search for and develop substitute products. The long-term effect of these implicit costs can be reduced economic growth, and reduced prospects for worker income levels on a widespread and permanent basis. Accounting for these implicit costs in EPA's BCAs would help provide more transparency into the economic impacts of the Agency's regulations.

Cost Modeling Methods

The preamble to the proposed rule provides a discussion of three alternative levels of complexity for cost analysis modeling, engineering-based cost estimation, partial equilibrium (PE) modeling, and computable general equilibrium (CGE) modeling. It identifies the general conditions under which a BCA should use a higher level of complexity for its cost analysis.[54] In brief, a PE level of modeling is necessary when the sector(s) affected by a regulation will likely respond with behavioral changes, but which are confined to a small number of markets/sectors. A CGE level of modeling becomes important when broader economy-wide impacts are expected that would not be captured by a PE model of just a few markets (and also when long-term economic productivity impacts may occur). This is most likely to result when regulatory costs are likely to be passed through into product prices – and especially when those products are broadly consumed by many other sectors. The proposed rule itself, however, is silent on any requirements for best practices in cost analysis, while having much to say about requirements for the conduct of the benefits and associated risk analyses that are input to a BCA. The final rule should be expanded to include procedural requirements for cost modeling decisions, as described below, to transparently show how best practices are also being applied for the cost side of each BCA.

[53] Exec. Order No. 12866, Sec. 6(a)(3)(C)(ii), (1993).
[54] See NPRM at pp. 35619-20.

Choosing the appropriate complexity for the cost analysis involves regulation-specific professional judgment.[55] The Associations therefore recommend against adoption of any bright lines to determine when a PE model would be necessary, and/or when a CGE model becomes an essential supplement to a PE analysis. However, we do recommend that the rule require that the cost modeling decisions be discussed in an explicit and transparent manner for each significant rulemaking BCA.[56] If an engineering-based cost estimate is all that is used, data should be provided to support EPA's view that the affected sectors' actions will have de minimis impacts on their suppliers and on the sector's product prices. If the cost analysis uses only a PE model, EPA should evaluate its projected price and output results to make the case that there is de minimis possibility that these effects might filter into the economy at large. Such a case might be made if the affected sector is very narrow (e.g., accounts for a minimal share of GDP or is a small segment of the sector that it is a part of), if it has only a narrow range of suppliers, if the affected sector supplies only a narrow segment of the economy, if it has little trade exposure, and/or if the other cost model(s) project a de minimis product price effect. Recognizing that no bright lines can be drawn for any one of these criteria, the explanation supporting a decision not to use a CGE analysis should consider all the criteria as a set. However, when a regulation will affect a sector that supplies a wide swath of the economy (i.e., for regulations targeting either electricity, natural gas, or petroleum product production), the final rule should specify that CGE analysis will be treated as the presumptive cost evaluation method, and if CGE is not used, the BCA should be accompanied by a detailed explanation of why even small price effects in the affected sector's outputs would not be expected to have economy-wide effects.[57]

The proposed rule's preamble focuses solely on how well the different types of cost models can be expected to estimate total social cost. We recommend that the rule expand its recognition of the role of economy-wide modeling plays in policy evaluation. That is, in addition to providing theoretically correct estimates of total social cost, CGE models provide important additional economic impact information, such as the geographic, sectoral and income distribution of a regulation's burden, energy, and employment impacts. Such information is generally expected of RIAs. The final rule should also therefore require that the discussion of the decision on cost modeling method associated with a rulemaking should specifically address the need to understand potential economic impacts at an economy-wide level, and whether the selected cost modeling method(s) can provide such information.

The greater complexity of CGE modeling entails greater uncertainty. However, it will be more valuable to obtain insight on the potential significance of economy-wide effects than to have a narrow but inaccurate point estimate of the social cost that is inaccurate because it misses important economy-wide effects. This tradeoff should be addressed by adding a requirement in

[55] This view is consistent with the NPRM at 35619: "[A] good regulatory analysis cannot be developed according to a formula. Conducting high-quality analysis requires competent professional judgment….For example, the extent to which compliance cost is a sufficient measure of social costs will depend on whether a regulation is expected to result in changes in prices and quantities within and across markets."

[56] This specific requirement would be in accordance with the principles stated in the NRPM at 35627: "The Agency must describe the models, data, and assumptions used to estimate benefits and costs, and the evaluation and selection process for these analytical decisions."

[57] We note that a CGE model can be used in combination with an engineering or PE model, in cases where the latter can provide more informed estimates of compliance spending, while the former can provide insights about how such costs (capital and operating) would be likely to filter through the rest of the economy.

the final rule for transparent evaluation of model uncertainty in the cost estimate. Regardless of the level of cost modeling that is decided, the final rule should require that the regulatory cost estimates (and other economic impact estimates) be presented in a manner that conveys their uncertainty, and a reasoned explanation for methods selected to analyze those uncertainties.[58] Recognizing that the more complex forms of cost models also are more affected by model uncertainty than by statistical uncertainty, the final rule should specify that the Agency must provide a plausible range of cost estimates developed via individual and joint sensitivity analyses that vary the most critical ("sensitive") model parameters. A discussion of the evidence supporting the alternative model parameters used to develop these plausible alternative estimates must also be provided.

EPA should also require transparent analysis of the full employment impacts of significant rulemakings.

Performing economy-wide modeling can help more accurately estimate the broader impacts of a regulation on employment, but additional types of analysis may be important. Section 321(a) of the CAA specifically calls on EPA to "conduct continuing evaluations of potential loss or shifts of employment which may result from the administration or enforcement" of the CAA, and to investigate "threatened plant closures or reduction in employment."[59] Congress recognized early on that regulations -- particularly environmental regulations -- may impose significant long-term burdens on businesses and workers, as discussed further below. Including more on these employment impacts, beyond just listing projected changes in job numbers, would provide helpful input to the public and policymakers, and should be required in the final rule.

It is important to capture the impacts of regulations on displaced workers that often remain unemployed when displaced from long-held jobs. In 2012, the Bureau of Labor Statistics' Displaced Worker Survey went out to 6.1 million workers who lost long-tenured jobs and found that 44 percent were still unemployed up to three years after losing their full-time jobs.[60] Not only do these job losses cut off workers' incomes for themselves, but their unemployment also impacts their families and communities. It is important that a BCA capture the social impact of such enduring employment impacts.

Becoming unemployed after having a long-tenured job may mean the loss of health insurance, increased food insecurity, detrimental effects on physical and mental health, and other indirect impacts. Workers who lose long-term jobs may find it more difficult to transition to another field, even if training is provided, and may prefer to remain in their community as opposed to moving elsewhere in search of work. The longer someone is unemployed, the more difficult it may be to rejoin the workforce. Returning workers may have depressed wages on rejoining the workforce, leading to permanent reductions in lifetime earnings and wages.[61]

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[58] This specific requirement would be in accordance with the NPRM at 35627: the Agency "must present benefits and cost estimates in ways that convey their uncertainty. The Agency must provide a reasoned explanation for the scope and specific quantitative or qualitative methods chosen to analyze uncertainties."

[59] Clean Air Act, 42 U.S.C. § 7621.

[60] Impacts of Regulations on Employment, Examining EPA's Oft-Repeated Claims that Regulations Create Jobs, U.S. Chamber of Commerce, 2013.

[61] Measuring the True Impact of Job Loss on Future Earnings, P. Krolikowski, Federal Reserve Bank of Cleveland, 2017.

In addition to the impacts on individuals and families, shuttering large industrial facilities has often imposed indirect costs on state and local governments due to a lower tax base. Moreover, when an industrial facility closes, there have typically been spillover impacts to associated businesses such as restaurants, hotels, and others that provide services and supply chain support to the facility. It is important that the Agency work to capture these impacts in regulatory cost estimates.

The final rule should require a discussion in the BCA of the most appropriate analysis methods for addressing the types of employment impacts described above, and if such methods are not applied as part of the BCA, the Agency should be required to provide a qualitative discussion and assessment of their potential magnitude.

The rule should require EPA to use the current discount rates specified in OMB Circular A-4.

Although the Agency did not discuss the application of social discount rates to the future benefit and cost estimates of agency regulatory analysis, it is an important topic. Applying social discount rates to future benefits and costs helps adjust for the fact that they occur at different time periods in the future, and that people value consumption today over consumption in the future. In terms of the precise discount rates to use, we support the use of OMB's current discount rates specified in Circular A-4 at three percent and seven percent when estimating the future value of future benefits and costs.

In 2003, OMB revised its guidance to agencies on the appropriate discount rate to apply to future estimates of benefits and costs. The discount rate OMB had previously instructed agencies to apply was a single rate—10 percent—and had been applied for two decades prior to 2003. Transitioning from a single discount rate number to two different rates provides more insight into the time-dependent range of benefits and costs that are estimated for regulations. Providing a range is helpful from a pragmatic standpoint as policy makers make decisions between policy alternatives.

The rule should limit departures from the rule to instances where application of the rule is technically infeasible and EPA has sought public comment on the use of the exemption.

Section 83.3(b) of the proposed rule states that EPA must provide a reasoned explanation for any departures from best practices in the BCA, including a discussion of the likely effect of the departures on the results of the BCA. While the Associations recognize that there may be instances where departures are necessary, the final rule should limit this authority to instances where: (1) the application of the requirements are technically infeasible; and (2) EPA has provided notice and sought public comment on its proposed decision to depart from the rule's requirements.

EPA should present BCA in a manner consistent with reasoned economic and scientific judgements about uncertainties. In addition, the net benefits of each CAA rule should be presented based on the targeted pollutant without co-benefits, before presenting the net benefits including co-benefits.

The Associations generally support these presentation-related transparency requirements that comport with many of the most important elements of the Information Quality Act. The presentation of the results of the analysis is a critical component of the BCA. In presenting the results, EPA should avoid presenting summary statistics that omit uncertainties or that do not reflect the full range of uncertainties. Care should be taken to present the full range of uncertainties based on the full range of concentration-response functions, and the impact of other key scientific uncertainties that may not be captured in the concentration-response function, such as the existence and level of potential thresholds. While central tendency estimates should be presented along with the full range, the presentation should not present central tendency estimates in isolation.

As discussed above, the Associations recommend that EPA consider using presentation tools such as break-even diagrams as ways of exploring how major uncertainties can be combined. In all cases, EPA should make every effort to identify explicit and implicit assumptions that involve policy choices.

As discussed above, in presenting summary information of the results of the BCA, EPA should also include in the preamble and in the BCA the results of a determination of whether the statutory-objective benefits justify the costs of the recommended option. If the Agency selects an option where the benefits fail to justify the costs, EPA should include in the summary the reasons why EPA was compelled to select an option with higher costs than benefits.

i. Issues with criteria pollutant co-benefits and how to resolve them through greater consistency in the risk analysis underlying the benefits calculations.

The first part of these comments has explained the legal basis for excluding criteria pollutant co-benefits as the primary justification for any regulation under the CAA. There are also sound policy reasons for an approach that segregates and presents net benefits without co-benefits. Notably, a large number of the highly impactful regulations promulgated under the CAA are not determined by benefit-cost or net benefit considerations. Instead the standards are based solely on risk considerations, such as the primary NAAQS under Section 109. Even though EPA cannot directly consider the benefit-cost analysis in setting NAAQS, the BCA for alternative NAAQS standards under consideration provides valuable information to Congress and the public about how well different portions of a statute are performing in attaining their original objectives, and whether the design of any particular portions of the statute merits reconsideration. In other words, RIAs should help guide regulatory design under current statute design, but should also, over a longer view, help guide statute design.

This need for transparency has important implications for the role of co-benefits. RIAs (or other types of BCA documents) that obscure the relative benefits from the targeted pollutant reductions behind purported benefits due to other pollutants that are already strictly regulated by other portions of the same statute fail to be useful in informing improved policy design. Worse, they can become a force to promote substantial regulatory complexity that can severely hamper business and consumer decision making while doing little or nothing to improve the overall

public health and environmental amenities that could be attained by a simpler and more focused effort to address the most significant sources of air pollutant risks.

If the CAA were to require optimization of the total benefits from all types of air pollutants simultaneously, then co-benefits from other air pollutants would evaporate as a concept – all air pollutant benefits would be targeted benefits.[62] However, such optimization is not the reality under the CAA. The CAA is structured to address different types of pollutants under different provisions, with very different criteria or objectives. These different criteria imply different kinds of societal value judgments, or trade-offs -- some of which directly disallow net benefit optimization, and indeed require a regulatory stringency that exceeds the BCA optimum for that pollutant.[63] To let estimates of co-benefits for criteria pollutants to provide the main BCA-based justification for regulation of other air pollutants would be tantamount to letting the *concept* of BCA drive regulation of a criteria pollutant even further beyond its benefit-cost optimum.

Fortunately, this seeming conundrum is easily resolved if the co-benefits are calculated in a manner that is consistent with the Administrator's judgments that there are de minimis expected public health risks from criteria pollutant exposures below the primary NAAQS, after accounting for scientific uncertainties. In other words, the consistent risk assumption is that there *are* no expected co-benefits from reductions of a criteria pollutant in locations where it is already below its primary NAAQS. By simply making the calculation of criteria pollutant co-benefits using statutorily consistent assumptions, inclusion of such co-benefits in a BCA for a non-criteria pollutant regulation will not be unreasonable to do but will be quite small in magnitude as long as implementation of the NAAQS is included in the benefits analysis's emissions baseline(s), as it should be.

We thus strongly recommend that criteria pollutant benefits and co-benefits be calculated using assumptions consistent with the regulatory determination that each NAAQS protects the public health with an adequate margin of safety. Specifically, this means that only potential coincidental reductions of criteria pollutants that are projected to occur in locations with ambient concentrations still above the NAAQS should be considered for inclusion in a net benefits calculation. Any co-benefits that are calculated in locations with baseline concentrations *below* the NAAQS should not be included in a net total benefits calculation, nor presented in a summary net benefits presentation because they are inconsistent with legally binding statutory determinations and should not be considered reliable. Appendix 1 provides a more extended discussion of the basis for this recommendation.

j. Transparency in presentation of net benefits.

[62] Other forms of ancillary benefits -- i.e., benefits from reducing phenomena that are not, in and of themselves, air quality-related -- would remain as a relevant consideration even when considering alternative multi-pollutant regulations.

[63] For example, the requirement that a primary NAAQS protect the public health with an adequate margin of safety without regard to cost implies an outcome in which the expected value of marginal costs is nearing zero. Since control costs normally rise at a linear or even greater rate, the statutorily correct primary NAAQS standard will be more stringent than the optimum that would be prescribed by benefit-cost analysis.

The proposed BCA rule calls for a two-stage method for presenting its results.[64] In the first, it would require that an aggregate "net benefits" table be provided in the preamble of the regulation, "consistent with E.O. 12866 in CAA rulemakings." The second stage would then present an analysis that separates the benefits into targeted and non-targeted benefits and presents net benefits using just the targeted benefits. The proposed rule requests comment on alternative presentation formats to the two-stage format presently proposed.[65] Below, we comment on the inadequacies of the proposed two-stage method and provide our recommendation for an alternative single-stage presentation format that will achieve greater transparency regarding net targeted benefits without sacrificing consistency with RIA guidance on presenting net total benefits.

As discussed in earlier sections, the Associations believe that because benefit-cost analysis is not the objective for determining the level of stringency under most of these segments of the CAA, net targeted benefits should be given the primary attention in a discussion of the justification for each significant regulatory action and should be presented as an integral part of the first table summarizing the analysis results. Mandating that targeted components of net benefits be presented separately in the executive summary would be an improvement over most of past practice. However, we find that the use of two tables, even if required to be presented in immediate sequence, unacceptably diminishes the importance of clarifying to policy makers and the public how well the regulation serves its statutory objectives. It is also very confusing, as is evident from a review of the RIA for the final ACE rule (EPA, 2019),[66] which appears to meet the intent of the proposed rule's presentation requirements.

We also note that net total benefits that include co-benefits from pollutants regulated under other segments of the CAA can only misguide the long-term process of policy design improvement, <u>if</u>

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[64] NPRM p. 35622: ("EPA proposes to codify into regulation two presentational requirements for the preamble of all future significant CAA regulations. First, in order to ensure standardized presentation of the summary of the benefit-cost analysis results consistent with E.O. 12866 in CAA rulemakings, EPA proposes to codify into regulation the requirement to present a summary in the preamble of the overall benefit-cost analysis results, including total costs, benefits, and net benefits. Second, to enhance transparency about the extent to which a rule is achieving its statutory objectives, EPA proposes, in addition to a clear reporting of the overall results of the benefit-cost analysis, an additional presentation in the preamble of the public health and welfare benefits that pertain to the specific objective (or objectives, as the case may be) of the CAA provision or provisions under which the rule is promulgated. This second presentation would include a listing of the benefit categories arising from the environmental improvement that is targeted by the relevant statutory provision, or provisions and would report the monetized value to society of these benefits.")

[65] NPRM p. 35623-4: "EPA requests comment on alternative approaches to increasing transparency about the extent to which a rule is achieving its statutory objectives. In particular, EPA solicits comment on whether, instead of, or in addition to, the presentational requirements proposed in Section IV.C of this preamble, EPA should require a detailed disaggregation of both benefit and cost categories within the table that summarizes the overall results of the benefit-cost analysis in the preamble of future significant CAA rulemakings. The goal of this disaggregation would be to clarify what public health and welfare benefits pertain to the specific statutory objective, or objectives, of the CAA provision, or provisions, under which the rule is promulgated, but would allow the reader to see this information in the same location as the estimates of all the other welfare effects, both positive and negative, resulting from the regulation."

[66] EPA. 2019. *Regulatory Impact Analysis for the Repeal of the Clean Power Plan, and the Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units.* EPA-452/R-19-003. Office of Air Quality Planning and Standards, Health and Environmental Impact Division, Research Triangle Park, NC June. https://www.epa.gov/sites/production/files/2019-06/documents/utilities_ria_final_cpp_repeal_and_ace_2019-06.pdf

they are calculated with the inconsistent assumptions described above. We thus also recommend that the final rule require that any summary table, whether in the two-stage format proposed, or following our recommend one-table alternative, should only include co-benefits from criteria pollutant health effects that are calculated with consistent input assumptions.

The one-table format we recommend would have the following structure. Its rows would report benefits and associated net benefits in three distinct layers of relevance to the policy evaluation. It would start with a summary of the aggregated targeted benefits, then incorporate aggregated ancillary benefits for co-incidental effects not tied to health effects of criteria pollutant, and end with aggregated benefits for criteria pollutant co-benefits that are calculated only for baseline ambient concentrations above the NAAQS (i.e., using assumptions consistent with those used for each respective criteria pollutant's NAAQS regulatory determinations). The calculated cumulative net benefits as of each incremental row of the table would be provided in an additional column, so that the top row would provide the net targeted benefits, and the bottom row would present the net total benefits that are required under EO 12866.

Table 1 below provides an illustrative example of our recommended single-summary table presentation, based on the present value estimates of benefits and costs[67] that are reported in the first two tables in the executive summary of the RIA for the final ACE rule (EPA, 2019).[68] The result on the row labelled "Net Targeted Benefits" is the same as the result in RIA Table ES-2, and the result on the row labelled "Net Total Benefits" is the same as the result in RIA Table ES-1. (Copies of these two tables from the ACE RIA are provided in Appendix 2.) Although the final ACE RIA did not provide any ancillary benefits estimates other than those for criteria pollutant health effects, we recommend that the summary table include such an intermediate row, allowing for recognition that there are more forms of ancillary benefits than those associated with reductions in criteria pollutants below their NAAQS levels, and to keep those less controversial forms of ancillary benefits in a separate category when moving from net targeted benefits to net benefits that includes the consistently-calculated criteria pollutant health co-benefits.

The final row of Table 1 reports criteria pollutant co-benefits from that RIA (both $PM_{2.5}$ and ozone), but only those that are associated with populations in areas with baseline concentrations exceeding their respective NAAQS levels. Thus, the results shown in Table 1 cannot be immediately observed in the RIA Tables ES-1 and ES-2. They are, nevertheless, based on information in later parts of the RIA.[69]

[67] Best practice calls for use of present values, but if a BCA were to also report results in equivalent annualized values, these could be presented in a separate table. The information about the net benefits at each stage from targeted to total does not change in relative terms, so we would recommend against providing the additional way of presenting benefit-cost analysis results unless a case can be made that it has independent usefulness.

[68] Copies of the original two tables from EPA (2019) are provided in Appendix 2.

[69] The RIA tables contain $PM_{2.5}$ and ozone co-benefits calculated down to zero concentrations, which are $4,000 to $9,800 for the 3% discount rate and $2,000 to $5,000 for the 7% discount rate. To estimate consistently calculated co-benefits, we used information in the RIA itself reporting that <1% its $PM_{2.5}$ co-benefits reported to be in areas projected to still exceed the $PM_{2.5}$ NAAQS. The RIA does not report similar information for ozone, so we have assumed that 5% of its ozone co-benefits occur in areas projected to still exceed the ozone NAAQS -- hence, we call this example table an illustrative one.

As can be seen, net targeted benefits appear as the first category of net benefits, and are given visual emphasis (-$980 million and -$910 million, respectively). The bottom line presents the net total benefits that the proposed BCA rule says is required under EO 12866. In this illustrative example, net total benefits are also negative, because this summary table includes only co-benefits that are consistently estimated. If any other estimates of co-benefits that violate the consistency assumption were to be calculated, they should be required to be reported separately and not shown in the summary table that would be mandated under the final rule.

Table 1. Illustrative Example of One-Stage Method for Presenting Net Targeted and Net Total Benefits with Consistent Assumptions for Co-Benefits Estimates from the Final ACE RIA (Present Value Method, millions of 2016$)

	3% Discount Rate		**7% Discount Rate**	
	Quantified Estimates	Cumulative Net Ben	Quantified Estimates	Cumulative Net Ben
Social costs	$1,600	-$1,600	$970	-$970
Targeted benefits	$640		$62	
Net Targeted Benefits		**-$980**		**-$910**
Ancillary benefits	n/a		n/a	
Net Targeted & Ancillary Benefits		-$980		-$910
Criteria pollutant health co-benefits *calculated consistently*	$47 to 137		$37 to 113	
Net Total Benefits		-$933 to -$843		-$933 to -$797

The example format of Table 1 does not reference non-quantified benefits but this is solely because the ACE RIA summary tables that it is based on also do not indicate presence of non-quantified benefits. However, it would be perfectly reasonable to add descriptors and notes where significant forms of unquantified benefits are believed to exist. Another example of this one-step net benefits summary format based on the more complex RIA for the proposed Mercury and Air Toxics Standards[70] is provided in Appendix 2. That example shows how the presence of unquantified benefits can also be recognized in the tabular summary.

We emphasize that the recommended summary table does not provide disaggregated details of all the underlying benefits that are accounted for in the column of "quantified estimates." This is not to suggest that the additional disaggregated detail is unimportant, but only that such details can be provided in a more detailed format following the provision of this high-level summary of the key outcomes of the benefit-cost analysis calculations.

In summary, the proposed single summary table format can eliminate the potential for confusion among readers about the relationship between the two alternative net benefit estimates, simplifies

[70] EPA. 2011. *Regulatory Impact Analysis of the Proposed Toxics Rule: Final Report.* March. https://www.epa.gov/sites/production/files/2020-07/documents/utilities_ria_proposed-mact-nsps_2011-03.pdf

the summary of the benefit-cost analysis results, and remains consistent with the requirements of EO 12866. It thus furthers a key objective of the Proposed rule that "[t]he EPA proposes that the benefits, costs, and net benefits of each regulatory option evaluated in the benefit-cost analysis be presented in a manner designed to be objective, comprehensive, and easily understood by the public."

H. The Associations offer the following additional comments on key issues raised in the proposed rule.

a. EPA's proposed framework for conducting BCA is appropriate; additional improvements are recommended.

<u>The final rule should focus on significant regulations.</u>

Regarding EPA's request for comment on the economic significance threshold for requiring a BCA to be undertaken, we recommend that the rulemaking should apply to any rule projected to have an effect on the economy of $100 million or more in a given year, or otherwise projected to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities."

Applying the BCA rule in this way will promote the better understanding of the potential impacts of the regulation on consumers, individual industries, and federal, state, and local governments. Preparing this information and presenting it to the public will provide for more opportunity to comment on various provisions of the rulemaking to promote better, more transparent regulatory policy.

With regard to EPA's request for comment on whether the Agency should adjust for inflation the economically significant threshold of $100 million in benefits, costs, or transfers in any given year, we recommend that the Agency not make any inflation adjustments. One reason not to inflate the $100 million threshold is to maintain consistency with EO 12866, which is not inflation adjusted. Creating an inflation adjusted number will only create confusion concerning the definition and which set of standards apply. Another reason to not adjust the threshold for inflation is that increasingly stringent emissions standards may mean an ever growing number of smaller businesses to could be impacted, and those businesses would benefit from the proposed rule's transparency and other provisions.

<u>The proposed regulatory framework is appropriate and could be improved with additional clarifications.</u>

The proposed rule would require that benefit-cost analyses produced by the Agency must consist of three elements: a statement of need, examination of regulatory options, and an assessment of all benefits and costs of these options relative to a baseline scenario. This overarching framework is appropriate and necessary to achieve the goals of the rulemaking.

We support requiring inclusion of a statement of need that establishes the rationale and purpose underlying the rulemaking, consistent with agency guidance detailed in OMB Circular A-4 and Executive Order 12866. A concise and coherent statement of need helps to set the foundation for developing the subsequent analysis of benefits and costs, particularly as it relates to assessing environmental or public health improvements targeted by the relevant statutory provision from which the rule derives its authority.

The proposed rule would also require EPA to analyze the benefits and costs of at least three regulatory options – one more stringent and one less stringent than the proposed or finalized option. This provides decision makers and the public with important perspective on not only the various options' relative impact on net social benefits, but also the sensitivity of stringency options on other individual factors that comprise the overall forecasts. This perspective adds granularity to complex, nuanced decisions and helps stakeholders better understand the direction and magnitude of alternatives to the preferred option.

In addition to those three regulatory options, the Agency should also consider a fourth option, the implementation of voluntary programs. Such an approach would need to be appropriate to the circumstances.

Additionally, in preparing BCAs, the Agency must develop a baseline that appropriately considers relevant factors based on transparent and reasonable assumptions. Without such a baseline, accurate assessment of (and comparisons between) proposed policy options is not possible. As noted in the proposed rule, a reasonable baseline must attempt to account for exogenous changes in the economy that could have large impacts on benefit-cost analysis projections (e.g., changes in demographics, economic activity, consumer preferences, or technology).

In cases with highly uncertain or interdependent baseline scenarios, it may be advisable for the BCAs to incorporate multiple baselines that account for these varying factors. For example, multiple baseline scenarios may be warranted when the accuracy and precision of baseline inputs are both highly influential and highly uncertain. Similarly, in the event of two or more proposed rules overlapping in time and scope of impact, the BCAs of these rules should include multiple baselines to limit potential double-counting of both costs and benefits.

The issue of double-counting of benefits has been a particular concern with past EPA BCAs under the CAA. Smith (2011)[71] found that the simultaneous advancement of multiple CAA-related rulemakings resulted in changes between proposed and final RIAs' baseline assumptions about implementation of other regulations that created inconsistencies in BCA estimates between the proposed and final stages and revealed examples of double-counting. For example, during 2011, 4 proposed and 7 final CAA regulatory impact analyses were released, each of which typically did not incorporate projected benefits from the other concurrent rulemakings.[72] For one rule, the changing baseline was the primary reason why $PM_{2.5}$ related co-benefits for mortality

[71] Smith, A.E. 2011. "An Evaluation of the $PM_{2.5}$ Health Benefits Estimates in Regulatory Impact Analyses for Recent Air Regulations," Final Report NERA Economic Consulting. Available at: https://www.nera.com/content/dam/nera/publications/archive2/PUB_RIA_Critique_Final_Report_1211.pdf
[72] *Id.* p. 29.

fell from 17,000 to 11,000 (35%) between the proposed and final versions of the rule.[73] As the report concluded:

> It is nearly impossible to keep the baselines straight when multiple regulations are in the proposal stage at the same time. However, a simple prescription can be applied to EPA's current practice that would help minimize the problem. If any RIA will be accounting for co-benefits from a pollutant that it does not directly address, such as those from $PM_{2.5}$ in a NESHAP rulemaking, then the baseline for that RIA should include "existing" rules, even if not fully implemented yet. It should also explicitly incorporate any reasonably anticipated future standards and/or rulemakings that will deal with that pollutant before allowing any co-benefits from that pollutant to be counted in some unrelated RIA. This may be an uncertain task, but it can certainly be handled by at least considering two baselines:
>
> > Baseline A: Include only the present level of current standards, but ensure that all of them are simulated as attained at their respective attainment deadlines.
> > Baseline B: Incorporate reasoned assumptions regarding levels of new regulations that are known to be on the verge of modification, even if not yet promulgated or even proposed, and accounting for their future attainment deadlines.[74]

This recommendation is consistent with the guidance of OMB Circular A-4, which states "When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines."

b. EPA should conduct periodic retrospective analysis of major CAA regulatory programs if EPA has can assess health or the environment outcomes using metrics that are independent from the measurements and estimation methods that were used to justify the rule.

Executive Order 13563, "Improving Regulation and Regulatory Review," requires agencies to "consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome." Notwithstanding this requirement, EPA has historically not taken meaningful steps to improve existing regulations and rulemaking processes through retrospective review and has instead devoted the bulk of its resources to the development and issuance of new regulations.

Retrospective analyses, however, could provide useful data to help EPA improve environmental outcomes while minimizing regulatory burdens.[75] Retrospective analyses will not only help EPA promulgate better regulations; they can help EPA improve the analytical framework through

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[73] *Ibid.*
[74] *Id.* pp. 30-31.
[75] *See* Tengs, Tammy O., and John D. Graham. "The opportunity costs of haphazard social investments in lifesaving." In Risks, costs, and lives saved: Getting better results from regulation, Robert Hahn, Ed. (1996): 172; s*ee also* Aldy, Joseph E. "Learning from experience: an assessment of the retrospective reviews of agency rules and the evidence for improving the design and implementation of regulatory policy." Administrative Conference of the United States (2014).

which the Agency makes regulatory decisions. Unless EPA looks back to evaluate its prior analyses of costs and benefits of rules, it is unlikely to substantially improve its prospective analyses. Once a rule has been finalized and implemented, EPA has an opportunity to examine whether the Agency's prior projections of risks, benefits, and costs were reasonable. This is useful data in identifying sources of over-and under-estimation and provides a basis for more realistic calibration of prospective estimates.

While the Associations support EPA's interest in conducting more retrospective reviews of its regulations, we caution that there are many challenges which EPA must first work through before undertaking any extensive efforts. Additionally, retrospective review of cost and benefits can be a resource intensive effort for both the Agency and the impacted industry. EPA will need to ensure that the retrospective reviews are conducted to minimize the costs on the Agency and industry and still yield meaningful improvements to the Agency's cost and benefit calculations. The Associations suggest that EPA ensure that the impacted industry has the ability and desire to support such an effort. Stated differently, EPA could refrain from conducting a retrospective review unless the impacted industry requests such an effort for a specific rulemaking. If there is a process to initiate this effort in advance of an industry's efforts to achieve compliance with a rule, tracking of costs could be significantly improved.

That said, there are still many complications which create challenges in accurately conducting a retrospective review to deliver meaningful results. EPA will need to address these challenges prior to engaging with any specific retrospective review. One such complication is that it is very difficult to calculate ex post costs that can reliably be compared to ex ante compliance cost estimates. EPA's Science Advisory Board (SAB) noted this difficulty in 2012 when it was asked to review and comment on the Retrospective Cost Study of the Costs of EPA Regulations: An Interim Report of Five Case Studies (March 2012) (RCS). The RCS was composed of five case studies developed by EPA's National Center for Environmental Economics (NCEE) to investigate how well the Agency has predicted the costs of regulatory compliance by comparing EPA's cost estimates to ex post costs.

Dr. Anne E. Smith of NERA Economic Consulting provided written comments and testimony in the SAB's proceedings. As noted in those comments, in retrospective comparisons of costs, it is difficult to establish the counterfactual, and to separate regulation-specific costs from other simultaneously-occurring costs. These difficulties are no different than the difficulties of establishing an appropriate baseline when estimating future compliance costs. This implies that ex post estimates may be no more reliable than their ex ante counterparts. As such, EPA's efforts to improve the means by which it estimates costs can also improve the Agency's ability to analyze compliance costs retrospectively.

As discussed above, EPA's cost estimates have generally been limited to consideration of the costs of installing and running the technologies that will control the emissions/effluents that are the target of the regulation, and not the potential secondary costs incurred by the control technology's interference with other functions of the total plant system or the long-term macro-economic impacts on overall economic productivity. The Associations recommend that EPA focus on improving the Agency's consideration of these costs in cost-benefit analyses as a means to also improve EPA's ability to evaluate these costs retrospectively. Moreover, if EPA decides

to conduct retrospective costs analyses and/or further evaluate its ability to conduct meaningful comparisons of ex ante and ex post costs, it should specifically seek out ex post evidence of unanticipated indirect cost and economy-wide impacts that may have been incurred.

Finally, the SAB's 2012 review ultimately concluded that the RCS's small sample size of cases and exclusive reliance on publicly available information to estimate ex post compliance costs made it impossible to determine whether EPA tended to over-or under-estimate compliance costs in cost-benefit analyses. While the Associations recognize that EPA may be able to improve its ex post compliance cost estimates by requesting actual ex post compliance cost data from companies, we do not believe it is appropriate for the Agency to compel companies to provide this information. We believe that EPA should ensure that the impacted industry is interested and willing to participate in a retrospective review prior to beginning the information collection process. Compliance cost information can be very sensitive and is typically treated as highly-confidential business information that will need to be managed in a particularly sensitive manner by EPA. This is particularly true when considering indirect costs like process impediments, production decreases, or increased energy usage. Moreover, this information can be very difficult to compile.

The regulated community already has voluminous reporting requirements and has labored under far too many Agency information collection requests. The Associations therefore request that EPA not undertake any retrospective review that further burdens the regulated community with more compulsory information requests, unless it first notice and convene a workshop with the impacted industry to ensure that a retrospective review can be supported by the impacted industry.

I. Peer review

BCAs and risk assessments should undergo peer review in accordance with EPA's Peer Review Handbook. The Handbook states the following regarding peer review: "It is conducted by qualified individuals (or organizations) who are independent of those who performed the work and who are collectively equivalent in technical expertise to those who performed the original work (i.e., peers)."[76] Adherence to the Handbook will further ensure adherence to best practices due to these stipulations regarding technical expertise.

[76] US EPA Peer Review Handbook, 4th Edition. Science and Technology Policy Council. October 2015. EPA/100/B-15/001. Page 20.

APPENDIX 1 – Additional discussion of reasons to calculate criteria pollutant co-benefits consistently with $PM_{2.5}$ NAAQS

In this appendix we explain in more detail how the past use of inconsistent assumptions about scientific uncertainties in estimating criteria pollutant health benefits has caused inclusion of those co-benefits in RIAs to have become unnecessarily controversial. As has been noted in the main body of the comments above, a requirement that criteria pollutant co-benefits be calculated with assumptions consistent with the scientific judgments made in setting each NAAQS would largely eliminate the concerns created when they are included in benefit-cost analysis targeting other pollutants. It is for this reason that the Associations emphasize the importance of that recommendation. This section also explains how economists' formulations that claim to provide a theoretical basis for including co-benefits calculated to zero concentration are flawed because they too are based on assumptions inconsistent with the NAAQS regulatory judgment.

Much controversy exists over whether co-benefits of criteria pollutants (which are already regulated stringently under the CAA) should be included in BCA to justify regulations of other pollutants. Concerns with the practice have been based on legal issues, implications for creating bad information about needs for improvement of statutory constructs, proliferation of unnecessarily complex web of regulatory requirements, and inconsistency. The legal rationale for excluding co-pollutants from other CAA BCAs has been articulated in the main body of these comments. The concerns with bad policy design signals and unnecessarily complex regulatory requirements have been articulated in Smith (2011).[77] While the prior arguments remain relevant, a more significant point is made in Smith (2016),[78] which identifies a fundamental inconsistency in Agency assumptions that underpin its computations of benefits for criteria pollutant co-benefits.

Smith (2016) explains how the Agency sets the NAAQS levels for $PM_{2.5}$ and ozone somewhat below the level at which the Administrator concludes there is minimal confidence in continuation of the C-R relationship to yet lower concentrations. In contrast, the Agency's estimates of the benefit of tightening the NAAQS—even in its NAAQS-setting RIAs—have assumed that the C-R relationship continues with certainty down to zero, and linearly so. This assumption is clearly inconsistent with the formal rationale for choosing that NAAQS level. Smith (2016) demonstrates how over 70% of the benefits in the RIA for the 2012 $PM_{2.5}$ NAAQS were eliminated when using assumptions more consistent with the Agency's rationale for its choice of NAAQS level. That paper also examines the degree of overstatement bias that results with these inconsistent assumptions are employed in the calculation of $PM_{2.5}$ co-benefits for non-NAAQS regulations—a 95% overstatement in the case of the MATS RIA.

The fundamental reason for this huge overstatement in the case of non-NAAQS regulations is because regulations that only coincidentally produce reductions in criteria pollutant precursors (i.e.,

[77] Smith, A.E. 2011. "An Evaluation of the $PM_{2.5}$ Health Benefits Estimates in Regulatory Impact Analyses for Recent Air Regulations," Final Report NERA Economic Consulting. Available at: https://www.nera.com/content/dam/nera/publications/archive2/PUB_RIA_Critique_Final_Report_1211.pdf

[78] Smith, A.E. 2016. "Inconsistencies in Risk Analyses for Ambient Air Pollutant Regulations," *Risk Analysis*, Vol. 36(9), September, pp. 1737-1744. doi: 10.1111/risa.12517.

in areas where the targeted non-NAAQS pollutant will need to be reduced) have a high probability of reducing criteria pollutant(s) in the locations where their ambient levels are already below the NAAQS. In other words, there is a high degree of spatial mismatch between areas where coincidental criteria pollutant reductions will occur and where baseline criteria pollutant levels are deemed to present high or even moderate concern with their impact on the public health.[79]

Paying no attention to the real-world considerations noted above regarding the construction and application of air quality policy in the U.S., economists and other proponents of inclusion of criteria pollutant co-benefits have repeatedly argued that there is no theoretical basis for excluding any forms of ancillary benefits from an RIA. For the most part, they refer to Circular A-4, which calls for inclusion of all ancillary benefits. More recently, however, Aldy, et al., (2020)[80] released a white paper that makes a theoretical case for inclusion of benefits from co-reductions of non-targeted pollutants in benefit-cost analyses. While the formulation of Aldy, et al. may appear elegant as a theoretical matter, it is deeply flawed by two strong implicit assumptions that render it unrealistic in the face of the real-world conditions of air quality. One assumption that is implicit (i.e., not acknowledged by the authors) is that every ton of emission of an air pollutant has equivalent impact whether it is emitted in a location where no people reside, or in the center of a city. This assumption is simply unrealistic, although it certainly simplifies the theoretical formulation.

More importantly, however, is that Aldy, et al.'s entire formulation is predicated on the also-unstated assumption that a ton of pollutant (or an associated increment in ambient concentration) has equal health risk whether it is experienced by a population that already faces very low ambient concentrations of the criteria pollutant, or very high ambient concentrations. In other words, the theoretical formulation is predicated on the assumption of a linear risk or C-R relationship to zero – the very same assumption that is inconsistent with the rationales for the PM and ozone NAAQS. Thus, their formulation fails to address the spatial mismatch issues that lie at the heart of the reasons why estimates of criteria pollutant co-benefits from regulations that do not target the criteria pollutants are unreliable estimates.[81] The implicit assumptions render Aldy, et al. an academic exercise with minimal relevance to the real-world conditions of U.S. air quality and clean air policy.

We conclude by agreeing that—as a matter of decision making to optimize social welfare—it remains appropriate to include all forms of ancillary benefits in a benefit-cost analysis, *provided that they are estimated in a manner that is consistent with reasoned scientific judgments about*

[79] NAAQS, in contrast, are designed to achieving criteria pollutant reductions in the areas that have relatively high baseline concentrations, specifically to avoid such a spatial mismatch. It is this feature of using the NAAQS to address criteria pollutant health risks that is often described as its greater "regulatory efficiency," e.g., as used in the following statement at p. 35622 of the NPRM: "Disaggregating benefits into those targeted and ancillary to the statutory objective of the regulation may cause EPA to explore whether there may be more efficient, lawful and defensible, or otherwise appropriate ways of obtaining ancillary benefits, as they may be the primary target of an alternative regulation that may more efficiently address such pollutants, through a more flexible regulatory mechanism, better geographic focus, or other factors."

[80] Aldy, J.E., Kotchen, M., Evans, M., Fowlie, M., Levinson, A., and Palmer, K. 2020. "Co-Benefits and Regulatory Impact Analysis: Theory and Evidence from Federal Air Quality Regulations." Prepared for the NBER Environmental and Energy Policy and the Economy Conference. May 18. Available at: http://conference.nber.org/conf_papers/f136946.pdf

[81] The risk-based nature of the NAAQS determination is not even mentioned in Aldy, et al., (2020).

uncertainties in physical risk relationships.[82] We have demonstrated how this can and should be done with Table 1 in the main text and associated discussion. There is nothing in Table 1 that is inconsistent with Circular A-4, nor with the prescriptions of economists such as Aldy, et al. The only difference is in the willingness to acknowledge the meaning of NAAQS-setting determination and to approach each rulemaking with consistent assumptions.

Clearly, if co-benefits of criteria pollutants for regulations targeting other pollutants were to be estimated using assumptions consistent with the NAAQS determinations of where scientific uncertainties drive the expectation of public health risks to insignificant levels, co-benefits estimates will have much less power to bias net total benefits estimates to a degree that has created so much controversy on the issue.

[82] EPA has itself articulated the need to consistently incorporate these judgments about scientific uncertainties in any set of criteria pollutant calculations at 78 Fed. Reg. 3154 (January 15, 2013): "[i] the Administrator were to consider the size of the $PM_{2.5}$-related co-benefits in deciding whether regulating EGUs under CAA section 112(d) is appropriate and necessary, he should also consider taking into account key assumptions affecting the size and distribution of these co-benefits and potential uncertainty surrounding them. In the past, EPA has highlighted a number of these assumptions as having particularly significant effect on estimates of PM-related benefits, including assumptions about: The causal relationship between PM exposure and the risk of adverse health effects; the shape of the concentration response relationship for long-term exposure-related $PM_{2.5}$ and the risk of premature death; the toxicity of individual $PM_{2.5}$ particle components; the levels of future PM2.5; the validity of the reduced-form technique used to relate $PM_{2.5}$ emission precursors to the number and value of $PM_{2.5}$ adverse health effects; and the approach used to assign a dollar value to adverse health effects. The Agency has separately noted that, in general, it is more confident in the size of the risks we estimate from simulated $PM_{2.5}$ concentrations that coincide with the bulk of the observed PM concentrations in the epidemiological studies that are used to estimate the benefits. Likewise, the Agency is less confident in the risk estimated from simulated $PM_{2.5}$ concentrations that fall below the bulk of the observed data in these studies [fn29 omitted]. Furthermore, when setting the 2012 PM NAAQS, the Administrator acknowledged greater uncertainty in specifying the ''magnitude and significance'' of PM-related health risks at PM concentrations below the NAAQS. As noted in the preamble to the 2012 PM NAAQS Final rule, in the context of selecting an alternative NAAQS, 'EPA concludes that it is not appropriate to place as much confidence in the magnitude and significance of the associations over the lower percentiles of the distribution in each study as at and around the long term mean concentration.' "

APPENDIX 2 – Additional details regarding summary table recommendation

Figure A-1 presents copies of Tables ES-1 and ES-2 of the ACE Final RIA[83] that serve as the basis for the values presented in Table 1 of these comments

Figure A-1. Copies of tables of net total and net targeted benefits in Final ACE RIA (EPA, 2019)

Table ES-1 Present Value and Equivalent Annualized Value of Compliance Costs, Domestic Climate Benefits, Ancillary Health Co-Benefits, and Net Benefits, Illustrative Policy Scenario, 3 and 7 Percent Discount Rates, 2023-2037 (millions of 2016$)

	Costs		Domestic Climate Benefits		Ancillary Health Co-Benefits		Net Benefits	
	3%	7%	3%	7%	3%	7%	3%	7%
Present Value	1,600	970	640	62	4,000 to 9,800	2,000 to 5,000	3,000 to 8,800	1,100 to 4,100
Equivalent Annualized Value	140	110	53	6.9	330 to 820	220 to 550	250 to 730	120 to 450

Notes: All estimates are rounded to two significant figures, so figures may not sum due to independent rounding. Climate benefits reflect the value of domestic impacts from CO_2 emissions changes.

Table ES-2 Present Value and Equivalent Annualized Value of Compliance Costs, Domestic Climate Benefits, and Net Benefits Associated with Targeted Pollutant (CO_2), Illustrative Policy Scenario, 3 and 7 Percent Discount Rates, 2023-2037 (millions of 2016$)

	Costs		Domestic Climate Benefits		Net Benefits associated with the Targeted Pollutant (CO_2)	
	3%	7%	3%	7%	3%	7%
Present Value	1,600	970	640	62	(980)	(910)
Equivalent Annualized Value	140	110	53	6.9	(82)	(100)

Notes: Negative net benefits indicate forgone net benefits. All estimates are rounded to two significant figures, so figures may not sum due to independent rounding. Climate benefits reflect the value of domestic impacts from CO_2 emissions changes. This table does not include estimates of ancillary health co-benefits from changes in electricity sector SO_2 and NO_X emissions.

[83] EPA. 2019. *Regulatory Impact Analysis for the Repeal of the Clean Power Plan, and the Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units.* EPA-452/R-19-003. Office of Air Quality Planning and Standards, Health and Environmental Impact Division, Research Triangle Park, NC June. https://www.epa.gov/sites/production/files/2019-06/documents/utilities_ria_final_cpp_repeal_and_ace_2019-06.pdf

Additional Illustrative Example of One-Table Summary Format Based on RIA for Proposed Utility MACT Rule

Figure A-2 below is a copy of the net benefits summary table from the RIA for the proposed utility MACT rule (Table 1-1, EPA 2011).[84] Figure A-3 below is a copy of the table that provides information disaggregating the social benefits totals in that RIA (Table 1-3, EPA 2011). Note that this disaggregation provides no information about which estimate is targeted and which is some form of ancillary benefit. It also provides so much detail that it is very difficult for analysts seeking to create a table that provides only a modest disaggregation of total benefits into two or three categories will have difficulty seeing the bottom line.

As a contrast to the relevant tables in EPA (2011) shown in Figures A-2 and A-3, Table A-1 provides another illustrative example of our recommended single-step net benefits summary table for the proposed utility MACT RIA. For Table A-1, we treat mercury benefits as targeted benefits, CO_2 as ancillary benefits, and the sum of all $PM_{2.5}$ health risks as criteria pollutant co-benefits. Table A-1 also illustrates how the alternative format that we recommend would incorporate references to unquantified benefits. Table A-1 contains estimates of the consistently-calculated co-benefits. This approximation is based on Figure 6-15 of the RIA, which reports that only 5% of the co-benefits reported in the original RIA tables were in locations with $PM_{2.5}$ above the NAAQS.

[84] EPA. 2011. *Regulatory Impact Analysis of the Proposed Toxics Rule: Final Report.* March. https://www.epa.gov/sites/production/files/2020-07/documents/utilities_ria_proposed-mact-nsps_2011-03.pdf

Figure A-2. Copy of net benefits summary table in EPA (2011)

Table 1-1. Summary of EPA's Estimates of Benefits, Costs, and Net Benefits of the Proposed Toxics Rule in 2016[a] (billions of 2007$)

Description	Estimate (3% Discount Rate)	Estimate (7% Discount Rate)
Social costs[b]	$10.9	$10.9
Social benefits[c,d]	$59 to $140 + B	$53 to $130 + B
Net benefits (benefits-costs)	$48 to $130	$42 to $120

[a] All estimates are rounded to two significant digits and represent annualized benefits and costs anticipated for the year 2016. For notational purposes, unquantified benefits are indicated with a "B" to represent the sum of additional monetary benefits and disbenefits. Data limitations prevented us from quantifying these endpoints, and as such, these benefits are inherently more uncertain than those benefits that we were able to quantify. A listing of health and welfare effects is provided in Table 1-5. Estimates here are subject to uncertainties discussed further in the body of the document.

[b] The reduction in premature mortalities account for over 90% of total monetized benefits. Valuation assumes discounting over the SAB-recommended 20-year segmented lag structure described in Chapter 6. Results reflect 3 percent and 7 percent discount rates consistent with EPA and OMB guidelines for preparing economic analyses (U.S. EPA, 2000; OMB, 2003).

[c] Social costs are estimated using the MultiMarket model, the model employed by EPA in this RIA to estimate economic impacts of the proposal to industries outside the electric power sector. This model does not estimate indirect impacts associated with a regulation such as this one. Details on the social cost estimates can be found in Chapter 9 and Appendix E of this RIA.

[d] Potential benefit categories that have not been quantified and monetized are listed in Table 1-5.

Figure A-3. Copy of table disaggregating total benefits in EPA (2011)

Table 1-3. Estimated Monetary Value of Reductions in Incidence of Health and Welfare for the Proposed Toxics Rule (in billions of 2007$)[a,b,c]

Health Effect		*Eastern U.S.*	*Western U.S.*	*Total*
Avoided IQ Loss Associated with Methylmercury Exposure from Self-Caught Fish Consumption among Recreational Anglers				
3% discount rate				$0.004 - $0.006
7% discount rate				$0.000005 - $0.000009
Adult premature death (Pope et al. 2002 PM mortality estimate)				
3% discount rate	$PM_{2.5}$	$53 ($4.2—$160)	$0.9 ($0.1—$2.8)	$54 ($4.3—$160)
7% discount rate	$PM_{2.5}$	$48 ($3.8—$140)	$0.8 ($0. 1—$2.5)	$48 ($3.8—$150)
Adult premature death (Laden et al. 2006 PM mortality estimate)				
3% discount rate	$PM_{2.5}$	$140 ($12—$390)	$2.4 ($0.2—$6.9)	$140 ($12—$400)
7% discount rate	$PM_{2.5}$	$120 ($11—$350)	$2.2 ($0.2—$6.3)	$120 ($11—$360)
Infant premature death	$PM_{2.5}$	$0.3 ($-0.3—$1.2)	<$0.01	$0.3 ($-0.3—$1.2)
Chronic Bronchitis	$PM_{2.5}$	$2.1 ($0.1—$9.6)	$0.05 (<$0.01—$0.2)	$2.1 ($0.1—$9.8)
Non-fatal heart attacks				
3% discount rate	$PM_{2.5}$	$1.2 ($0.2—$2.9)	$0.02 (<$0.01—$0.05)	$1.2 ($0.2—$2.9)
7% discount rate	$PM_{2.5}$	$1.1 ($0.2—$2.8)	$0.02 (<$0.01—$0.03)	$1.2 ($0.2—$2.9)
Hospital admissions—respiratory	$PM_{2.5}$	<$0.01	<$0.01	$0.02 ($0. 01—$0.03)
Hospital admissions—cardiovascular	$PM_{2.5}$	<$0.01	<$0.01	$0.1 ($0.05—$0.14)
Emergency room visits for asthma	$PM_{2.5}$	<$0.01	<$0.01	<$0.01
Acute bronchitis	$PM_{2.5}$	<$0.01	<$0.01	<$0.01
Lower respiratory symptoms	$PM_{2.5}$	<$0.01	<$0.01	<$0.01
Upper respiratory symptoms	$PM_{2.5}$	<$0.01	<$0.01	<$0.01
Asthma exacerbation	$PM_{2.5}$	<$0.01	<$0.01	<$0.01
Lost work days	$PM_{2.5}$	$0.1 ($0.1—$0.1)	<$0.01	$0.1 ($0.1—$0.1)
Minor restricted-activity days	$PM_{2.5}$	$0.3 ($0.2—$0.5)	<$0.01	$0.3 ($0.2—$0.5)
Social cost of carbon (3% discount rate, 2016 value)	CO_2			$0.57

(continued)

Table 1-3. Estimated Monetary Value of Reductions in Incidence of Health and Welfare for the Proposed Toxics Rule (in billions of 2007$)[a,b,c] (continued)

Health Effect	*Eastern U.S.*	*Western U.S.*	*Total*
Monetized total Benefits			
(Pope et al. 2002 $PM_{2.5}$ mortality estimate)			
3% discount rate	$57 ($4.6—$170)	$1 ($0.1—$3.1)	$59 ($4.6—$180)
7% discount rate	$52 ($4.1—$160)	$0.9 ($0.1—$2.8)	$53 ($4.2—$160)
(Laden et al. 2006 $PM_{2.5}$ mortality estimate)			
3% discount rate	$140 ($12—$410)	$2.5 ($0.2—$7.2)	$140 ($12—$410)
7% discount rate	$130 ($11—$370)	$2.2 ($0.2—$6.6)	$130 ($11—$370)

[a] Estimates rounded to two significant figures. The negative estimates for certain endpoints are the result of the weak statistical power of the study used to calculate these health impacts and do not suggest that increases in air pollution exposure result in decreased health impacts. Confidence intervals reflect random sampling error and not the additional uncertainty associated with benefits scaling described above.

[1] The national scale assessment conducted for the RIA focuses on the exposures to methylmercury in populations who consume self-caught freshwater fish (recreational fishers and their families, especially women of child-bearing age). Benefits reflect estimated avoided IQ loss for children, as projected based on fertility rates applied to the women of child-bearing age, among all recreational freshwater anglers in the 48 contiguous U.S. states.

[2] As noted in chapter 5, monetized benefits estimates are for an immediate change in MeHg levels in fish (i.e., the potential lag period associated with fully realizing fish tissue MeHg levels was not reflected in benefits modeling). If a lag in the response of MeHg levels in fish were assumed, the monetized benefits could be significantly lower, depending on the length of the lag and the discount rate used. As noted in the discussion of the Mercury Maps modeling, the relationship between deposition and fish tissue MeHg is proportional in equilibrium, but the MMaps approach does not provide any information on the time lag of response.

[3] Monetized benefits estimates reported here are for the implementation year: 2016. As such, certain health endpoints that take years to manifest, such as avoided IQ loss from MeHg prenatal exposure, may not be fully quantified in the analysis year.

Table A-1. Illustrative example of the single-step version of our recommended net benefits table, if it were to have been used in the proposed utility MACT RIA, EPA (2011) ($ billions)

	3% Discount Rate		7% Discount Rate	
	Quantified Estimates	Cumulative Net Ben	Quantified Estimates	Cumulative Net Ben
Social costs	$10.9	-$10.9	$10.9	-$10.9
Targeted benefits	$0.005		$0.000007	
Net Targeted Benefits		**-$10.9+TB**		**-$10.9+TB**
Ancillary benefits	$0.57		$0.57(*)	
Net Targeted & Ancillary Benefits		-$10.3+TB+AB		-$10.3+TB+AB
Criteria pollutant health co-benefits *calculated consistently*	$3.2-$7.2		$2.2-$6.2	
Net Total Benefits		-$7 to -$3 +TB+AB+CB		-$2 to -$6 +TB+AB+CB

TB: list unquantified targeted benefits here

AB: list unquantified ancillary benefits here

CB: list unquantified criteria pollutant health benefits here

(*) CO_2 ancillary benefits computed at 3% in the 7% discount rate cases