

ENVIRONMENTAL PROTECTION AGENCY

42 CFR 7601(a)(1)

[EPA-HQ-OAR-2020-00044]

RIN 2060-AU51

Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Environmental Protection Agency (EPA) is proposing processes that it would be required to undertake in promulgating regulations under the Clean Air Act (CAA) to ensure that information regarding the benefits and costs of regulatory decisions is provided and considered in a consistent and transparent manner. This proposed rule addresses, among other things, issues raised in the June 13, 2018 advance notice of proposed rulemaking, “Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process,” and proposes how the concepts described in that advance notice would be implemented in rulemakings conducted by the EPA using its authorities under the CAA. The EPA is proposing to establish procedural requirements governing the development and presentation of benefit-cost analyses (BCA), including risk assessments used in the BCA, for significant rulemakings conducted under the CAA. Together, these requirements would help ensure that the EPA implements its statutory obligations under the CAA, and describes its work in implementing those obligations, in a way that is consistent and transparent.

DATES: Comments must be received on or before *[insert date 45 days after date of publication in the Federal Register]*

Public Hearing: If anyone contacts us requesting a public hearing on or before [INSERT DATE], we will hold a hearing. Additional information about the hearing, if requested, will be published in a subsequent Federal Register document.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OAR-2020-00044, by any of the following methods:

- Federal eRulemaking Portal: <https://www.regulations.gov/> (our preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. EPA-HQ-OAR-2020-00044 for this rulemaking. Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the “Public Participation” heading of the SUPPLEMENTARY INFORMATION section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via https://www.regulations.gov or email, as there is a temporary suspension of mail delivery to EPA, and no hand deliveries are currently accepted. For further information on EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Organization of this document. The following outline is provided to aid in locating information in this preamble.

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I. Public Participation:

A. Written Comments

Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2020-00044,

at <https://www.regulations.gov> (our preferred method), or the other methods identified in the ADDRESSES section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

The EPA is temporarily suspending its Docket Center and Reading Room for public visitors to reduce the risk of transmitting COVID-19. Written comments submitted by mail are temporarily suspended and no hand deliveries will be accepted. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via <https://www.regulations.gov>. For further information and updates on EPA Docket Center services, please visit us online at <https://www.epa.gov/dockets>.

The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding

COVID-19.

B. Public Hearing

The EPA will hold one or more virtual public hearings on this proposed rule. These will be announced in a separate Federal Register notice that provides details, including specific dates, times, and contact information for these hearings. Please note that EPA is deviating from its typical approach because the President has declared a national emergency. Because of current CDC recommendations, as well as state and local orders for social distancing to limit the spread of COVID-19, EPA cannot hold in-person public meetings at this time.

II. General Information

A. Does this action apply to me?

This proposed regulation does not regulate the conduct or determine the rights of any entity or individual outside the Agency, as this action pertains only to internal EPA practices. However, the Agency recognizes that any entity or individual interested in EPA's regulations may be interested in this proposal. For example, this proposal may be of particular interest to entities and individuals concerned with how EPA conducts benefit and cost analyses.

B. What is the Agency's authority for taking this action?

The Agency proposes to take this action under the CAA using 42 U.S.C. 7601(a)(1). Section 301(a)(1) of the CAA provides authority to the Administrator "to prescribe such regulations as are necessary to carry out his functions" under the CAA. Such authority extends to internal agency procedures that increase the Agency's ability to provide consistency and transparency to the public in regard to the rulemaking

process under the CAA. The EPA solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

This is a proposed rule of agency organization, procedure or practice. This proposed procedural rule would not regulate any person or entity outside the EPA and would not affect the rights or obligations of outside parties. As a rule of Agency procedure, this rule is exempt from the notice and comment requirements set forth in the Administrative Procedure Act. See 5 U.S.C. 553(b)(A). Nonetheless, the Agency voluntarily seeks comment because it believes that the information and opinions supplied by the public will inform the Agency's views.

The D.C. Circuit has explained that “the critical feature of a rule that satisfies the so-called procedural exception [to the APA’s notice and comment requirements] is that it covers agency actions that do not themselves alter the rights or interests of parties” *James A. Hurson Assocs. v. Glickman*, 229 F.3d 277, 280 (D.C. Cir. 2000); *National Mining Association v. McCarthy*, 758 F.3d 243 (D.C. Cir. 2014) (holding that EPA’s interagency plan for enhanced consultation and coordination is a procedural rule because it does not alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the Agency); *Batterton v. Marshall*, 648 F.2d 708 (D.C. Cir. 1980) (“The critical question is whether the agency action jeopardizes the rights and interests of parties.”). This rule would not regulate the conduct or determine the rights of any entity outside the federal government.

C. What action is the Agency taking?

This proposed action consists of three elements. First, the proposed regulation

provides that the EPA will prepare a BCA for all future significant proposed and final regulations under the CAA. Second, the EPA proposes that the BCA be developed using the best available scientific information and in accordance with best practices from the economic, engineering, physical, and biological sciences. Third, the EPA proposes additional procedural requirements to increase transparency in the presentation of the BCA results, while maintaining the standard practices of measuring net benefits consistent with E.O. 12866. Together, these requirements would help ensure that the EPA implements its statutory obligations under the CAA in a way that is consistent and transparent. In this notice, the EPA solicits comment on all aspects of this proposal and how it can best be implemented in accordance with existing law and prior statements of policy that have called for increasing consistency and transparency. Each of the key elements of the action is discussed in more detail below, followed by a summary of specific solicitations for comment.

III. Background

As the EPA works to advance its mission of protecting public health and the environment, it seeks to ensure that its analyses of regulatory decisions provided to the public continue to be rooted in sound, transparent and consistent approaches to evaluating benefits and costs.

The Supreme Court noted in *Michigan v. EPA* that “[c]onsideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions.” *Michigan v. EPA*, 135 U.S. 2699, 2707 (2015). Many environmental statutes, including the CAA, contemplate

the consideration of costs as part of regulatory decision-making in many instances. Several of these statutes, including the CAA, contain provisions that explicitly require some form of cost consideration when establishing a standard. Additionally, several other provisions use terminology that in context implicitly direct the EPA to consider costs, alone or in conjunction with benefits and other factors. For example, Section 112(n)(1)(A) of the CAA directs the Administrator to “regulate electric utility steam generating units under [section 112], if the Administrator finds such regulation is appropriate and necessary.” “Read naturally in the present context, the phrase ‘appropriate and necessary’ requires at least some attention to cost.” *Michigan*, 135 S. Ct. at 2707 (2015). Therefore, in light of the varying statutory provisions in the CAA that apply to or otherwise address cost consideration, the Agency proposes to provide analysis to the public that will present all of the benefits and costs in a consistent manner for all significant CAA rulemakings.

Thorough and careful economic analysis is informative for developing sound environmental policies. High quality economic analyses enhance the effectiveness of environmental policy decisions by providing policy makers and the public with information needed to systematically assess the likely consequences of various actions or options. BCA, a type of economic analysis, can serve an integral informative role in the regulatory development process. In general terms, a BCA is an evaluation of both the benefits and costs to society as a result of a policy and the difference between the two (i.e., the calculation of net benefits (benefits minus costs)). It provides information about whether a policy change has the potential to improve the aggregate well-being of society.

The usefulness of BCA in informing the development of environmental regulations has been recognized both within and outside government for decades. As discussed below, Presidential Executive Orders and statutes have been in place for decades formally requiring the preparation of BCA in the development of major Federal regulations, and the courts have examined the use of BCA in several regulatory contexts. In addition, the usefulness of formal BCA in informing regulatory policy debates on protecting and improving public health, safety, and the natural environment has been emphasized in the academic literature. For example, as explained in seminal work by prominent economists Arrow et al. (1996a, 1996b), BCA “can provide an exceptionally useful framework for consistently organizing disparate information, and in this way, it can greatly improve the process and, hence, the outcome of policy analysis. If properly done, BCA can be of great help to agencies participating in the development of environmental regulations...” (1996b). Arrow et al. recommend that “Benefit-cost analysis should be required for all major regulatory decisions,” and that “the precise definition of ‘major’ requires judgment.”

Benefit-cost analyses have been an integral part of executive branch rulemaking for decades. Presidents since the 1970s have issued executive orders requiring agencies to conduct analysis of the economic consequences of regulations as part of the rulemaking development process. President Ford’s 1974 Executive Order (E.O.) 11821 required government agencies to prepare inflation impact statements before issuing major regulations.¹ These inflation impact statements essentially turned into

¹ EXECUTIVE ORDER 11821 — Inflation Impact Statements, FEDERAL REGISTER, VOL. 39, NO. 231—FRIDAY, NOVEMBER 29, 1974 (pages 41501-41502) .

benefit-cost analyses based on the understanding that a regulation would not be truly inflationary unless its costs to society exceeded the benefits it produced,² and the E.O. was renamed as *Economic Impact Statements* with E.O. 11949 in 1976.³ President Carter's 1978 E.O. 12044, *Improving Government Regulations*, included formal requirements for conducting regulatory analysis at a minimum "for all regulations which will result in (a) an annual effect on the economy of \$100 million or more; or (b) a major increase in costs or prices for individual industries, levels of government or geographic regions."⁴ Regulatory analyses under E.O. 12044 were required to contain "a succinct statement of the problem; a description of the major alternative ways of dealing with the problem that were considered by the agency; an analysis of the economic consequences of each of these alternatives and a detailed explanation of the reasons for choosing one alternative over the others."

In 1981, President Reagan issued E.O. 12291, *Federal Regulation*, which imposed the first requirements for conducting formal benefit-cost analysis in the development of new major Federal regulations. Among its provisions, it explicitly required that: "(a) Administrative decisions shall be based on adequate information concerning the need for and consequences of proposed government action; (b) Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society; (c) Regulatory objectives shall be chosen to maximize the net benefits to society; (d) Among alternative approaches to

² https://obamawhitehouse.archives.gov/omb/infoereg_chap1#tnfrp

³ EXECUTIVE ORDER 11949 – Economic Impact Statements, FEDERAL REGISTER, VOL. 42, NO. 3— WEDNESDAY, JANUARY 5, 1977 (page 1017). <https://www.govinfo.gov/content/pkg/FR-1977-01-05/pdf/FR-1977-01-05.pdf>

⁴ EXECUTIVE ORDER 12044 – Improving Government Regulations, FEDERAL REGISTER, VOL 43, NO. 58-- FRIDAY, MARCH 24, 1978 (Pages 12659-12670).

any given regulatory objective, the alternative involving the least net cost to society shall be chosen; and (e) Agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.” Under E.O. 12291, major regulations included “any regulation that is likely to result in: (1) An annual effect on the economy of \$100 million or more; (2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.”⁵

In 1993, E.O. 12291 was revoked and replaced by President Clinton’s E.O. 12866, *Regulatory Planning and Review*, which is still in effect today. E.O. 12866 requires that for all significant regulatory actions pursuant to Section 3(f), an agency provide “an assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate...” For regulatory actions meeting criteria listed under Section 3(f)(1) – that is, any regulatory action that is “likely to result in a rule that may...have an annual effect on the economy of \$100 million or more or 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” – E.O. 12866 further requires that this assessment include a

⁵ <https://www.archives.gov/federal-register/codification/executive-order/12291.html>

quantification of benefits and costs to the extent feasible. In addition, E.O. 12866 states that, to the extent permitted by law, agencies “should assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs”; “in choosing among alternative regulatory approaches...should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach”; and that “[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.”

In 1995, the Unfunded Mandates Reform Act of 1995 (UMRA) included analytical requirements for all regulatory actions that include federal mandates “that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.” An action contains a federal mandate if it imposes an enforceable duty on state, local or tribal governments, or the private sector. The analytical requirements under UMRA are similar to the analytical requirements under E.O. 12866, and thus the same analysis may permit compliance with both analytical requirements.

More recent Executive Orders also reaffirm the requirements and principles in E.O. 12866. The former Administration’s E.O. 13563, issued in 2011 and also still in effect today, reaffirms the requirements and other principles and definitions in E.O. 12866 and embraces benefit-cost analysis: “In applying these principles, each agency is

directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.”⁶ More recently, this Administration’s E.O. 13777, issued in 2017, directs agencies to identify regulations that “impose costs that exceed benefits.”⁷ E.O. 13783, also issued in 2017, similarly reaffirms the importance of benefit-cost analysis: “In order to ensure sound regulatory decision making, it is essential that agencies use estimates of costs and benefits in their regulatory analyses that are based on the best available science and economics.”⁸

The Office of Management and Budget’s (OMB’s) *Circular A-4* (OMB 2003), which remains in effect today, provides guidance to Federal agencies on the development of regulatory analysis as required under E.O. 12866 and a variety of related authorities.⁹ In developing Circular A-4, OMB first developed a draft that was subject to public comment, interagency review, and external peer review. As summarized in E.O. 13783, “...OMB Circular A-4...was issued after peer review and public comment and has been widely accepted for more than a decade as embodying the best practices for conducting regulatory cost-benefit analysis.”¹⁰ The document encourages transparency in practices, including the expression of costs and benefits in monetary units that allow for the evaluation of “incremental benefits and costs of successively more stringent regulatory alternatives” such that an agency can “maximize

⁶ <https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review>

⁷ Enforcing the Regulatory Reform Agenda (82 FR 12285, March 1, 2017).

⁸ <https://www.govinfo.gov/content/pkg/FR-2017-03-31/pdf/2017-06576.pdf>.

⁹ https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/. Circular A-4 refines and replaces OMB’s “best practices” document of 1996, which was issued as a guidance in 2000 and reaffirmed in 2001. All these versions of the 1996 document were superseded by Circular A-4.

¹⁰ <https://www.govinfo.gov/content/pkg/FR-2017-03-31/pdf/2017-06576.pdf>

net benefits.”¹¹

EPA’s *Guidelines for Preparing Economic Analyses* (hereafter, the *Guidelines*)¹² complements Circular A-4 by providing the Agency with more detailed peer-reviewed guidance on how to conduct BCA and other types of economic analyses for both environmental regulatory actions and non-regulatory management strategies, with the intent of improving compliance with E.O. 12866 and other executive orders and statutory requirements (e.g., Small Business Regulatory Enforcement Fairness Act of 1996 provisions). The *Guidelines* are updated periodically – building on work issued in 1983 (then titled *Guidelines for Performing Regulatory Impact Analysis*), 2000, and most recently in 2010 – to account for growth and development of economic tools and practices. The *Guidelines* establish a scientific framework for analyzing the benefits, costs, and other economic impacts of regulations and policies, including assessing the distribution of costs and benefits among various segments of the population. In addition to presenting the well-established scientific foundations for economic analysis, they incorporate recent advances in theoretical and applied work in the field of environmental economics. Updates of the *Guidelines* are led by the EPA’s National Center for Environmental Economics (NCEE) in consultation with economists from across the Agency and OMB. All chapters undergo an external peer review, either through EPA’s Science Advisory Board or through independent reviews by external experts, prior to being finalized.¹³

¹¹ https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/

¹² <https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses>

¹³ The EPA is in the process of a periodic update of the *Guidelines*. The EPA anticipates that among the changes within this update, the current Section 9.2.3.3, “Impacts on employment”, will be replaced with a discussion based on more recent literature and feedback from the Economy Wide Modeling Science Advisory Board Panel. For more details regarding Chapter 9, see: <https://www.epa.gov/sites/production/files/2017-09/documents/ee-0568-09.pdf>.

Given the history described above pertaining to the use of BCA by executive agencies, and given that several statutes, including the CAA, include provisions that require some form of cost consideration, the federal courts have also developed significant case law regarding regulatory cost consideration and the usefulness of BCA. This case law addresses when, and if, such use is required or permissible and how it may be employed in reasoned decision-making. As a general matter, while certain statutory provisions may prohibit reliance on BCA or other methods of cost consideration in decision making,¹⁴ such provisions do not preclude the Agency from providing additional information regarding a proposed or final rule to the public. For example, while the CAA prohibits the EPA from considering cost when establishing requisite National Ambient Air Quality Standards (NAAQS) for criteria pollutants¹⁵, the EPA nonetheless provides Regulatory Impact Analyses (RIAs)¹⁶ to the public for these rulemakings.¹⁷ The agency believes that the information provided as a result of the procedural requirements of this proposal, if finalized, would increase transparency and consistency across CAA rulemakings; would provide the public with additional information in the CAA rulemaking process; and would provide the Agency with supplemental information for potential use by the Agency when it is appropriate to be considered. Whether the Agency utilizes any information produced as a result of these

For more details regarding the update of the Guidelines in general, see: <https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/30D5E59E8DC91C2285258403006EEE00?OpenDocument>.

¹⁴ See, e.g., *Whitman v. Am. Trucking Ass 'ns*, 531 U.S. 457 (2001) (holding that Section 109(b) of the CAA unambiguously barred cost considerations when setting the National Ambient Air Quality Standards.

¹⁵ *Id.*

¹⁶ A regulatory impact analysis, or “regulatory analysis” for brevity, as prepared under E.O. 12866, consists of a benefit-cost analysis and any related cost-effectiveness analyses and assessments of economic and distributional impacts (OMB 2003).

¹⁷ See, e.g., U.S. EPA, Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone (2014), <https://www3.epa.gov/ttn/ecas/regdata/RIAs/20141125ria.pdf>.

procedural requirements would be determined by the statutes and regulations governing particular subsequent rulemakings. Any such information would be in addition to the information provided by other methodologies and analyses as directed by specific CAA statutes and regulations.

The Supreme Court has held that agencies may conduct and consider a BCA even when a statute does not explicitly require one. In *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 222-224 (2009), the Supreme Court clarified that neither *American Textile Mfrs. Inst. V. Donovan*, 452 U.S. 490 (1981) (*American Textile Mfrs.*) nor *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001) (*American Trucking*), stands for the broad proposition that statutory silence in regard to BCA always implies prohibition of BCA. Concluding that the EPA is permitted to use BCA in determining the content of regulations promulgated under Clean Water Act section 1326(b). The Court reasoned “that [CWA] § 1326(b)'s silence is meant to convey nothing more than a refusal to tie the agency's hands as to whether cost-benefit analysis should be used, and if so to what degree.” *Id.* at 222; *see also id.* at 212, 219-20, 226.

The Supreme Court noted that its decisions in *American Trucking* and *American Textile Mfrs.* “do not undermine this conclusion.” 556 U.S. at 223. The Court highlighted that in *American Trucking*, it had held that the text of section 109 of the Clean Air Act, “interpreted in its statutory and historical context . . . unambiguously bars cost considerations” when air quality standards are set pursuant to that provision. *American Trucking*, 531 U.S. at 471, *quoted in Entergy Corp.*, 556 U.S. at 223. The *Entergy Corp.* Court further elaborated that “[t]he relevant ‘statutory context’ [in *American Trucking*] included other provisions in the [CAA] that expressly authorized consideration of costs,

whereas § 109 did not.” 556 U.S. at 233. The Court concluded that *American Trucking* “stands for the rather unremarkable proposition that sometimes statutory silence, when viewed in context, is best interpreted as limiting agency discretion.” 556 U.S. at 223. The Court further noted that in *American Textile*, the Court had relied, in part, on the absence of mention of BCA in the statute to hold that the agency was not required to conduct a BCA when setting certain health and safety standards. 556 U.S. at 223. “[U]nder *Chevron*, that an agency is not required to [engage in cost-benefit analysis] does not mean that an agency is not *permitted* to do so.” *Id.* Thus, the Supreme Court has confirmed that a statute need not have explicitly required that the agency conduct a BCA in its decision-making process for the agency to do so.

The Supreme Court additionally acknowledged in *Entergy Corp.* that “whether it is ‘reasonable’ to bear a particular cost may well depend on the resulting benefits.” 556 U.S. at 225-226. This concept was further elaborated upon by the Court in *Michigan v. EPA*, which held, in the context of the term “appropriate and necessary” contained in Section 112(n)(1)(A) of the CAA, that the term required consideration of cost. 135 S. Ct. 2699, 2706 (2015). In doing so, the Supreme Court stated that “[o]ne would not say that it is even rational, never mind ‘appropriate,’ to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits”, concluding that “[n]o regulation is ‘appropriate’ if it does significantly more harm than good.” *Id.* at 2707. The D.C. Circuit recently echoed this concept in *Mingo Logan Coal Co. v. EPA*. While the D.C. Circuit panel ultimately concluded that the cost issue had been forfeited by petitioners, in response to then Judge Kavanaugh’s dissent which argued that cost consideration should be required, the panel stated, “[i]ndeed, we do not quibble with his

general premise—and that of the many legal luminaries he cites—that an agency should generally weigh the costs of its action against its benefits.” 829 F.3d 710, 723 (D.C. Cir. 2016). In general, when cost consideration is either required or permitted by the CAA, the courts have not mandated a specific type of cost consideration but have granted the Agency broad discretion in determining its methodology. *Michigan*, 135 S. Ct. at 2711 (“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.”); *see also Sierra Club v. Costle*, 657 F.2d 298, 345 (D.C. Cir. 1981) (“[S]ection 111(a) explicitly instructs the EPA to balance multiple concerns when promulgating a NSPS.”); *id.* at 321 (“The text gives the EPA broad discretion to weigh different factors in setting the standard.”); *Lignite Energy Council v. EPA*, 198 F.3d 930, 933 (D.C. Cir. 1999) (“Because section 111 [of the CAA] does not set forth the weight that [should be] assigned to each of these factors, we have granted the agency a great degree of discretion in balancing them”); *Husqvarna AB v. EPA*, 254 F.3d 195, 200 (D.C. Cir. 2001) (“Section 213 [of the CAA] ... simply directs the EPA to consider cost. ... Because section 213 does not mandate a specific method of cost analysis, we find reasonable the EPA's choice to consider costs on the per ton of emissions removed basis.”).

Additionally, lower courts have noted the usefulness of BCA and have utilized the information provided therein to inform their analysis when reviewing agency regulations. Several of these cases utilize information from agency-created BCAs and/or RIAs as

evidence that an agency ignored alternatives or acted in an arbitrary and capricious manner when taking action.

For example, in *Advocates for Highway and Auto Safety v. FMCSA*, 429 F.3d 1136 (D.C. Cir. 2005), the D.C. Circuit relied in part on a BCA in invalidating, as arbitrary and capricious, a final rule promulgated by Federal Motor Carrier Safety Administration (FMCSA) intended to ensure that drivers of commercial motor vehicles received adequate training. In its analysis, the D.C. Circuit highlighted an incongruity between methods of training shown to be effective and the final rule, noting that “[f]rom a purely economic perspective, the agency's disregard of the Adequacy Report [containing a BCA] is baffling in light of the evidence in the record.” *Id.* at 1146. The D.C. Circuit pointed to a training regimen that “according to the agency's own calculations, [would] produce benefits far in excess of costs.” *Id.* Noting the agency's findings that “the program's estimated 10–year cost of between \$4.19 billion to \$4.51 billion would yield a benefit ranging from \$5.4 billion to \$15.27 billion, depending on analytic assumptions,” the court concluded that the BCA for the rule “lends no support to FMCSA's position. In the final rule, FMCSA says practically nothing about the projected benefits.” *Id.*;

In *Public Citizen, Inc. v. Mineta*, 340 F.3d 39 (2nd Cir. 2003), the Second Circuit determined that a National Highway Traffic Safety Administration (NHTSA) rule regarding tire pressure monitoring system (TPMS) requirements was arbitrary and capricious, as the NHTSA BCA showed that alternatives would be safer and more cost-effective. The court stated that it may “be difficult to weigh economic costs against safety benefits. But the difficulty of the task does not relieve the agency of its obligation

to perform it under [certain vehicle safety laws] and State Farm.” *Id.* at 58 (citing *Motor Vehicles Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983)). The Second Circuit observed that NHTSA “instead, presents us with a rulemaking record that does not explain why the costs saved were worth the benefits sacrificed.” *Id.* The court noted that the BCA “discloses that the added cost for a system that worked all of the time, rather than half of the time, was less than \$10 per car, and that the adoption of the four-tire, 25 percent standard alone was the most cost effective means of preventing crashes caused by significantly under-inflated tires.” *Id.*

Finally, in *NRDC v. EPA*, 824 F.2d 1258 (1st Cir. 1987), the First Circuit vacated, in part, and remanded rules for long-term disposal of high-level radioactive waste under Nuclear Waste Policy Act of 1982 based in part on the Agency’s selection of a 1,000-year design criterion rather than a longer-term one. The court determined that it was unreasonable agency action to not adopt cheap methods of increasing protections. In doing so, the court observed that “[l]ikewise, EPA’s Final [RIA] of 40 C.F.R. Part 191 demonstrates that more rigorous site selection could produce sites with such impermeable geologic media that compliance with the individual protections for a much longer duration would not even require the extra cost of ‘very good’ engineered canisters.” *Id.* at 1289.

With this history in mind as a backdrop and following E.O. 13777 noted above, the EPA is proposing to establish requirements to ensure that the EPA consistently assesses the costs and benefits of significant CAA rules. The EPA opened a public docket¹⁸ in April 2017 to solicit feedback and identify regulations that “impose costs that

¹⁸ See EPA, Evaluation of Existing Regulations (82 FR 17793). All public comments are accessible online in our docket on the Regulations.gov website identified by Docket ID No. EPA-HQ-OA-2017-0190.

exceed benefits.” Among the public comments received, a large cross-section of stakeholders stated that the agency either underestimated costs, overestimated benefits, or evaluated benefits and costs inconsistently in its rulemakings. Per E.O. 13777 and based on these public comments, the EPA decided to take further action to evaluate opportunities for reform.

In June 2018, the EPA issued an Advance Notice of Proposed Rulemaking (ANPRM), “Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process” (83 FR 27524, June 13, 2018), to solicit public input on potential approaches for increasing consistency and transparency in how the EPA considers benefits and costs in the rulemaking process. Informed by the public comments received on that ANPRM, on May 13, 2019, the Administrator issued a memorandum¹⁹ to EPA’s Assistant Administrators announcing the intention to propose statute-specific rules that outline how consistency and transparency concepts will be implemented in future rulemakings. The memorandum outlined the following principles for developing these regulatory proposals, consistent with applicable laws and regulations: ensuring that the Agency balances benefits and costs in regulatory decision-making; increasing consistency in the interpretation of statutory terminology; providing transparency in the weight assigned to various factors in regulatory decisions; and promoting adherence to best practices in conducting the technical analysis used to inform decisions.

This proposed rule is the first statute-specific rulemaking in this effort. The EPA is proposing to codify the procedural requirements governing the development of BCA,

¹⁹ Available at: <https://www.epa.gov/environmental-economics/administrator-wheeler-memorandum-increasing-consistency-and-transparency>.

including risk assessments used as inputs to the BCA, for significant rulemakings conducted under the CAA, and proposes additional procedural requirements to increase transparency in the presentation of the benefits resulting from significant CAA regulations. Together, these requirements would ensure a consistent approach to the EPA's CAA benefit-cost analyses under the CAA and would provide transparency by requiring the generation of relevant information in all significant rulemakings.

IV. Rationale and Summary of the Proposed Requirements

A. Preparation of Benefit-Cost Analyses for Significant Regulations

The EPA seeks to codify the practice of preparing BCAs in the development of future significant CAA regulations. Specifically, EPA proposes that all future significant proposed and final regulations promulgated under the Clean Air Act be accompanied by a BCA. The EPA proposes to define a significant regulation as a proposed or final regulation that is determined to be a “significant regulatory action” pursuant to E.O. 12866 Section 3(f) or is otherwise designated as significant by the Administrator. Regulations meeting either of these factors are generally those that the EPA anticipates would have the largest annual impact on the economy (i.e., greater than \$100 million) as well as those that are important to analyze for other policy reasons. For example, a rule projected to have less than a \$100 million annual effect on the economy could disproportionately affect a single industry, population subgroup, or geographic area. Such rules, or ones that are notably novel or significant for other policy reasons, would benefit from rigorous analysis to inform the public and decision makers about the magnitude and disposition of both their benefits and costs on affected entities.

B. Best Practices for the Development of Benefit-Cost Analysis

In response to the ANPRM, the EPA received comments from a wide range of stakeholders emphasizing the importance of conducting BCA in accordance with best practices from the economic, engineering, physical, and biological sciences. One theme raised by some commenters was that there is inadequate adherence to existing EPA and OMB guidance for how to conduct BCA. Some commenters pointed to recent CAA regulatory BCAs conducted pursuant to E.O. 12866 as examples of a lack of transparency or improper analytic assumptions. As one example, some commenters contend that some BCAs have double-counted benefits that arise from another regulation. The EPA agrees that there is a risk of such a misestimation if the pollution concentration levels resulting from existing regulations are not carefully accounted for in the baseline of the analysis. In other words, this type of double-counting can be avoided if the Agency follows the best practices for BCA of correctly specifying the baseline. Several commenters recommended that the EPA issue binding procedural requirements to ensure transparency and consistent adherence to best practices for BCA. This proposed rule seeks to ensure consistent adherence to best practices for BCA of future CAA regulations by codifying these requirements into regulation. The EPA proposes that BCAs for significant proposed and final CAA regulations be developed in accordance with the best available scientific information and best practices from the economic, engineering, physical, and biological sciences. Specifically, the EPA proposes to codify into regulation several best practices for the conduct and presentation of BCA. In addition, the EPA would require that a reasoned explanation be

provided 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.

The proposed requirements itemized in the following subsections are among the best practices outlined in existing peer-reviewed OMB and EPA guidance documents developed in response to longstanding presidential orders discussed above: OMB's Circular A-4 (2003) and its associated guidance (2010, 2011a, 2011b)²⁰, EPA's Guidelines for Preparing Economic Analyses (2010). These guidance documents are grounded in the economics literature pertaining to the conduct of BCA. Benefit-cost analysis as a discipline is a branch of applied microeconomic welfare economics and is summarized in numerous textbooks such as Boardman et al. (2018), Farrow (2018), Brent (2006), Mishan and Quah (2007), and Hanley and Spash (1996).²¹ This discipline is applied routinely to environmental economics issues and the theory of BCA and its application can be found in standard environmental economic textbooks such as Phaneuf and Requate (2016) and Perman et al. (2012).²² Specific lists of best practices and guidance for practitioners can also be found in articles by Robinson and Hammit (2016), Sunstein (2014), Farrow (2013), Farrow and Viscusi (2011), Krutilla (2005), and notably in an article on the principles and standards by Nobel laureate Kenneth Arrow

²⁰ Office of Management and Budget, U.S., 2003. Circular A-4: Regulatory Analysis. Office of Management and Budget, U.S., 2010. Agency Checklist: Regulatory Impact Analysis. Office of Management and Budget, U.S., 2011a. Circular A-4, "Regulatory Analysis" Frequently Asked Questions (FAQs). Office of Management and Budget, U.S., 2011b. Circular A-4, "Regulatory Impact Analysis: A Primer".

²¹ Farrow, S. ed., 2018. Teaching Benefit-Cost Analysis: Tools of the Trade. Edward Elgar Publishing. Brent, R.J. ed., 2004. Applied Cost-Benefit Analysis. Edward Elgar Publishing. Mishan, E.J. and Quah, E., 2007. Cost-benefit analysis. Routledge. Hanley, N. and Spash, C., 1996. Cost benefit analysis and the environment.

²² Phaneuf, D.J. and Requate, T., 2016. A course in environmental economics: theory, policy, and practice. Cambridge University Press. Perman, R., Ma, Y., McGilvray, J. and Common, M., 2003. Natural resource and environmental economics. Pearson Education. Krutilla, K., 2005. Using the Kaldor - Hicks tableau format for cost - benefit analysis and policy evaluation. Journal of Policy Analysis and Management: The Journal of the Association for Public Policy Analysis and Management, 24(4), pp.864-875.

and a number of prominent economists (Arrow et al., 1996).²³

Since best practices for the conduct of BCA inherently require that the inputs to analysis reflect the best available information²⁴, the EPA is also taking the opportunity in this proposal to require that the EPA follow certain best practices regarding the incorporation of information as an input to BCA for significant CAA regulations. In particular, risk assessments often provide key inputs to the development of EPA's health benefit estimates in a BCA, and several commenters recommended that additional consistency and transparency be applied in the assessment of risks leading to the estimation of benefits. Through this rulemaking, the EPA proposes requirements to ensure the consistent and transparent use of risk assessments in BCA of CAA regulations. These proposed requirements include elements that are responsive to recommendations from the National Academies of Sciences, Engineering and Medicine (National Academies) and EPA's Science Advisory Board (SAB) to improve the utility of risk assessment for use in BCAs for CAA regulations. This proposal is also consistent with the 2007 OMB and OSTP Updated Principles for Risk Analysis²⁵, which also builds off of the National Academies and SAB recommendations as well as EPA's Risk Characterization Handbook.²⁶

Key elements of a Benefit-Cost Analysis. The key elements of a rigorous

²³ Robinson, L.A. and Hammitt, J.K., 2013. Skills of the trade: valuing health risk reductions in benefit-cost analysis. *Journal of Benefit-Cost Analysis*, 4(1), pp.107-130. Sunstein, C.R., 2014. The real world of cost-benefit analysis: thirty-six questions (and almost as many answers). *Columbia Law Review*, pp.167-211. Farrow, S., 2013. How (not) to lie with benefit-cost analysis. *The Economists' Voice*, 10(1), pp.45-50. Farrow, S. and Viscusi, W.K., 2011. Towards principles and standards for the benefit-cost analysis of safety. *Journal of Benefit-Cost Analysis*, 2(3), pp.1-25.

²⁴ See EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency (https://www.epa.gov/sites/production/files/2019-08/documents/epa-info-quality-guidelines_1.pdf).

²⁵ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2007/m07-24.pdf>

²⁶ <https://www.epa.gov/risk/risk-characterization-handbook> (EPA 100-B-00-002, December 2000).

regulatory BCA include: 1) a statement of need; 2) an examination of regulatory options; and 3) to the extent feasible, an assessment of all benefits and costs of these regulatory options relative to the baseline (no action) scenario.

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, EPA will exercise its subject matter expertise in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. Even when a benefit or cost cannot be expressed in monetary units, EPA will try to measure it in terms of its physical units. If it is not possible to measure the physical units, EPA will describe material benefits or costs qualitatively.

Statement of Need. Each regulatory BCA should include a statement of need that provides (1) a clear description of the problem being addressed, (2) the reasons for and significance of any failure of private markets or public institutions causing this problem, and (3) the compelling need for federal government intervention in the market to correct the problem. This statement sets the stage for the subsequent analysis of benefits and costs and allows one to judge whether the problem is being adequately addressed by the policy. Additional discussion of a thorough regulatory statement of need can be found in OMB (1993, B. Introduction, The Need for Federal Regulatory Action) and EPA (2010, Chapter 3).

Regulatory Options. The BCA must analyze the benefits and costs of regulatory options, or other notable deviations from the proposed or finalized option. Where there is a continuum of options (such as options that vary in stringency), the BCA must

analyze at least three options which accomplish the stated objectives of the Clean Air Act (unless the BCA explains the rationale for analyzing fewer than three options, as further described below) and must explain why they were selected: the proposed or finalized option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the proposed or finalized option; and a less stringent option that costs less (and presumably generates fewer benefits) than the proposed or finalized option. Even when a continuum of options is not applicable, an analysis of regulatory options provides an opportunity to analyze a variety of parameters including different compliance dates, enforcement methods, standards by size or location of facilities, and regulatory designs (e.g., performance vs. technology standards). If fewer than three options are analyzed, or if there is a continuum of options and the options analyzed do not include at least one more stringent (or otherwise more costly) and one less stringent (or otherwise less costly) option than the proposed or finalized option, then the BCA must explain why it is not appropriate to consider more alternatives. For further discussion, see OMB Circular A-4, E. Identifying and Measuring Benefits and Costs, General Issues, 3. Evaluation of Alternatives.

Baseline. The baseline in a BCA serves as a basis of comparison with the regulatory options considered. It is the best assessment of the way the world would look absent the regulatory action. The choice of a baseline requires consideration of a wide range of potential factors, including exogenous changes in the economy that may affect relevant benefits and costs (e.g., changes over time in demographics, economic activity, consumer preferences, and technology); impacts of regulations that have been promulgated by the agency or other government entities; and the degree of compliance

by regulated entities with other regulations. Accounting for other existing regulations in the baseline is especially important in order to avoid double counting of the incremental benefits and costs from other existing regulatory actions affecting the same environmental condition (e.g., ambient air quality). When the EPA determines that it is appropriate to consider more than one baseline (e.g., one that accounts for another EPA regulation being developed at the same time that would affect the same environmental condition), the BCA must provide a reasoned explanation for the baselines used in sensitivity analyses and must identify the key uncertainties in the forecast(s). These proposed requirements for developing a baseline are consistent with best practices as outlined in OMB's Circular A-4 (1993) and EPA's Guidelines (2010).

Measuring Benefits and Costs. A BCA evaluates the favorable effects of a policy action and the opportunity costs associated with the action. It addresses the question of whether the benefits from the policy action are sufficient for those who gain to theoretically compensate those burdened such that everyone would be at least as well off as before the policy. In other words, many regulations can be thought of as a requirement to divert resources from activities with a higher net return in private markets alone to those with a higher net return when all impacts are counted, thus the calculation of net benefits (benefits minus costs) helps ascertain the economic efficiency of a regulation.

In keeping with best practices, the appropriate measures of benefits and costs to use in a regulatory BCA are social benefits and social costs. When assessing a regulation, the social benefits are the society-wide positive changes in well-being, and social costs are the society-wide opportunities foregone, or reductions in well-being.

Willingness to pay (WTP) is the correct measure of these changes in BCA.²⁷ WTP provides a full accounting of an individual's preference for an outcome by identifying what the individual would give up to attain that outcome. WTP is measured in monetary terms to allow a comparison of benefits to costs in the net benefit calculation. If the BCA departs from these best practices (e.g., where WTP is hard to measure), it must include a robust explanation for doing so. For further discussion, see OMB Circular A-4, E. Identifying and Measuring Benefits and Costs, General Issues, 2. Developing a Baseline and Guidelines (2010/2014), Chapter 5. Baseline.

While based on the same underlying conceptual framework, social benefits and social costs are often evaluated separately due to practical considerations. The social benefits of reduced pollution are often attributable to changes in outcomes not exchanged in markets, such as improvements in public health or ecosystems. In contrast, the social costs generally are measured through changes in outcomes that are exchanged in markets. As a result, different techniques are used to estimate social benefits and social costs however, in both cases the goal is to estimate measures of WTP to provide consistency.

Methods for Estimating Benefits and Costs. Although the most appropriate methods for estimating social costs and social benefits can often be regulation-specific, there are best practices for selecting these methods. The EPA proposes that all BCAs

²⁷ Willingness to pay means the largest amount of money that an individual or group would pay to receive the benefits (or avoid the damages) resulting from a policy change, without being made worse off. The principle of WTP captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit. In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual's "willingness-to-accept" (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost. WTP is generally considered to be more readily measurable. Market prices provide rich data for estimating benefits and costs based on WTP if the goods and services affected by the regulation are traded in well-functioning competitive markets. See Hanley and Spash (1993), Freeman (2003), Just et al. (2005), and Appendix A of the Guidelines (2010/14).

will rely on such best practices and will provide reasoned explanations for methods selected. These best practices include the use of a framework that is appropriate for the characteristics of the regulation being evaluated. As discussed in OMB Circular A-4, a good regulatory analysis cannot be developed according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions. 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. Other considerations when selecting an estimation method include the ability of an estimation approach to capture certain types of costs, to adequately reflect the geographic and sectoral detail and scope of the rule, and to reflect how costs may change over time, among other considerations.

During the estimation process, analysts must consider how social cost and benefit endpoints may be affected by behaviors in the baseline and potential behavioral changes from the policy. For example, three broad frameworks for estimating social cost -- compliance cost, partial equilibrium, and general equilibrium -- offer different scopes in terms of the degree to which behavioral response and other market imperfections are included. In general, analysts can improve the accuracy of cost estimates by reducing known biases due to the omission of potentially important behavioral responses or missing opportunity costs. However, adopting more complex approaches can reduce the precision of estimates due to data and modeling limitations. A compliance cost approach typically identifies the private expenditures associated with

compliance in the regulated sector(s). Compliance cost estimates typically exclude behavioral responses outside of the choice of compliance activity and may, therefore, not capture some opportunity costs associated with regulations. However, with adequate data, this approach can generate highly detailed and relatively precise information on compliance options and costs, reflecting the heterogeneity of regulated entities. This can provide a reasonable estimate of the social cost of a regulation when changes in the regulated sector's outputs and input mix are expected to be minimal and no large market effects are anticipated. A partial equilibrium analysis captures supply and demand responses in the regulated sector due to compliance activities and may, therefore, provide a more complete estimate of compliance costs in addition to any lost profits and consumer welfare due to reductions in output. In other words, behavioral responses can have important impacts on both the size and distribution of benefits and costs, and therefore can provide a fuller picture of the social impact of a particular regulation. Partial equilibrium analyses may be extended to consider a small number of related sectors in addition to those directly regulated (e.g., upstream markets that supply intermediate goods to the regulated sector, or markets for substitute or complementary products). A partial equilibrium approach is preferred for estimating social cost when the regulation will result in appreciable behavioral change, but the effects will be confined primarily to a single market or a small number of markets. When broader economy-wide impacts are expected as a result of the regulation, a partial equilibrium approach will miss these effects. In this case, a general equilibrium approach may be more appropriate to more adequately estimate social cost.

A general equilibrium approach, which captures linkages between markets

across the entire economy, is most likely to add value when both relevant relationships among sectors and pre-existing market distortions are expected to be significant. Market distortions are factors such as pre-existing taxes, externalities, regulations, or imperfectly competitive markets that move consumers or firms away from what would occur in the absence of such distortions. For example, when an environmental regulation affects the real wage such that individuals opt to work fewer hours, it can exacerbate pre-existing inefficiencies in the labor market due to taxes, regulatory barriers, or other market imperfections. This represents a welfare cost not captured by compliance cost estimates. The impacts of a regulation also may interact with pre-existing distortions in other markets, which may cause additional impacts on welfare either positively or negatively. In cases such as these, a general equilibrium approach may be capable of identifying how the costs of complying with a regulation flow through the economy, such as through changes in substitution among factors of production, trade patterns, and demand for goods and services. These effects are partially or wholly missed by compliance cost and partial equilibrium approaches. For further discussion, see Guidelines (2010/2014), Chapter 8, Analyzing Costs, 8.1. The Economics of Social Cost.

The estimated social benefits reported in a BCA should link regulatory requirements to the value that individuals place on the beneficial outcomes,²⁸ or benefit endpoints, that can be meaningfully expected as a result of those requirements.

²⁸ As a practical matter, the value of any adverse public health or welfare outcomes (sometimes referred to as “disbenefits”) resulting from the regulatory requirements are usually also included on the benefits side of the ledger in regulatory BCAs, although it is theoretically appropriate to include them on the cost side. Such adverse outcomes could include adverse economic, health, safety, or environmental consequences that occur due to a rule (e.g., adverse safety impacts from vehicle emission standards) and are not already accounted for in the direct cost of the rule.

Benefits assessment is, therefore, typically a multi-step process. The starting point is identifying the changes in environmental contaminants or stressors that are likely to result from policy options relative to the baseline. These changes are often characterized through air quality modeling. The next step is to identify the benefit endpoints that may be affected by changes in environmental quality, such as human health improvements, ecological improvements, aesthetic improvements, and reduced materials damages. The EPA recognizes that the strength of scientific evidence for different health or environmental endpoints varies, and that strength of scientific evidence should be strongest when the benefits are estimated. As further discussed in OMB's M 19-15, this concept is referred to as "fitness for purpose," whereby information anticipated to have a higher impact must be held to higher standards of quality.²⁹

The EPA proposes to select the endpoints for which the scientific evidence indicates there is (a) a clear causal or likely causal relationship between pollutant exposure and effect, and subsequently, (b) an anticipated change in that effect in response to changes in environmental quality or exposures is expected as a result of the regulation under analysis. EPA takes comment on an alternative approach that would select all endpoints for which there is a positive WTP conditional on the available scientific literature.

Once benefit endpoints are identified, decisions must be made about whether and how to quantify changes in each endpoint. From among the endpoints identified

²⁹ OMB's M-19-15 refers back to OMB's 2002 *Guidelines, which* characterize a subset of agency information as "influential scientific, financial, or statistical information" that is held to higher quality standards. This is scientific, financial, or statistical information that "the agency can reasonably determine ... will have or does have a clear and substantial impact on important public policies or important private sector decisions."

above, the EPA proposes to quantify effects for endpoints which scientific evidence is robust enough to support such quantification. If the Agency determines that some benefits should be discussed only qualitatively, for example, due to limited scientific evidence or limited resources for developing concentration response functions, the Agency must provide a reasoned explanation for that decision. Additional information on choosing and quantifying health endpoints is described further below.

Quantification is then followed by valuation of these endpoints when data and methods allow. There are well-defined economic principles and well-established economic methods for valuation as detailed in OMB and Agency guidance, including Circular A-4 and the EPA Guidelines for Preparing Economic Analyses. Finally, the valued endpoints should be aggregated to the extent possible and supported by scientific and economic practice to provide the basis for characterizing the benefits of each policy option.

In some instances, it may be possible to value bundles of attributes or endpoints using reduced-form techniques, such as the hedonic property method. Care and professional judgment are necessary in determining the appropriateness of bundling of several endpoints versus modeling separate endpoints. Even if bundling is thought to be appropriate, it can be useful to think through the multi-step process above conceptually to: (a) assess whether there are benefit endpoints not reflected in the reduced form valuation estimate that should be included through additional analysis, or (b) compare the magnitudes of multi-step and reduced-form, revealed-preference benefits estimates so that each can provide a check on the reliability of the other.

In summary, the EPA proposes that, to the extent supported by the scientific

criteria, as discussed above, as well as practicable in a given rulemaking, (1) BCAs will quantify all benefits; (2) BCAs will monetize all the benefits by following well-defined economic principles using well-established economic methods; and (3) BCAs will qualitatively characterize benefits that cannot be quantified or monetized. In addition, the EPA proposes that the Agency must explain any departure from the best practices for the BCA described in Circular A-4; this includes discussing the likely effect of the departures on the size of the benefits estimate. More discussion of these best practices and estimation methods is provided in Circular A-4 and EPA's Guidelines for Preparing Economic Analyses, and the literature cited therein.

Quantifying Health Endpoints in a BCA: Decisions about whether and which changes in the health endpoints should be quantified should be informed by the Agency's evaluation of the relevant scientific literature establishing a link between chemical exposure and health endpoint and the nature of the concentration-response function (i.e., the amount of change in the frequency or severity of the health endpoint expected as the distribution of air quality changes.) In its evaluation, the Agency should explicitly state when scientific judgments or assumptions were used and their effect on the concentration-response function, if known. The Agency would select among concentration-response relationships from studies that satisfied the following minimum standards: (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; (3) concentration-response functions must be parameterized from scientifically robust studies; and (4) when an epidemiological study is used, further criteria include: (a) it must assess the influence of confounders; (b) the study location

must be appropriately matched to the analysis; and (c) the study population characteristics must be sufficiently similar to those of the analysis. When multiple studies satisfy these criteria, the EPA would characterize multiple concentration-response functions reflecting the full set of studies as a means of providing a broader representation of the effects estimate, including high quality studies that do not find a significant concentration-response relationship.

When selecting multiple concentration-response functions, 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. EPA proposes to require that decisions about the choice of the number of alternative concentration-response functions quantified for each endpoint be based on the extent to which it is technically feasible to quantify alternative concentration-response relationships given the available data and resources. Decisions should also consider the sensitivity of net benefits to the choice of concentration-response function. EPA proposes to present results in a manner that promotes transparency in the assessment process by selecting and clearly identifying concentration-response functions 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.

Once the Agency has identified the concentration-response functions to be used for quantifying the selected health endpoints, the Agency proposes that the BCA, or related technical support document, must characterize:

- the variability in the concentration-response functions across studies and models, including plausible alternatives;
- the assumptions, defaults, and uncertainties, their rationale, and their influence on the resulting estimates;
- the extent to which scientific literature suggests that the nature of the effect may vary across demographic or health characteristics;
- the potential variability of the concentration-response function over the range in concentrations of interest for the given policy;
- the influence of potential confounders on the reported risk coefficient;
- the likelihood that the parameters of the concentration-response differ based on geographic location; and
- 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.

In cases where existing Agency documents (e.g., an Integrated Science Assessment for criteria pollutants) provide the causal analysis, concentration-response analysis, or the factors indicated above to be included in the BCA, the BCA may reference this synthesis. Evidence from epidemiologic, experimental, and controlled human exposure studies may suggest that certain demographic subgroups are subject to risks that differ from the general population; in these instances, it may be appropriate to select concentration-response relationships that quantify risks among these specific subgroups.

BCA requires a comparison of expected costs and expected benefits, so BCA for

CAA regulations must include the determination of expected benefits. When feasible, a probability distribution of risk is appropriate to use when determining the expected benefits for CAA regulations. When it is infeasible to estimate a probability distribution, the EPA proposes that measures of the central tendency of risk be used. Upper-bound risk estimates must not be used unless they are presented in conjunction with lower bound and central tendency estimates.

Uncertainty Analysis. For various reasons, including the reason that the future is unpredictable, the benefits and costs of future regulatory options are not known with certainty. BCAs should identify uncertainties underlying the estimation of both benefits and costs and, to the extent feasible, quantitatively analyze those that are most influential. Specifically, the EPA must 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. The EPA must also present benefit and cost estimates in ways that convey their uncertainty. The BCA must include a reasoned explanation for the scope of the uncertainty analysis and must specify specific quantitative or qualitative methods chosen to analyze uncertainties. Quantitative uncertainty analyses may consider both statistical and model uncertainty where the data are sufficient to do so. Furthermore, where data are sufficient to do so, the BCA must consider sources of uncertainty independently as well as jointly. The BCA should also discuss the extent to which qualitatively assessed costs or benefits are characterized by uncertainty.

Where probability distributions for relevant input assumptions are available, characterize significant sources of uncertainty in the assessment, and can be feasibly

and credibly combined, the EPA proposes that BCAs characterize how the probability distributions of the relevant input assumption uncertainty would impact the resulting distribution of benefit and cost estimates. The EPA should report probability distributions for each health benefit whenever feasible. In addition to characterizing these distributions of outcomes, it is useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of the findings. If this proposed rule is adopted, there will be instances when calculating expected values is not practicable due to data or other limitations. In such instances, the EPA would strive to present a plausible range of benefits and costs. Additional discussion of these best practices related to uncertainty analysis is provided in OMB's Circular A-4, Treatment of Uncertainty, and throughout EPA's Guidelines for Preparing Economic Analyses Guidelines.

Principle of Transparency. The EPA proposes that BCA of significant CAA regulations include, at a minimum, a detailed and clear explanation of:

- The overall results of the BCA. The EPA proposes that the benefits, costs, and net benefits of each regulatory option evaluated in the BCA be presented in a manner designed to be objective, comprehensive, and easily understood by the public.
- How the benefits and costs were estimated, including the assumptions made for the analysis. BCAs must include a clear explanation of the models, data, and assumptions used to estimate benefits and costs, and the evaluation and selection process for these analytical decisions. This explanation would also include an explanation of procedures used to

select among input parameters for the benefit and cost models. Such an explanation could include methods used to quantify risk and to model the fate and transport of pollutants.

- All non-monetized and non-quantified benefits and costs of the action. BCAs must provide available evidence on all non-monetized and non-quantified benefits and costs, including why they are not being monetized or quantified and what the potential impact of those benefits and costs might be on the overall results of the BCA.
- The primary sources and potential effects of uncertainty. The BCA must present the results of the assessment of the sources of uncertainty that are likely to have a substantial effect on the results. Any data and models used to analyze uncertainty must be fully identified, and the quality of the available data must be discussed.

Finally, to the extent permitted by law, the EPA proposes to make the information (including data and models) that was used in the development of the BCA publicly available. If the data and models are proprietary, the EPA proposes to make the underlying inputs and assumptions used, primary equations, and methodologies available to the extent permitted by law, while continuing to protect information claimed as confidential business information (CBI), personally identifiable information (PII), and other privileged, non-exempt information.

Additional discussion of these best practices related to transparency is provided in OMB's Circular A-4, Transparency and Reproducibility of Results, and throughout EPA's Guidelines (2010).

C. Requirement for Additional Presentations of BCA Results in Rulemakings

One theme raised by many commenters on the ANPRM was that the EPA does not clearly distinguish benefit categories in its regulatory documents. These commenters stated that EPA's BCAs generally present benefits as an aggregate total, and that insufficient effort is made to clearly distinguish between the public health and welfare benefits attributable to the specific pollution reductions or other environmental quality goals that are targeted by the specific statutory provision or provisions that authorize the regulation, and other welfare effects of the regulation that are not the primary objective of the statutory provision or provisions. For example, some commenters pointed to reports that show that for regulations for which a BCA is available, the majority of the monetized benefits for CAA regulations were attributable to reductions in fine particulate matter (PM_{2.5}) even though the regulation did not target PM_{2.5}. This issue did not arise with respect to costs in the public comments received on the ANPRM.

While BCA requires a comparison of total social benefits and total social costs, commenters state that this comparison does not transparently communicate and may also create public confusion about the nature and scope of the statutory authority that provides the basis for the regulation, if a disproportionate share of social benefits arise from changes in environmental and other outcomes unrelated or secondary to the statutory objective of the regulation. While the Agency did not receive public comments on the presentation of costs, this principle of transparency would also apply to considerations of cost as contemplated by the statute when in pursuit those environmental benefits.

Following the principle of transparency, the EPA agrees with commenters that when presenting the results of a BCA, it is important to clearly distinguish between the social benefits attributable to the specific pollution reductions or other environmental quality goals that are targeted by the statutory provisions that give rise to the regulation, and other welfare effects. The disaggregation of welfare effects will be important to ensure that the BCA may provide, to the maximum extent feasible, transparency in decision making. These other welfare effects could include both favorable and adverse impacts on societal welfare. Analogous to how a regulation's interactions with existing imperfections or distortions in other markets (e.g., due to pre-existing taxes) could lead to additional social costs, a regulation could ameliorate or exacerbate other pre-existing externalities. For example, more stringent vehicle emissions standards could affect upstream refinery emissions or reduce the marginal cost of driving due to greater fuel efficiency and could lead to an increase in vehicle miles traveled that affects road safety, congestion, and other transport-related externalities.

Other welfare effects could also occur as a direct or indirect result of the compliance approaches used by regulated entities. For example, changes in other environmental contaminants may arise from the regulated sources. Likewise, the use of an abatement technology that reduces the emissions of HAPs into one medium (e.g., air) may change the emissions of another pollutant into the same medium (e.g., coming out of the same smokestack) or cause changes in emissions of pollutants into another medium (e.g., water) by the regulated sources. Changes in other environmental contaminants may also occur as a result of market interactions induced by the regulation. For example, a regulation may cause consumers or firms to substitute away

from one commodity towards another, whose increased production may be associated with changes in various environmental contaminants or other externalities.

The welfare effects associated with these changes should be accounted for in a BCA to the extent feasible, as it is the total willingness to pay for all changes induced by a regulation that determines their relative importance in evaluating economic efficiency.

Disaggregating benefits into those targeted and ancillary to the statutory objective of the regulation may cause the 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. This may be relevant when certain benefits are the result of changes in pollutants that the EPA regulates under a different section of the CAA or under another statute.

Proposed Requirements: 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 BCA results consistent with E.O. 12866 in CAA rulemakings, the EPA proposes to codify into regulation the requirement to present a summary in the preamble of the overall BCA results, including total costs, benefits, and net benefits. Second, to enhance transparency about the extent to which a rule is achieving its statutory objectives, the EPA proposes, in addition to a clear reporting of the overall results of the BCA, 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. If these benefit categories cannot be monetized, the EPA is proposing that the Agency must report the quantified estimates of these benefits to the extent practicable and must provide a qualitative characterization if they cannot be quantified. Similarly, if the statute directs or allows the Agency to consider costs, the EPA proposes to also provide a disaggregation of all relevant cost categories to the extent feasible in this section. This proposed requirement would serve as supplement to the BCA that is developed and presented according to best practices as outlined in Section IV.B. It does not replace or change any part of the RIA or the section of the preamble that summarizes the BCA results consistent with E.O. 12866. As discussed in Section V below, the EPA requests comment on alternative ways of increasing transparency about the extent to which a rule is achieving its statutory environmental objective. Finally, the EPA proposes that the presentational requirements described above be provided in the same section of the preamble of future CAA significant rulemakings.

V. Additional Considerations and Requests for Comment

A. Specifying How BCA Results Should Inform Regulatory Decisions

The EPA is proposing that the Agency undertake a BCA for significant regulations but is not proposing to specify how or whether the results of the BCA should inform significant CAA regulatory decisions. For example, the EPA is not proposing to

mandate that a significant CAA regulation be promulgated only when the benefits of the intended action justify its costs. Such a mandate would not be appropriate, for example, for regulations promulgated under provisions of the CAA that have been read by the courts to prohibit the consideration of costs in decision-making. For example, “[t]he text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations from the NAAQS-setting process.” *Am. Trucking Ass’n*s, 531 U.S. at 471. Thus, such a mandate would be improper for the NAAQS-setting process. There are other CAA provisions, however, that explicitly require the EPA to take costs into consideration in deciding how or whether to regulate. In addition, several provisions do not explicitly use the word “cost” but use terminology that implicitly requires or permits cost consideration. For example, terms such as “reasonable,” “appropriate,” “necessary,” or “feasible” have been interpreted as allowing for or even requiring the consideration of cost in decision making. Accordingly, when regulating pursuant to a CAA provision that either explicitly or implicitly requires or permits consideration of cost, it may be appropriate, depending on the statutory provision at issue, to consider whether the benefits of a regulation justify the costs in deciding whether or how to regulate.

In this proposal, the EPA solicits comment on how the Agency could take into consideration the results of a BCA in future rulemakings under specific provisions of the CAA. The EPA also solicits comment on approaches for how the results of the BCA could be weighed in future CAA regulatory decisions. For example, the EPA solicits comment on whether and under what circumstances the EPA could or should determine that a future significant CAA regulation be promulgated only when the benefits of the

intended action justify its costs. The EPA also solicits comment on whether and under what circumstances the EPA could determine that a future significant CAA regulation be promulgated only when monetized benefits exceed the costs of the action.

B. Other Areas of Solicitation for Public Comment

Applicability. EPA is requesting comment on whether this rulemaking should apply only to the subset of CAA significant regulations that are determined to be economically significant, which the EPA could define, consistent with E.O. 12866 Section 3(f)(1) and OMB *Circular A-4*, as those that are likely to have an effect on the economy (benefits, costs or transfers) of \$100 million or more in any one year (that is, a consecutive twelve-month period) or 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. These economically significant regulations are the same set of regulations for which E.O. 12866 requires the preparation of a BCA. The EPA also requests comment on whether the threshold of \$100 million in benefits and/or costs in any given year should be adjusted for inflation going forward, and, if so, whether such adjustments should be made assuming a base year of 1995 (as is done with the \$100 million expenditure threshold set forth in the Unfunded Mandates Reform Act). The EPA is requesting comment on whether certain elements of the proposed action should consider resource constraints when being implemented for CAA significant regulations, under the reasonable proposition embedded in EO 12866 that the intensity of the resources dedicated to an analysis should be coordinated and consistent with the level of impact of a decision.

Best Practices for the Development of BCA. The EPA is requesting comment whether it is appropriate to codify best practices for the development of BCA in this rulemaking and, if so, whether specific additional best practices should also be so codified. For example, the EPA solicits comment on whether this rulemaking should specify best practices related to assumptions about technological change and/or learning effects in BCA. The EPA further solicits comment as to whether any additional proposed requirements for BCAs would improve BCA consistency. EPA solicits comments as to whether non-domestic benefits and costs of regulations, when examined, should be reported separately from domestic benefits and costs of such regulations, just as this proposed rule would provide for a separate presentation of benefits limited to those targeted by the relevant statutory provision or provisions.

The EPA is requesting comment as to whether requirements related to risk assessments used in BCAs should be applied more broadly than as described in the proposed rule and, in particular, whether such requirements should apply to all risk assessments used in CAA significant rulemakings. For example, should EPA codify into regulation the proposed selection criteria for selecting among studies characterizing concentration-response relationships and the proposed requirement for synthesizing evidence across the literature? The EPA also solicits comment on whether to impose additional requirements for risk assessments. For example, should the EPA impose requirements for best practices related to any weight-of-evidence (WOE) frameworks that the Agency uses in the developments of CAA significant rulemakings? Should EPA impose additional requirements to ensure consistency and transparency in the assessment of bias and uncertainty in risk analyses (e.g., requirements relating to the

use of quantitative bias analysis, or requirements intended for consistency purposes such as requirements relating to the use of probabilistic risk analysis for reducing uncertainty in risk analysis)? The 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.

Additional Presentational Requirements to Increase Transparency. 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, the EPA should require a detailed disaggregation of both benefit and cost categories within the table that summarizes the overall results of the BCA 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. In addition, the EPA solicits comment on whether the EPA should require a separate presentation of all factors (e.g., particular benefit or cost categories, or other impacts) that are specifically listed as factors that the Administrator must consider in making a regulatory decision pursuant to the statutory provision(s) under which the regulation is being promulgated. This presentation would include a presentation of quantitative results for those factors that have been quantitatively assessed, and a qualitative discussion of any factors that were not quantified.

Retrospective Analysis. EPA requests comment on whether EPA should include a requirement for conducting retrospective analysis of significant CAA rulemakings. As discussed in the ANPRM, many previous administrations have periodically undertaken programs of retrospective review or issued executive orders urging agencies to reassess existing regulations and to eliminate, modify, or strengthen those regulations that have become outmoded in light of changed circumstances. But for the most part retrospective review has not become institutionalized practice as has prospective review (such as ex ante benefit-cost analysis conducted under Executive Order 12866) within EPA. The EPA received many comment letters on the ANPRM voicing support for increased retrospective review of Agency rules or programs to be able to evaluate the effectiveness of regulations and to design future improvements to increase efficiency. In this NPRM the EPA requests more specific comments on this issue. In particular, what form should a requirement take in the case of CAA regulations? For example, should the requirement pertain to analysis of an individual rule or a review of the cumulative burden of a set of rules regulating the same or related entities? Should it be applicable to all parts of CAA or just some provisions? What are the advantages and disadvantages of such a requirement? How can the Agency overcome the challenges conducting retrospective analysis in cases where the EPA's ability to collect information about the costs of compliance is limited or otherwise influenced by other statutes?

Sequence of Rules in Benefit-Cost Analysis. EPA seeks comment on how sequencing of rules might affect the estimation of benefits and costs.

Definitions. The EPA is requesting comment on whether there are additional terms that it should define to increase consistency and transparency in the development

of BCA to support CAA rulemaking actions.

Making Information Public. The EPA requests comments as to whether the proposed criteria regarding data, assumptions, and study selection reflect the Agency's commitment to be consistent and transparent. The EPA solicits comment on whether this rule should allow the Agency to use models offered by a third party only where the third party makes its models and assumptions publicly available (or allows the EPA to do so) to the extent permitted by law.

VI. References

The following is a listing of the documents that are specifically referenced in this notice. The docket includes these documents and other information considered by the EPA, including documents referenced within the documents that are included in the docket, even if a referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under the "For Further Information Contact" section above.

1. U.S EPA (U.S. Environmental Protection Agency). Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process; Advance notice of proposed rulemaking. (83 FR 27524, June 13, 2018).
2. OMB (Office of Management and Budget). (1996). Economic Analysis of Federal Regulations Under Executive Order 12866.
3. OMB (Office of Management and Budget). (2003). Circular A-4, "Regulatory Analysis."
4. U.S EPA (U.S. Environmental Protection Agency). (2010). Guidelines for

Preparing Economic Analyses.

5. Arrow, K., M. Cropper, G. Eads, R. Hahn, L. Lave, R. Noll, P. Portney, M. Russell, R. Schmalensee, V. Smith, and R. Stavins. 1996a. Benefit-Cost Analysis in Environmental, Health, and Safety Regulation: A Statement of Principles. Washington, D.C.: American Enterprise Institute, The Annapolis Center, and Resources for the Future.
6. Arrow et al. 1996b. Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation? *Science* 272: 221-222.

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed action is a significant regulatory action that was submitted to the OMB for review. Any changes made in response to OMB recommendations have been documented in the docket. The EPA does not anticipate that this rulemaking will have an economic impact on regulated entities. This is a rule of agency procedure and practice.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This proposed action is not expected to be an Executive Order 13771 regulatory action because it relates to “agency organization, management or personnel.”

C. Paperwork Reduction Act (PRA)

This proposed action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act (RFA)

I certify that this proposed action would not have a significant economic impact on a substantial number of small entities under the RFA. This action would not impose any requirements on small entities. This action would not regulate any entity outside the federal government.

E. Unfunded Mandates Reform Act (UMRA)

This proposed action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action proposed would impose no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This proposed action does not have federalism implications. It would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This proposed action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This proposed action is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this proposed action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

Increasing Consistency and Transparency in Considering Benefits and Costs in the
Clean Air Act Rulemaking Process

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List of Subjects in [citation]

Environmental protection, Administrative practice and procedure, Reporting and
recordkeeping requirements

Dated: _____.

Andrew Wheeler,
Administrator.

For reasons set forth in the preamble, the EPA proposes to amend 40 CFR Part 83 as follows:

PART 83 - INCREASING CONSISTENCY AND TRANSPARENCY IN CONSIDERING BENEFITS AND COSTS IN CLEAN AIR ACT RULEMAKING PROCESS

Authority: [42 U.S.C. 7601(a)(1)]

§__83._1 What definitions apply to this subpart?

Significant regulation means a proposed or final regulation that is determined to be a “significant regulatory action” pursuant to Section 3(f) E.O. 12866 or is otherwise designated as significant by the Administrator.

Benefit-cost analysis (BCA) means an evaluation of the favorable effects of a policy action and the opportunity costs, associated with the action. It addresses the question whether the benefits for those who gain from the action are sufficient to, in principle, compensate those burdened such that everyone would be at least as well off as before the policy. The calculation of net benefits (benefits minus costs) helps ascertain the economic efficiency of a regulation.

Baseline means the best assessment of the way the world would look absent the proposed or finalized action.

Regulatory options means, at a minimum, i) the proposed or finalized option; ii) a more stringent option which accomplishes the stated objectives of the Clean Air Act and that achieves additional benefits (and presumably costs more) beyond those realized by the proposed or finalized option; and iii) a less stringent option which accomplishes the stated objectives of the Clean Air Act and that costs less (and presumably generates fewer benefits) than the proposed or finalized option.

Social benefits, or benefits, means the positive changes in societal well-being incurred as a result of the regulation or policy action.

Social costs, or costs, means the sum of all opportunity costs, or reductions in societal well-being, incurred as a result of the regulation or policy action.

Opportunity cost means the value of the next best alternative to a particular activity or resource.

Compliance cost means the private cost that a regulated entity incurs to comply with a regulation (e.g., installation and operation of pollution abatement equipment).

Model means a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system. A formal representation of the behavior of system processes, often in mathematical or statistical terms. The basis can also be physical or conceptual.

Expected value is a measure of the central tendency of a set of data. It is usually the average or mean of the data. For a variable with a discrete number of outcomes, the expected value is calculated by multiplying each of the possible outcomes by the likelihood that each outcome will occur and then summing all of those values.

Sensitivity Analysis means an analysis that is used to assess how the final results or other aspects of an analysis change as input parameters change, particularly when only point estimates of parameters are available. Typically, a sensitivity analysis measures how a model's output changes as one of the input parameters change. Joint sensitivity analysis (varying more than one parameter at a time) is sometimes useful as well.

Data means the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as

keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party.

Publicly available means lawfully available to the general public from federal, state, or local government records; the Internet; widely distributed media; or disclosures to the general public that are required to be made by federal, state, or local law.

§83.2 How do the provisions of this subpart apply?

- a) The provisions of this subpart apply to benefit-cost analyses (BCA) prepared for all future significant regulations under the Clean Air Act (CAA). Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

§83.3 What requirements apply to EPA's preparations of Benefit-Cost Analyses (BCAs) under the Clean Air Act?

- a) Except as otherwise provided in paragraph (b) of this section, the Agency must develop BCAs of significant CAA regulations in accordance with best available scientific information and best practices from the economic, engineering, physical, and biological sciences, including the following practices.

- 1) In preparing the BCA, the Agency must include:

- i) A statement of need;

- ii) An examination of regulatory options; and

- iii) To the extent feasible, an assessment of all benefits and costs of these regulatory options relative to the baseline scenario.

- 2) In preparing the BCA, the Agency must include a statement of need that

provides: a clear description of the problem being addressed, the reasons for and significance of any failure of by private markets or public institutions causing this problem, and the compelling need for federal government intervention in the market to correct the problem.

3) In preparing the BCA the Agency must analyze the benefits and costs of regulatory options, as well as the benefits and costs of other notable deviations from the proposed for which the Agency is soliciting comment or the finalized option. Where there is a continuum of options (such as options that vary in stringency), the Agency must analyze at least three regulatory options (as provided in section XX(a)(3)(i)) and explain why these were selected.

If fewer than three options are analyzed, or if there is a continuum of options and the options analyzed do not include at least one more stringent and one less stringent option than the proposed or finalized option, then the Agency must explain why it is not appropriate to analyze more options.

4) In preparing the BCA, the Agency must use a baseline that appropriately considers relevant factors and relies on transparent and reasonable assumptions. The factors for which the Agency must account in the baseline include, but are not limited to, the following:

- i) Exogenous changes in the economy that may affect benefits and costs (e.g., changes in demographics, economic activity, consumer preferences, or technology);
- ii) Regulations promulgated by the Agency or other government entities; and
- iii) The degree of compliance by regulated entities with other regulations.

In rulemaking actions where the Agency determines it is appropriate to consider more than one baseline (e.g., one that accounts for another EPA regulation being developed at the same time that affects the same environmental condition), the Agency must provide a reasoned explanation for the baselines used and must identify the key uncertainties in the forecast(s).

5) In preparing the BCA, the Agency must rely on the use of a framework that is appropriate for the characteristics of the regulation being evaluated and must provide an explanation for the approach adopted.

6) The Agency must consider how costs and benefits may be affected by consumer and producer behavior in the baseline and potential behavioral changes from the policy scenarios.

7) During the estimation of benefits, the Agency must link regulatory requirements to the value that individuals place on the change in benefit endpoints that can be meaningfully attributed to those requirements. The Agency must select benefit endpoints that the scientific evidence indicates there is i) a clear causal or likely causal relationship between pollutant exposure and effect, and subsequently, ii) an anticipated change in that effect in response to changes in environmental quality or exposures expected as a result of the regulation under analysis. The Agency must quantify effects for endpoints which scientific evidence is robust enough to support such quantification.

8) The Agency 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

9) When selecting and quantifying health endpoints in a BCA, the Agency must:

(i) explain the basis for significant judgments, assumptions, data, models, and inferences used or relied upon in the assessment or decision;

(ii) describe the sources, extent and magnitude of significant uncertainties associated with the assessment;

(iii) When selecting concentration-response relationships from the scientific literature, the Agency must select from studies where each selected study meets the criteria in paragraphs (b)(8)(iii)(A) through (C) of this section.

(A) the study was externally and independently peer-reviewed consistent with Federal guidance;

(B) the pollutant analyzed in the study matches the pollutant of interest in the regulation;

(C) concentration-response functions must be parameterized from scientifically robust studies;

(D) when an epidemiological study is used further criteria include that the study must assess the influence of confounders, that the study location must be appropriately matched to the analysis, and that the study population characteristics must be sufficiently similar to those of the analysis.

(iv) When multiple studies satisfy these 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. The Agency would also include studies that meet the criteria above and that do not find a significant

concentration-response relationship.

(v) The Agency must base decisions about the choice of the number of alternative concentration-response functions quantified for each endpoint on the extent to which it is technically feasible to quantify alternative concentration-response relationships given the available data and resources.

(vi) The Agency must select and clearly identify concentration-response functions 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.

(vii) Once the Agency has identified the concentration-response functions to be used for quantifying the selected health endpoints, the Agency must characterize, in a BCA or related technical support document:

- (A) the variability in the concentration-response functions 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.

(viii) When feasible, the Agency must use a probability distribution of risk when determining expected benefits. When it is infeasible to estimate a distribution, the Agency must use measures of the central tendency of risk. Upper-bound risk estimates must not be used unless they are presented in conjunction with lower bound and central tendency estimates.

10) The Agency must identify uncertainties underlying the estimation of both benefits and costs and, to the extent feasible, quantitatively analyze those that are most influential; and 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.

(i) To the extent feasible, the Agency must use quantitative methods to analyze uncertainties that have the largest potential effect on benefits or cost estimates.

(ii) The Agency must 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.

(iii) Where data are sufficient to do so, the Agency must consider sources of uncertainty both independently and jointly.

(iv) To the extent feasible, The Agency must also consider, and transparently acknowledge, the extent to which qualitatively-assessed costs or benefits are

characterized by uncertainty.

(v) Where probability distributions for relevant input assumptions are available, characterize significant sources of uncertainty in the assessment, and can be feasibly and credibly combined, the Agency must characterize how the probability distributions of the relevant input assumption uncertainty would impact the resulting distribution of benefit and cost estimates.

(vi) Except as provided in this paragraph, the Agency must provide expected-value estimates of benefits and costs as well as distributions about each of the estimates. In cases where estimates based on expected values are not feasible, the Agency must present a plausible range of benefits and costs.

11) In presenting the results of the BCA the Agency must include the following elements:

(i) The Agency must present the overall results of the BCA (benefits, costs, and net benefits of each regulatory option evaluated in the BCA) in a manner designed to be objective, comprehensive, reproducible to the extent reasonably possible, and easily understood by the public.

(iii) The Agency must describe how the benefits and costs were estimated in the BCA, including the assumptions made for the analysis. 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. The Agency must provide an explanation of procedures used to select among input parameters to the benefit and cost models, and any methods used to quantify risk and to model fate and transport of

pollutants.

(iv) Consistent with the best available scientific information, the Agency must discuss non-monetized and non-quantified benefits and costs of the action. The Agency must present available evidence on non-monetized and non-quantified benefits and costs, including explanations as to why they are not being monetized or quantified and discussions of what the potential impact of those benefits and costs might be on the overall results of the BCA.

(v) The Agency must assess the sources of uncertainty that are likely to have a substantial effect on the results of the BCA and present the results of this assessment. The Agency must identify any data and models used to analyze uncertainty in the BCA, and the quality of the available data shall be discussed.

12) To the extent permitted by law, the Agency must ensure that all information (including data and models) used in the development of the BCA is publicly available. If the data and models are proprietary, the Agency must make available, to the extent permitted by law, the underlying inputs and assumptions used, equations, and methodologies used by EPA, while continuing to provide appropriate protection for information claimed as confidential business information (CBI), personally identifiable information (PII), and other privileged, non-exempt information.

b) The Agency 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.

§83.4 What additional requirements apply to EPA's presentation of BCA results for all significant rules promulgated under the Clean Air Act?

- a) The Agency must provide, in addition to the reporting of the overall results of the BCA as specified in §___._(a)(10)(i), a summary in the preamble of the overall BCA results, including total costs, benefits, and net benefits.
- b) The Agency must provide 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.
 - (i) This presentation must list the benefit categories arising from the environmental improvement that is targeted by the relevant statutory provision and report the monetized value to society of these benefits.
 - (ii) If these benefit categories cannot be monetized, the Agency must report the quantified estimates of these benefits to the extent possible and provide a qualitative characterization if they cannot be quantified.
- c) When the CAA provision or provisions under which the rule is promulgated contemplate the consideration of specific costs, the Agency must provide a transparent presentation of how those specific costs relate to total costs, to the extent possible.
- d) The presentations specified in (a), (b), and (c) must be placed in the same section in the preamble of the regulation.