

The EPA Administrator, Andrew R. Wheeler, signed the following final rule on 12/8/2020, and EPA is submitting it for publication in the Federal Register (FR). While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of compliance. Please refer to the official version in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (<https://www.govinfo.gov/app/collection/fr>) and on Regulations.gov (<https://www.regulations.gov>) in Docket No. EPA-HQ-OAR-2020-0044. Once the official version of this document is published in the FR, this version will be removed from the Internet and replaced with a link to the official version.

6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR 83**

**[EPA-HQ-OAR-2020-0044; FRL 10018-56-OAR]**

**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:** Final rule.

**SUMMARY:** This rule establishes processes that the Environmental Protection Agency (EPA) will 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. The EPA is establishing procedural requirements governing the preparation, development, presentation, and consideration of benefit-cost analyses (BCA), including risk assessments used in the BCA, for significant rulemakings conducted under the CAA. Together, these requirements will 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:** This final rule is effective **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, but does not apply to final rules for which a proposal was published prior to the effective date.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR-2020-0044. All documents in the docket are listed on the <http://www.regulations.gov> web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <http://www.regulations.gov>.

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**SUPPLEMENTARY INFORMATION:**

Preamble acronyms and abbreviations. The EPA uses multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms:

ANPRM Advanced Notice of Proposed Rulemaking

BCA Benefit-cost analysis

BenMAP Benefits Mapping and Analysis Program (BenMAP)

CAA Clean Air Act

CBI Confidential business information

CFR Code of Federal Regulation

CRA Congressional Review Act

EPA Environmental Protection Agency

IOM Institute of Medicine

NAAQS National Ambient Air Quality Standards

NHTSA National Highway Traffic Safety Administration

NPRM Notice of Proposed Rulemaking

IRIS Integrated Risk Information System

ISA Integrated Science Assessments

PII Personally identifiable information

SAB Science Advisory Board

WTA Willingness-to-accept

WTP Willingness to pay

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

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- H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
- I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use
- J. National Technology Transfer and Advancement Act
- K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
- L. Congressional Review Act

### **I. Executive Summary**

#### *A. Purpose of the Regulatory Action*

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 assess the likely consequences of various actions or options. Transparency about how these economic analyses are developed and how they are used in decision-making is essential to allowing interested parties to hold decision makers accountable for their decisions. BCA, a type of economic analysis, can serve an integral informative role in the regulatory development process. It provides detailed information about the value of benefits and costs of a policy to affected parties and whether a policy change has the potential to improve the aggregate well-being of society.

The purpose of this action is to codify procedural best practices for the preparation, development, presentation, and consideration of BCA in regulatory decision-making under the CAA. This codification will 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. This transparency is important to allow interested parties to understand and evaluate the adequacy and accuracy of the BCA and the role the analysis played in significant regulatory decision-making.

The Agency is taking this action pursuant to CAA section 301(a). 42 U.S.C. 7601(a)(1). Section 301(a)(1) 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. See *NRDC v. EPA*, 22 F.3d 1125, 1148 (D.C. Cir. 1994) (“[Section 301] is sufficiently broad to allow the promulgation of rules that are necessary and reasonable to effect the purposes of the Act.”).

*B. Summary of the Major Provisions of the Regulatory Action*

This final rule consists of three elements. First, it requires the EPA to prepare a BCA for all future significant proposed and final regulations under the CAA. The rule also requires that the Agency consider the BCA in promulgating the regulation except where the statutory provision or provisions under which a significant regulation is promulgated prohibit it.

Second, the rule requires EPA to develop the BCA using the best available scientific information and in accordance with best practices from the economic, engineering, physical, and biological sciences. The final rule codifies best practices consistent with the EPA’s *Guidelines* for Preparing Economic Analyses (hereafter “*Guidelines*”) and the Office of Management and Budget’s (OMB) Circular A-4, and also requires that risk assessments used to support BCAs should follow best methodological practices for risk characterization and risk assessment.

Third, the rule imposes additional procedural requirements to increase transparency in the presentation and consideration of the BCA results. Specifically, the rule provides that the preambles of significant proposed and final CAA regulations must include a section that contains:

- a. A summary presentation of the overall BCA results for the rule, including total costs, benefits, and net benefits;
- b. An additional reporting of the public health and welfare benefits that pertain to

- the specific objective(s) of the CAA provision(s) under which the rule is promulgated;
- c. A transparent presentation of how specific costs contemplated in the CAA provision(s) under which the rule is promulgated (to the extent specified), relate to total costs, to the extent possible; and
  - d. When the CAA statutory provision or provisions under which the rule is promulgated permit consideration of the BCA, a description of how the Agency considered the BCA.

Together, these requirements will help ensure that the EPA implements its statutory obligations under the CAA in a way that is consistent and transparent. The provisions of the final rule codify best practices for the preparation, development, presentation, and consideration of BCA as articulated in the principles and requirements of Executive Order 12866. This final rule does not change any other requirements pertaining to CAA rules specified in executive orders and existing guidance documents. For example, this final rule does not change the requirements for what types of analysis should be included in regulatory impact analyses prepared under E.O. 12866.

## **II. General Information**

### *A. Does this action apply to me?*

This rule 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 rule. For example, this rule may be of particular interest to entities and individuals concerned with how the EPA conducts BCA.

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

The Agency is taking this action pursuant to CAA section 301(a). 42 U.S.C. 7601(a)(1). Section 301(a)(1) 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. See *NRDC v. EPA*, 22 F.3d 1125, 1148 (D.C. Cir. 1994) (“[Section 301] is sufficiently broad to allow the promulgation of rules that are necessary and reasonable to effect the purposes of the Act.”).

This is a rulemaking of agency organization, procedure, or practice. This 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 and delayed effective-date requirements set forth in the Administrative Procedure Act. See 5 U.S.C. 553(a)(2),(b)(A),(d). Nonetheless, the Agency voluntarily sought public comment on the proposed rule because it believed that the information and opinions supplied by the public would inform the Agency's views. *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978) (“Agencies are free to grant additional procedural rights in the exercise of their discretion.”) In addition, even assuming *arguendo* that the notice-and-comment requirements of the Act applied to this action, EPA has determined that there would be good cause, consistent with 5 U.S.C. 553(d)(3), for making this final rule effective immediately because the goals of the rule, ensuring transparency and consistency in BCAs for significant CAA rulemakings, are crucial for ensuring

confidence in EPA decision-making. Because this is a procedural rule that only applies internally to ensure that EPA follows existing best practices with respect to BCA and to ensure that EPA explains how EPA considered the results, the rationale for delayed effectiveness to allow time to adjust to the new requirements does not apply.

In addition, the EPA received comments and recommendations on the proposed rule from the EPA Science Advisory Board (SAB), pursuant to its statutory duties to offer advice and comments on the scientific and technical basis of certain planned EPA actions pursuant to the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA).<sup>1</sup> Finally, the EPA also reviewed comments received from the SAB during the course of its review of the forthcoming update of the EPA's *Guidelines*.<sup>2</sup>

### III. Background

#### A. Summary of Executive Orders, guidances, and court rulings related to regulatory BCA

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.

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<sup>1</sup> The ERDDAA requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations, together with relevant scientific and technical information on which the proposed action is based. On the basis of this information, the SAB may provide advice and comments. The SAB final report on the proposed rule is available at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/0/82e89c7a596e9efa852585a50064d32e!OpenDocument&TableRow=2.3#2>.

<sup>2</sup> Information about the SAB review of the forthcoming update of the EPA's *Guidelines* is available at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/30D5E59E8DC91C2285258403006EEE00?OpenDocument>.

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 statutory provisions use terminology that in context implicitly direct or allow 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 is finalizing procedural requirements 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.<sup>3</sup> These inflation impact statements essentially turned into 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,<sup>4</sup> and the E.O. was renamed as *Economic Impact Statements* with E.O. 11949 in 1976.<sup>5</sup> 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."<sup>6</sup> 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, E.O. 12291 explicitly required that: "(a) Administrative decisions shall be based on adequate information concerning the need for and consequences of proposed government action;

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<sup>3</sup> EXECUTIVE ORDER 11821 — Inflation Impact Statements, **FEDERAL REGISTER**, VOL. 39, NO. 231—FRIDAY, NOVEMBER 29, 1974 (pages 41501-41502) .

<sup>4</sup> [https://obamawhitehouse.archives.gov/omb/inforeg\\_chap1#tnfrp](https://obamawhitehouse.archives.gov/omb/inforeg_chap1#tnfrp)

<sup>5</sup> 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>

<sup>6</sup> EXECUTIVE ORDER 12044 – Improving Government Regulations, **FEDERAL REGISTER**, VOL 43, NO. 58--FRIDAY, MARCH 24, 1978 (Pages 12659-12670).

(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 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.”<sup>7</sup> 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.”

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

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<sup>7</sup>EXECUTIVE ORDER 12291 – Federal Regulation, **FEDERAL REGISTER**, VOL 46--FEBRUARY 19, 1981 (Page 13193).

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 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.<sup>8</sup>

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<sup>8</sup> While the analytical requirements are the same, the dollar thresholds do not exactly coincide because the \$100 million threshold is not adjusted for inflation under E.O. 12866.

More recent Executive Orders also reaffirm the requirements and principles in E.O. 12866. E.O. 13563, issued in 2011 and 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.”<sup>9</sup> More recently, E.O. 13777, issued in 2017, directs agencies to identify regulations that “impose costs that exceed benefits.”<sup>10</sup> 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.”<sup>11</sup>

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.<sup>12</sup> 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.”<sup>13</sup> The document

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<sup>9</sup> <https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review>

<sup>10</sup> Enforcing the Regulatory Reform Agenda (82 FR 12285, March 1, 2017).

<sup>11</sup> <https://www.govinfo.gov/content/pkg/FR-2017-03-31/pdf/2017-06576.pdf>.

<sup>12</sup> [https://obamawhitehouse.archives.gov/omb/circulars\\_a004\\_a-4/](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.

<sup>13</sup> <https://www.govinfo.gov/content/pkg/FR-2017-03-31/pdf/2017-06576.pdf>

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 “identify the alternative that maximizes net benefits.”<sup>14</sup>

EPA’s *Guidelines for Preparing Economic Analyses* (hereafter, the *Guidelines*)<sup>15</sup> 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, the *Guidelines* 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 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 be

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<sup>14</sup> [https://obamawhitehouse.archives.gov/omb/circulars\\_a004\\_a-4/](https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/)

<sup>15</sup> <https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses>

being finalized.<sup>16</sup>

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,<sup>17</sup> such provisions do not preclude the Agency from providing additional information regarding the impacts of a proposed or final rule to the public. For example, while the CAA prohibits the EPA from considering cost when establishing or revising requisite National Ambient Air Quality Standards (NAAQS) for criteria pollutants<sup>18</sup>, the EPA nonetheless provides Regulatory Impact Analyses (RIAs)<sup>19</sup> to the public for these rulemakings.<sup>20</sup>

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*,

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<sup>16</sup> 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/ce-0568-09.pdf>. For more details regarding the update of the *Guidelines* in general, see: <https://yosemite.epa.gov/sab/sabproduct.nsf//LookupWebProjectsCurrentBOARD/30D5E59E8DC91C2285258403006EEE00?OpenDocument>.

<sup>17</sup> 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.

<sup>18</sup> *Id.*

<sup>19</sup> 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).

<sup>20</sup> 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>.

*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 a potential factor always implies prohibition of consideration of that factor. Therefore, the Supreme Court concluded that the EPA was 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, not that *American Trucking* stands for the proposition that statutory silence always unambiguously bars cost consideration, but, rather 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 approach for cost consideration but have granted the Agency broad discretion in determining its methodology. See *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, 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 CFR 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.

## B. Summary of the Proposed Rule

With the history discussed above in mind as a backdrop and following E.O. 13777 noted above, the EPA opened a public docket<sup>21</sup> in April 2017 to solicit feedback and identify regulations that “impose costs that exceed benefits.” Among the public comments received, a large cross-section of industry 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

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<sup>21</sup> 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.

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 memorandum<sup>22</sup> 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.

In June 2020, the EPA issued a Notice of Proposed Rulemaking (NPRM), “Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process” (85 FR 35612, June 11, 2020). The proposed rule was the first statute-specific rulemaking in this effort. The EPA proposed to codify the procedural requirements governing the development of BCA, including risk assessments used as inputs to the BCA, for significant rulemakings conducted under the CAA, and proposed

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<sup>22</sup> Available at: <https://www.epa.gov/environmental-economics/administrator-wheeler-memorandum-increasing-consistency-and-transparency>.

additional procedural requirements to increase transparency in the presentation of the benefits and costs resulting from significant CAA regulations. Together, these requirements were proposed to ensure a consistent approach to the EPA's BCAs under the CAA and to provide transparency by requiring the provision of relevant information in all significant rulemakings. In the proposed rule, the EPA also solicited comment on how the Agency should take into consideration the results of a BCA in future rulemakings under specific provisions of the CAA, among other topics. Discussion of topics where the EPA solicited comment, and comments and responses where EPA has made modifications in the final rule, is included in Section V of this preamble. Responses to the rest of the comments are provided in the Response to Comments Document.

#### **IV. Description of the Final Rule**

This final rule consists of three elements. In the first element, it requires the EPA to prepare a BCA for all future significant proposed and final regulations promulgated under the CAA and to consider the BCA in the decision-making process when permitted for consideration under the specific provision of the CAA under which the future regulation is promulgated. The EPA believes that in keeping with OMB's Circular A-4 and Executive Order 12866 that the requirement to prepare a BCA would create consistency with well-understood and established processes and determinations for what constitutes a "significant" rulemaking. Therefore, in this final rule, a significant regulation will include any 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. Consideration of the results of BCA in

regulatory decision-making is also consistent with the requirements of E.O. 12866. If the provision or provisions under which the rule is promulgated prohibit the consideration of the BCA, the final rule requires the Agency to identify the specific provision that bars such consideration.

The second element of the final rule requires EPA to develop the BCA using the best available scientific information and in accordance with best practices from the economic, engineering, physical, and biological sciences. The final rule codifies general best practices consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., EPA's *Guidelines for Preparing Economic Analyses* (hereafter "*Guidelines*") and the Office of Management and Budget's (OMB) *Circular A-4*), and also requires that risk assessments used to support BCAs should follow best methodological practices for risk characterization/assessment. The final rule does not replace any detailed guidance for Agency analysis, including Executive Orders (e.g., E.O. 12866), OMB Circulars (e.g., *Circular A-4*), and EPA documents (e.g., *Guidelines for Preparing Economic Analyses*).

The specific best practices that are required in this final rule are as follows. The BCA must include a statement of need, an examination of regulatory options which would contribute to the stated objectives of the CAA, and to the extent feasible, an assessment of all benefits and costs of these regulatory options relative to the baseline scenario. The baseline used in the BCA must appropriately consider relevant factors and rely on transparent and reasonable assumptions. In preparing the BCA, the Agency must rely on the use of a framework for estimating costs and benefits that is appropriate for the characteristics of the regulation being evaluated and must provide an explanation for the

approach adopted. In estimating costs and benefits, the Agency must consider how costs and benefits may be affected by consumer and producer behavior both in the baseline and in the policy scenarios. The BCA must include, to the extent supported by scientific literature as well as practicable in a given rulemaking: a quantification of all benefits; a monetization of benefits that follows well-defined economic principles using well-established economic methods, appropriate data and/or studies; and a qualitative characterization of benefits that cannot be quantified or monetized.

Regarding the process of selecting health benefit endpoints for quantification, the final rule requires that this process will be based upon scientific evidence that indicates there is a clear causal or likely causal relationship between pollutant exposure and effect, and that sufficient data and understanding allows the agency to reasonably model the anticipated change in that effect in response to changes in environmental quality or exposures expected as a result of the regulation under analysis. The evaluation of the scientific evidence necessary to select and quantify health benefit endpoints should follow the systematic review process, must emphasize transparency and replicability, and give more weight to higher quality data, models, and/or analyses that have been peer reviewed. The models used to quantify the concentration-response relationships should take into account the breadth and quality of the available evidence regarding the nature and magnitude of the risk to the populations affected by the regulation. The presentation of results should characterize the sensitivity of the choice of the concentration-response function on the magnitude and the uncertainty associated with estimated benefits.

The BCA must include an identification of uncertainties underlying the estimation

of both benefits and costs and, to the extent feasible and appropriate, quantitatively analyze those that are most influential; and must present benefits and cost estimates in ways that convey their uncertainty, including acknowledging unquantified benefits and costs, where appropriate. The BCA must include a reasoned explanation for the scope and specific quantitative or qualitative methods chosen to analyze uncertainties.

The final rule also requires that the overall results of the BCA (benefits, costs, and net benefits of each regulatory option evaluated in the BCA) be presented and described in a manner designed to be objective, comprehensive, reproducible to the extent reasonably possible, and easily understood by the public. 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 data and models are proprietary, the Agency must make available, to the extent practicable, the underlying inputs and assumptions used, equations, and methodologies used by EPA. The BCA shall 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.

The third element of the final rule imposes additional procedural requirements to increase transparency in the presentation and consideration of the BCA results. Specifically, the rule requires the preamble of significant proposed and final CAA regulations to include a section that contains a summary presentation of the overall BCA results for the rule, including total benefits, costs, and net benefits. Within this summary presentation, if any benefits and costs accrue to non-U.S. populations they must be reported separately to the extent possible. This section of the preamble should also provide an additional reporting of the public health and welfare benefits that pertain

to the specific objective(s) of the CAA provision(s) under which the rule is promulgated and a transparent presentation of how specific costs contemplated in the CAA provision(s) under which the rule is promulgated (to the extent specified), relate to total costs, to the extent possible. Finally, when the CAA statutory provision or provisions under which the rule is promulgated permit consideration of the BCA, this section of the preamble should contain a description of how the Agency considered the BCA.

Together, these requirements will help ensure that the EPA implements its statutory obligations under the CAA with high quality regulations in a way that is consistent and transparent and that these procedures are made enforceable upon the Agency. The provisions of the final rule codify into regulation best practices for the preparation, development, presentation, and consideration of BCA as articulated in the principles and requirements of Executive Order 12866.

## **V. Responses to Significant Comments**

The EPA had a 45-day public comment period on the proposed rule, and also hosted a virtual public hearing on July 1, 2020, which included 50 speakers registered to provide testimony. In total, the EPA received 24,740 public comments, including several mass mail campaigns and 513 unique comment letters (including transcripts from the July 1 virtual public hearing). Of these, a total of 143 letters provided detailed, substantive comments. Commenters included environmental and health advocacy organizations, industry trade groups, academics, and State, Local, and Tribal governments.

### *A. Purpose of the Action*

Commenters supporting the EPA's proposed rulemaking argued that the

proposed requirements, if finalized, would provide more clarity and transparency, make common sense, enhance public accountability and understanding of the scientific inputs that drive the EPA's decisions, improve the integrity of the rulemaking process, and lead to better public policy. Commenters also stated that codification of best practices for conducting and presenting BCA would standardize procedures and would achieve consistency over time and provide for better transparency. Some commenters further argued the rule would deliver continued environmental improvement as well as a more predictable and achievable set of outcomes for the regulated community. In addition, a commenter stated that EPA's proposed rule, if finalized, would supersede, rather than duplicate, existing non-justiciable, non-statutory sources of guidance for Agency analysis, including EOs (e.g., EO 12866), OMB Circulars (e.g., *Circular A-4*), and EPA documents (e.g., EPA's *Guidelines*).

Commenters opposed to the proposed rule argued that the EPA does not explain how any of the Agency's previous BCAs have fallen short of any applicable legal requirements or failed to deliver on their purported policy benefits. Commenters stated that EPA has also not specifically detailed how the Agency's use of its own economic guidance (e.g., EPA's *Guidelines*) and OMB's Circular A-4 guidance has resulted in inadequate, inconsistent, or nontransparent practices or has compromised the Agency's abilities and disagreed with the need for a rulemaking. These commenters said that the EPA's proposal does not make the case that such shortcomings are so widespread among the EPA's existing BCA practices that the proposal was necessary. These commenters further stated the EPA does not identify any deficiencies in existing laws, orders, and guidelines, and, therefore, did not fully demonstrate how the proposed

changes will address the alleged problem. Some commenters further stated that the EPA's proposed rule creates an excessively burdensome set of procedures for completing a BCA that would be difficult for the agency to satisfy and would be prohibitively costly to complete. One commenter stated that increasing transparency and consistency in the analysis upon which regulatory decisions are based should not come at the cost of undermining the flexibility and accuracy needed for regulatory decision-making on the wide variety of air pollutants and sources regulated under the CAA. The commenter added that many of the consistency and transparency goals in the proposal are already being met through existing EPA practices, particularly requirements in EO 12866, and contended that setting a prescriptive process for conducting BCAs will lead to inflexibility that could prove detrimental to public health and the environment. One commenter argued that, given the clear credibility and reliability of the peer-reviewed and longstanding methodologies for developing BCAs (as acknowledged by the EPA itself throughout the proposal), it was arbitrary and capricious for the EPA to constrain its methodologies. A few commenters objected to the proposal's approach, as they believed that a regulation establishes rigid practices that then make it difficult for the EPA to readily adopt future improvements to best practices. On this issue, a few commenters further suggested that because analytical requirements evolve, the EPA should create a requirement to periodically update the best practices through a public notice and comment rulemaking process.

The EPA disagrees with commenters that this rule is unnecessary. The EPA continues to believe that codifying best practices into regulation provides additional certainty and increases the consistency and transparency of its analysis of the benefits

and costs of significant regulations under the CAA. The requirements promulgated in this action address the comments, by many, that the Agency has not consistently estimated, presented, and considered benefits and costs in line with best practices and principles set forth in longstanding executive orders governing regulatory analysis. Some commenters asserted that these inconsistencies were not identified by EPA and were not so widespread among the EPA's existing BCA practices that the proposal was necessary. However, EPA has not had procedural enforceable regulations in place to ensure consistency in its past BCA practices. To the extent that commenters assert that EPA's past practice has been consistent and transparent, it is not due to an enforceable standardized approach that would ensure such a result. Other commenters have noted the contrary belief, that EPA's practices in regard to BCA have indeed been inconsistent and have lacked transparency. Without enforceable procedural regulations for BCA, future regulations may be promulgated without consideration of, and public accountability concerning, their costs and benefits. Thus, the EPA has determined that the Final Rule is necessary to ensure that BCA practices are implemented in a consistent fashion prospectively. The requirements provide a practical framework to ensure that the BCA of significant CAA regulations follow best practices and complement more detailed existing guidances the EPA relies upon (e.g., OMB's *Circular A-4* and EPA's *Guidelines*) to develop quality regulations consistent with the CAA, and that these procedures are made enforceable upon the Agency. The final rule does not replace detailed guidance for Agency analysis, including Executive Orders (e.g., E.O. 12866), OMB Circulars (e.g., *Circular A-4*), and EPA documents (e.g., EPA's *Guidelines*).

### *B. Authority to Promulgate a Procedural Rule*

The EPA received comments on its legal authority to promulgate the proposed rule. We respond to some of the major comments below and to the rest in Chapter 4 of the Response to Comments Document. In particular, the EPA received comments that Section 301(a)(1) of the CAA both does and does not provide adequate authority to promulgate the proposed rule. Commenters asserted that Section 301(a)(1) explicitly authorizes the EPA Administrator “to prescribe such regulations as are necessary to carry out his functions” under the statute, noting the D.C. Circuit holding that Section 301(a)(1) “is sufficiently broad to allow the promulgation of rules that are necessary and reasonable to effect the purposes of the Act.” *NRDC v. EPA*, 22 F.3d 1125, 1148 (D.C. Cir. 1994). Commenters further noted how consistency and transparency advance the goals of the CAA. Other commenters argued that Section 301(a)(1) was not an adequate authority as the rule was not necessary, noting that Section 301(a)(1) does not provide the Administrator “carte blanche authority to promulgate any rules, on any matters relating to the Clean Air Act, in any manner that the Administrator wishes,” and only permits “the promulgation of rules that are necessary and reasonable to effect the purposes of the Act.” *Id.*

The EPA agrees with the commenters stating that Section 301(a)(1) of the CAA provides adequate authority for this final rulemaking. The EPA has determined that the authority in Section 301(a)(1) 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. In *NRDC*, the court stated that “[a]lthough section 301 does not provide the Administrator ‘carte blanche authority to promulgate any rules,

on any matter relating to the Clean Air Act, in any manner that the Administrator wishes,' *Spencer County*, 600 F.2d at 873, it is sufficiently broad to allow the promulgation of rules that are necessary and reasonable to effect the purposes of the Act." *Id.* Further finding that "[w]here, as here, Congress has erected no clear impediment to the issuance of binding rules, section 301 takes the agency as far as the second step of *Chevron*. Once there, the EPA provided a reasoned explanation for resorting to rulemaking." *Id.* Likewise, the Agency is not aware of any clear impediment to this rulemaking and this preamble provides a reasoned explanation of the purpose and need for this rulemaking.

The Agency believes that the information provided as a result of the procedural requirements of this rule will increase transparency and consistency across CAA rulemakings; provide the public with additional information in the CAA rulemaking process; and provide the Agency with supplemental information for use by the Agency when it is appropriate to be considered. These outcomes will better allow the Agency to fulfill the purpose described in Section 101(b)(1) of the CAA "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population". Further, Section 101(c) of the CAA states that "a primary goal of [the Act] is to encourage or otherwise promote reasonable Federal, State, and local governmental actions, consistent with the provisions of [the] Act, for pollution prevention." As noted above, the Supreme Court has stated 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). The information provided as a result of the procedural requirements of this rule will be in addition to the

information provided by other methodologies and analyses as directed by specific CAA statutes and regulations. Such an approach is consistent with reasonable rulemaking standards.

The EPA also received public comments asking for clarification as to whether the procedures in this final rule are enforceable against the Agency. The EPA received comments arguing that the procedures in this final rule are enforceable against the agency and comments that such procedures would not be and asking for clarification. The EPA agrees with commenters asserting that the procedures in this final rule are enforceable against the Agency. Generally, a court reviews an agency's compliance with its regulations, even where the regulatory requirements go beyond what is required by statute. See, e.g., *Service v. Dulles*, 354 U.S. 363, 388 (1957) ("While ... the Secretary was not obligated to impose upon himself these more rigorous substantive and procedural standards, neither was he prohibited from doing so, as we have already held, and having done so he could not, so long as the Regulations remained unchanged, proceed without regard to them."). See generally Wright & Miller, 32 FED. PRAC. & PROC. JUDICIAL REVIEW § 8165 (1st ed. Oct.. 2020 Update) ("One of the most firmly established principles in administrative law is that an agency must obey its own rules."). See also, e.g., *United States v. Nixon*, 418 U.S. 683, 696 (1974) ("So long as this regulation remains in force the Executive Branch is bound by it, and indeed the United States as sovereign composed of the three branches is bound to respect and to enforce it."); *Vitarelli v. Seaton*, 359 U.S. 535, 540 (1959); *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 266-67 (1954). Indeed, many courts have enforced non-legislative procedural rules against the agency. See, e.g., *Morton v. Ruiz*, 415 U.S. 199,

235 (1974) (enforcing an agency manual even though the manual was not a “legislative rule” but “solely an internal-operations brochure intended to cover policies that do not relate to the public,” because “[b]efore the BIA may extinguish the entitlement of these otherwise eligible beneficiaries, it must comply, at a minimum, with its own internal procedures.”); *NRDC v. Perry*, 940 F.3d 1072, 1077 (9th Cir. 2019). Thus, the Agency believes that this Final Rule is binding upon the Agency for significant CAA regulations, and that EPA’s compliance with these procedural requirements is subject to judicial review in challenges to such rulemakings.

Finally, the EPA received comments that the proposed rule was a procedural rule and comments, to the contrary, that the proposed rule was non-procedural because it altered the rights and interests of parties beyond EPA. The EPA disagrees with commenters asserting that the proposed rule was non-procedural because it altered the rights and interests of parties beyond EPA. 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, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.” *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); *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.”). In addition, the Supreme Court explained in *Chrysler Corp. v.*

*Brown*, that rules of internal agency management are considered procedural rules as opposed to substantive rules under the APA. 441 U.S. 281, 301-02 (1979). As the Supreme Court explained in *Chrysler Corp.*, “the central distinction among agency regulations found in the APA is that between ‘substantive rules’ on the one hand and ‘interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice on the other.’” 441 U.S. at 301. The Supreme Court further clarified that unlike procedural rules, substantive rules have legal force and effect on individual rights and obligations, and noted that whether a rule affects individual rights and obligations is an “important touchstone” for distinguishing substantive rules from other types of rules. *Chrysler Corp.*, 441 U.S. 281 at 302.

Because this rule covers requirements that apply to the agency’s rulemaking procedure and does not impose any obligations or grant any rights to third parties, it is procedural.

In this Final Rule, the EPA does not interpret or apply other provisions of the CAA. Subsequent substantive CAA rulemakings applying this rule will be subject to judicial review. By contrast, in this action, the EPA finalizes a rule governing internal agency procedures. This rule does not require any outside entity to take any action. Further, this rule would not regulate the conduct or determine the rights of any entity outside the federal government in the manner described above. Several comments noted that the rule would potentially create an enforcement mechanism were the Agency to fail to follow its own internal procedures. The Agency, as discussed above, believes that this Final Rule is binding upon the Agency for significant CAA regulations, and EPA’s compliance with these procedural requirements is subject to judicial review in challenges to such rulemakings. However, this does not render a rule non-procedural.

As discussed above, courts have generally enforced non-legislative procedural rules against agencies. Commenters assert that such enforcement in turn renders the rule non-procedural. If enforcement of a procedural rule rendered the rule substantive, there could be no history of enforcement of procedural rules; all such rules would simply be substantive. Clearly this cannot be the standard. The rule itself must alter the rights and interests of parties beyond EPA, rather than simply be binding upon the Agency, and this final rule does not regulate any party outside of the EPA, but, rather, exclusively governs the EPA's internal procedure.

### *C. Definitions*

Several commenters and the SAB provided specific recommendations for changes to some of the definitions in the proposed rule. Examples of terms that commenters or the SAB provided specific definitions for include, but are not limited to, "Benefit-cost analysis (BCA)", "Opportunity cost," "Social benefits," "Compliance cost," "Regulatory Options", and "Significant" regulation. These commenters provided references for their suggested definitions, which included guidance published by OMB, the EPA's *Guidelines*, and published economic journal articles, and they recommended that the EPA finalize the rule with these definitions. Discussed below are the definitions that we are revising or finalizing as proposed based on the comments received. Complete responses to other specific suggestions for additional terms to be defined are provided in Chapter 10 of the Response to Comments document, and in some of the remaining sections in this preamble where relevant.

*Baseline.* The EPA did not receive specific suggestions in the public comments on the definition of baseline. However, based on feedback from the EPA SAB on the

EPA *Guidelines* update, the EPA has decided to adopt a minor revision to the definition to clarify that it provides the counterfactual situation against which a policy should be assessed. The revision does not change the substantive meaning of the term. In the final rule, the definition of baseline is as follows: “Baseline means the best assessment of the way the world would evolve absent the regulation. It is the primary point of comparison for assessing the effects of the regulatory options under consideration.”

*Benefit-cost analysis (BCA)*. Some commenters recommended that EPA provide a more detailed definition of benefit-cost analysis. For example, one commenter claimed that as written, "benefit-cost analysis" lacks clarity, because a key term "favorable effects of a policy action" is undefined. The commenter further argued that evaluation of a benefits-cost analysis is incomplete without concise, clear directive to the EPA on what favorable effects may balance opportunity costs.

In their review of the proposed rule, the SAB recommended that the definition for BCA be revised to more closely align with the definition provided in OMB's *Circular A-4*. Specifically, the SAB recommended revising the definition to clearly state that BCA provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits (benefits minus costs) to society (ignoring distributional effects) (OMB, 2003). The SAB also recommended that the definition should indicate that costs should be opportunity costs and benefits represent the willingness-to-pay for a policy outcome valued by United States individuals.

The EPA agrees with the SAB and public comments that it would be helpful to provide a more comprehensive definition of BCA, drawing language more explicitly from

OMB's *Circular A-4* and avoiding undefined phrases such as "favorable effects". Thus, in this final rule the definition is revised as follows:

"Benefit-cost analysis (BCA) means an evaluation of the social benefits and social costs of a policy action. The social benefits of a policy are measured by society's willingness-to-pay for the policy outcome. The social costs are measured by the opportunity costs of adopting the policy. BCA addresses the question of whether the benefits for those who gain from the action are sufficient to, in principle, compensate those burdened by costs such that everyone would be at least as well off as before the policy. The calculation of net benefits (benefits minus costs) answers this question and helps ascertain the economic efficiency of the policy. Where all benefits and costs can be quantified and expressed in monetary units, BCA provides decision makers with a clear indication of the most economically efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects)."

The EPA does not agree with the SAB's recommendation to add "valued by United States individuals" because limiting the geographic scope of a BCA does not belong in a general definition of BCA. OMB *Circular A-4* allows impacts accruing to non-U.S. populations to be estimated and reported separately: "Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately" (OMB 2003). The EPA is including in this final rule a presentational requirement consistent with this guidance. See Section V.F of this Preamble.

*Compliance cost.* One commenter stated that the definition provided in the proposed rule fails to include all necessary costs of compliance, because costs of professional service and interrelated effects appear to be excluded. While the EPA believes that the definition provided in the proposed rule was broad enough to cover all private costs associated with compliance, the final rule revises the definition to: “Compliance cost means the private cost that a regulated entity incurs to comply with a regulation – for instance, through planning, design, installation and operation of pollution abatement equipment.”

*Data.* The EPA received limited specific suggestions in the public comments on the definition of data. Some commenters expressed concern that this language could be interpreted to exclude anonymized medical data from the definition of "data" and therefore preclude use of studies relying on such medical data in the EPA's BCAs. The EPA notes that the proposed definition for “data” is consistent with the EPA’s “Strengthening Transparency in Pivotal Science Underlying Final Significant Regulatory Actions and Influential Scientific Information” rulemaking.<sup>23</sup> Therefore, the EPA is finalizing this definition as proposed to maintain consistency with related EPA actions.

*Expected value.* The EPA did not receive specific suggestions in the public comments on the definition of expected value. However, based on feedback from the EPA SAB on the EPA *Guidelines* update, the EPA has decided to expand the definition for clarity. The revision does not change the substantive meaning of the term. In the final rule, the definition of expected value is as follows: “Expected value means the probabilistically weighted outcome that defines a statistical mean and a measure of the

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<sup>23</sup> <https://www.epa.gov/osa/strengthening-transparency-regulatory-science>.

central tendency of a set of 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.”

*Model.* The EPA did not receive specific suggestions in the public comments on the definition of model. Therefore, the EPA is finalizing the definition as proposed.

*Opportunity cost.* One commenter recommended that the EPA expand the definition of opportunity cost to explain how other concepts like willingness to pay capture the notion of opportunity cost. Further discussion of opportunity cost and how to measure it is provided in section V.E.5 of this Preamble. The EPA disagrees that an expanded definition of this term is needed in the regulatory text. Therefore, the EPA is finalizing this definition as proposed.

*Publicly available.* The EPA did not receive specific suggestions in the public comments on the definition of publicly available. Therefore, the EPA is finalizing this definition as proposed.

*Regulatory options.* One commenter criticized the proposed definition of “regulatory options” for bracketing the selected proposed or final option with one more stringent alternative and one less stringent alternative. In the commenter’s view, this bracketing results in biasing the EPA in favor of ultimately choosing central options rather than a more environmentally protective one that is more consistent with statutory guidance or requirements. In their review of the proposed rule, the SAB recommended that the definitions for regulatory options be revised to make clearer that for BCA, as opposed to cost-effectiveness analysis, the regulatory options should only help to solve a problem, not accomplish a goal or objective. For example, a less stringent option

might accomplish less, but at lower cost.

The EPA disagrees with the comment that analyzing one more stringent and one less stringent alternative than the selected option biases the Agency's decision. The analysis of these alternative options provides the public and decision makers information about the consequences of options that are more or less stringent than the selected option. The EPA agrees with the SAB's comment and is adopting the SAB recommended revisions to the definition to improve clarity. Specifically, the EPA is revising parts of the definition of regulatory options as indicated below:

“(2) From “A more stringent option which accomplishes the stated objectives of the Clean Air Act...” to “A more stringent option which contributes to 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”

“(3) from “A less stringent option which accomplishes the stated objectives of the Clean Air Act...” to “A less stringent option which contributes to the stated objectives of the Clean Air Act and that costs less (and presumably generates fewer benefits) than the proposed or finalized option.”

*Sensitivity Analysis.* The EPA did not receive specific suggestions in the public comments on the definition of sensitivity analysis. Therefore, the EPA is finalizing this definition as proposed.

*Significant regulation.* Several commenters were broadly supportive of the proposed definition of “significant regulation”. Additionally, several commenters supported the concept that the definition of a “significant regulation” should include

“those that would disproportionately affect an industry, group or area” or “those that are novel or relevant for other policy reasons,” with one commenter arguing that such inclusion is important to avoid adverse impacts on small businesses. One commenter stated that the E.O. 12866 language should be inserted into the BCA rather than referencing E.O. 12866, because executive orders can be changed or withdrawn in the future.

Some commenters advocated using the definition of “significant” from the Congressional Review Act (CRA). The commenters argued that adopting a definition from U.S. law is preferable to one from an executive order. Furthermore, the commenters also argued that the CRA is not limited to a narrow economic impact analysis that ignores the indirect impacts of a regulation on the broader economy. The commenters further stated that the EPA’s economic impact statements for any significant proposal should be consistent with the CRA and give approximate quantitative estimates of the potential economic impacts, the expected timing of these impacts, and the sectors of the economy that will experience the impact.

Several commenters objected to giving the Administrator the discretion to decide what constitutes a significant regulation, because with no specific decision criteria specified in the rule, the decisions would be arbitrary and contrary to the stated goals of the BCA rule for consistency and transparency. And some commenters expressed opposition to expanding rules requiring a BCA because it would deplete the EPA’s analytic, financial, and expertise resources without providing any benefit to public health or the environment.

As discussed in more detail below, after reviewing the comments on applicability,

in this final rule, EPA maintains the same definition of significant regulation as in the proposal and concludes it represents an appropriate scope for the rule. Specifically, EPA requires that all future significant proposed and final regulations promulgated under the CAA be accompanied by a BCA using the definition that a significant regulation is a proposed or final regulation that is determined to be a “significant regulatory action” pursuant to E.O. 12866 Section 3(f)<sup>24</sup> 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) or 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, will 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.

*Social benefits, or benefits.* One commenter argued that the definition of “social benefit or benefits” is overly broad and vague. Another recommended an expanded definition that included discussion of how to measure benefits. Another said the EPA’s definition is arbitrary and capricious and potentially unlawful because the proposed definition of “social costs” included the “sum” of all costs, but the proposed definition of social benefits, did not. The commenter contended that this apparent direction to include all costs but not necessarily all benefits would be inconsistent with the general

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<sup>24</sup> Separate from and independent of the requirements in this rulemaking, E.O. 12866 establishes broadly applicable conditions for regulatory analysis. More specifically, section 6 of E.O. 12866 establishes the analytic requirements for those actions OIRA determines to be a “significant regulatory action” and “significant regulatory actions within the scope of section 3(f)(1).” Sec. 6(a)(3)(B)-(C).

principles of BCA and would bias any such analyses. The EPA did not intend to create a disparity between the calculations of costs and benefits, so the Agency is adjusting the definition of social benefits to be consistent with the phrasing of the definition of social costs to avoid any confusion. In this final rule, social benefits, or benefits, means “the sum of all positive changes in societal well-being experienced as a result of the regulation or policy action.” Additional discussion of how benefits can be measured is provided in section V.E.5 of this Preamble.

*Social costs, or costs.* One commenter recommended an expanded definition of social cost to elaborate on how costs are measured. In this final rule, the EPA is adding a second sentence to the definition of social costs to further clarify what is included in opportunity costs. Additional discussion of how these costs can be measured is provided in section V.E.5 of this Preamble.

*D. Preparation and Consideration of BCA in Rulemaking*

In the proposed rule, the EPA proposed to require that all future significant proposed and final regulations promulgated under the CAA be accompanied by a BCA. Commenters supportive of the proposal were generally supportive of conducting BCA for all significant regulatory actions, though some commenters argued for a less expansive approach and others argued for broader application than the proposal. For example, as discussed above, some commenters argued that the EPA should use the definition of significant from the CRA. Other commenters recommended expanding the scope, for example, to 1) apply not only to BCA, but also to any related risk assessment to estimate both baseline risk and the risk-reduction benefits estimated in the BCA, and 2) clarify that its information quality standards apply to BCA, risk assessments, and

related risk analyses (e.g., IRIS assessments). Commenters opposed to the proposal found the scope too expansive and questioned the resource burden of the requirements.

After considering these comments, the EPA is finalizing the requirement that all future significant proposed and final regulations promulgated under the CAA be accompanied by a BCA. The EPA believes that in keeping with OMB's Circular A-4 and Executive Order 12866 that this requirement would create consistency with well-understood and established processes and determinations for what constitutes a "significant" rulemaking. Therefore, in this final rule, a significant regulation will include any 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.

At proposal, in addition to proposing the preparation of a BCA for all significant regulation, the EPA also solicited comment on how or whether the results of the BCA should inform significant CAA regulatory decisions. The EPA requested comment on how the Agency "could take into consideration the results of a BCA in future rulemakings under specific provisions of the CAA." 85 FR 35624. The EPA received numerous comments including recommendations that the Agency formulate a mandatory test that the benefits justify the costs of future significant rulemakings subject to this final rule, recommendations that the Agency not address how BCAs would be taken into consideration in future rules, and recommendations that no final rule be promulgated. Several commenters noted the importance of BCA and how it can inform decision makers. Commenters emphasized that consideration of benefits and costs is

part of long held requirements imposed by executive order. As one commenter summarized, “the clear direction of every president over the last four decades [is] that, to the extent permitted by law, executive agencies ‘shall . . . propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.’” In addition, the proposal highlighted the historical use of BCA by courts to inform their view of the appropriateness of agency actions and 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), *see* 85 FR 35615-617.

Based on the comments received, executive orders, and judicial decisions, the EPA has determined that, when permitted for consideration under the specific provision of the CAA under which a future regulation is promulgated, the Agency should consider in the decision-making process the BCA developed pursuant to this Final Rule, which would be part of the record of such a future rulemaking. *See* 42 U.S.C. 7607(d)(9); 5 U.S.C. 706(2); *see also Motor Vehicles Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (“Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”). The benefits and costs of a potential regulation, when permitted to be considered under the specific provision of the CAA under which a future regulation is promulgated, are of clear importance to decision-making and can provide justification for whether and how

the Agency decides to regulate. Consideration of the results of BCA in regulatory decision-making is also consistent with the requirements of E.O. 12866. However, the EPA declines to formulate a specific test or mandate of how to consider the BCA or what weight it should be given in such a future rulemaking. The precise details of what test would be appropriate could differ from one CAA provision to another, and the EPA has not proposed or requested comment on how such tests would be formulated under those specific provisions. Some commenters also expressed concern that the rule as proposed would limit or prohibit the Agency from considering other metrics or analyses, either generated by the Agency or submitted by commenters into the record of a future rulemaking proceeding. There is nothing in this final rule that would create such an outcome, as consideration of one metric does not bar consideration of another; commenters will retain the ability to provide the Agency with information, and the Agency will be required to consider such information and respond to comment as is dictated by the process governing the future CAA rulemaking. To provide the public with as much information and transparency as possible, the EPA is finalizing a requirement to identify when the CAA provision or provisions under which the future rule is promulgated permit consideration of the BCA, and if so, the Agency is required to provide a description in the preamble of how the Agency considered the results of the BCA. If the provision or provisions under which the rule is promulgated prohibit the consideration of the BCA, the final rule requires the Agency to identify the specific provision that bars such consideration.

#### *E. Best Practices for the Development of BCA*

The EPA received a wide range of comments on the proposed requirements to

codify best practices for the development of the BCA into a procedural regulation. In its review of the proposed rule, the SAB sought to limit its review to requirements in the proposed rule that would not be addressed by the SAB's review of the forthcoming update to the EPA's *Guidelines*. Therefore, the SAB did not advise on the details of each BCA best practice that the EPA proposed to codify. However, the SAB did emphasize that the EPA should consider carefully which aspects of BCA should be included in the final rule versus which aspects should be addressed in guidance, given the case-by-case nature of BCA. The EPA appreciates all the comments received and agrees with the SAB that it is important to think carefully about which best practices should be made enforceable and which best practices (or details thereof) should be addressed in guidance. The best practices codified in this final rule include the high-level best practices in conducting regulatory BCA. The EPA's *Guidelines* will continue to provide detailed guidance on how to implement these best practices. The EPA does not expect the forthcoming update of the EPA's *Guidelines* to include any changes to these high-level elements. We respond to some of the major comments in the discussions in the subsections below and to the rest in Chapter 7 of the Response to Comments Document.

After reviewing the comments, the EPA has included in this final rule the requirements outlined in the following subsections, which are the high-level 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)<sup>25</sup>, EPA's

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<sup>25</sup> Office of Management and Budget, U.S., 2003. Circular A-4: Regulatory Analysis. Office of Management and

*Guidelines* (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).<sup>26</sup> 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).<sup>27</sup> 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 and a number of prominent economists (Arrow et al., 1996).<sup>28</sup>

Since best practices for the conduct of BCA inherently require that the inputs to the analysis reflect the best available information<sup>29</sup>, the EPA is also finalizing the

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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".

<sup>26</sup> 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*.

<sup>27</sup> 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.

<sup>28</sup> Robinson, L.A. and Hammit, 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.

<sup>29</sup> 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](https://www.epa.gov/sites/production/files/2019-08/documents/epa-info-quality-guidelines_1.pdf)).

requirement 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 the 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 requires a consistent and transparent use of risk assessments in BCA of CAA regulations. These requirements include elements that are responsive to recommendations from the National Academies of Science, Engineering and Medicine (hereafter, "National Academies") and the EPA's SAB to improve the utility of risk assessment for use in BCAs for CAA regulations, as well as recommendations offered by the SAB in their review of the proposed rule. As an example, the National Academies has previously provided advice to the Agency regarding best practices for selecting concentration-response parameters, when it is appropriate to pool (or, combine) risk estimates and how to characterize uncertainty in those estimates. This rule is also consistent with the 2007 OMB and Office of Science and Technology Policy's Updated Principles for Risk Analysis<sup>30</sup>, which also builds off the National Academies and SAB recommendations as well as the EPA's Risk Characterization Handbook.<sup>31</sup>

1. *Key elements of a BCA.* The EPA did not receive comments on the proposed requirement that a BCA should include three key elements. The specific comments received on each element are provided in the corresponding subsections below. Therefore, EPA is finalizing the key elements of a BCA as proposed. The key elements

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<sup>30</sup> <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2007/m07-24.pdf>

<sup>31</sup> <https://www.epa.gov/risk/risk-characterization-handbook> (EPA 100-B-00-002, December 2000).

of a rigorous 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.

2. *Statement of Need.* Some commenters supported the EPA requiring a statement of need in the BCA stating that the requirement is consistent with agency guidance detailed in OMB's Circular A-4 and Executive Order 12866. These commenters argued that a concise and coherent statement of need helps to set the foundation for developing the subsequent analysis of benefits and costs, particularly as it relates to assessing environmental or public health improvements targeted by the relevant statutory provision from which the rule derives its authority.

Some commenters opposed the EPA requiring a statement of need in the BCA. These commenters argued a statement of need would be in conflict with many, if not most, of the EPA's rulemaking responsibilities under the CAA. Commenters further asserted that a citation to the provision of the CAA that requires the rulemaking should be sufficient for any statement of need. Furthermore, one commenter also argued that the EPA cannot apply the "statement of need" requirement to rulemakings subject to CAA section 307(d) requirements, because CAA section 307(d)(2) already includes a requirement that the notice of rulemaking shall be accompanied by "a statement of its basis and purpose."

None of the comments received have led the EPA to materially change its views from the proposal regarding the requirement for a statement of need. The EPA disagrees with the comment that a statement of need would conflict with the EPA's rulemaking responsibilities under the CAA. There is nothing in this final rule that would

create such an outcome, since an articulation of the statement of need does not bar the Agency from complying with any requirements of the CAA, including those of CAA section 307(d)(2). The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's *Circular A-4* (OMB, 1993) and EPA's *Guidelines* (EPA, 2010), which are the existing peer reviewed guidance documents implementing E.O. 12866. Therefore, the EPA is finalizing the requirement that 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 the regulatory statement of need can be found in OMB's *Circular A-4* (1993, B. Introduction, The Need for Federal Regulatory Action) and the EPA's *Guidelines* (2010, Chapter 3).

3. *Regulatory Options.* Commenters supporting the requirement to analyze the benefits and costs of at least three regulatory options argued that the proposed requirement provides decision makers and the public with important perspective on not only the various options' relative impact on net social benefits, but also the sensitivity of stringency options on other individual factors that comprise the overall forecasts. One commenter further suggested that the Agency also consider including a fourth option, the implementation of voluntary programs if appropriate to the circumstances.

Some commenters opposed the requirement to analyze the benefits and costs of at least three regulatory options. These comments provided various reasons including,

but not limited to: the EPA incorrectly assumes that a continuum of options is possible; requiring three regulatory options may lead to patently inappropriate or otherwise unacceptable options; requiring three regulatory options may lead the agency to put forward intentionally poor choices; and requiring three regulatory options may lead to unintended consequences such as leading the agency to evaluate options that are infeasible and impractical.

None of the comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's *Circular A-4* (OMB, 1993) and EPA's *Guidelines* (EPA, 2010), which are the existing peer reviewed guidance documents implementing E.O. 12866. These guidance documents provide additional details for how to select appropriate regulatory options for evaluation. OMB's Circular A-4 also allows for the possibility of evaluating an option whose selection would be prohibited under the specific statutory provision under which the rule is being promulgated because the identification of these statutory constraints and an estimate of their opportunity costs may provide useful information to Congress under the Regulatory Right-to-Know Act. The requirement to analyze at least three regulatory options also provides for cases where a continuum of options is not possible, which is further clarified below. Finally, there is nothing in this final rule that would prevent an additional evaluation of a voluntary program to address the problem articulated in the statement of need if appropriate to the circumstances. Therefore, the EPA is finalizing the requirement that the BCA analyze the benefits and costs of regulatory options. The final rule requires the BCA to analyze at least three options that contribute to the stated objectives of the CAA

(unless the BCA explains the rationale for analyzing fewer than three options, as further described below) and to explain why they were selected. Where there is a continuum of options (such as options that vary in stringency), the three options are required to include at a minimum: 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. When a continuum of options is not applicable, an analysis of three 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 relative to the baseline, 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 final rule requires the BCA to explain why it is not appropriate to consider more alternatives. For further discussion, see OMB's Circular A-4 (specifically, see section E. Identifying and Measuring Benefits and Costs, General Issues, 3. Evaluation of Alternatives).

4. *Baseline.* Many commenters supported the proposed requirement regarding the development of a baseline as consistent with best practices for BCA. Several commenters noted that defining the baseline scenario is one of the most important elements of a regulatory impact analysis, and multiple commenters supported the proposed requirements to develop a baseline that appropriately considers relevant factors based on transparent and reasonable assumptions. Additionally, some

commenters supported the explicit use of more than one baseline: “one baseline based solely on current standards and another based on the agency’s reasoned assumptions regarding the effect of all related pending regulations”; and stated that this is consistent with OMB’s Circular A-4.

Several commenters stated that the proposed requirements for developing a baseline will prevent “double-counting.” The commenters added that the issue of double counting of benefits has been a particular concern with past EPA BCAs under the CAA. Commenters referenced a report that found that the simultaneous advancement of multiple CAA-related rulemakings resulted in changes between proposed and final BCAs’ baseline assumptions about implementation of other regulations that created inconsistencies in BCA estimates between the proposed and final stages and revealed examples of double-counting. One commenter suggested that where ancillary benefits exist and have not been counted before by the EPA, the EPA must determine the most cost-effective regulatory means of achieving them. The commenter argued that this should ensure that the EPA properly and efficiently utilizes its regulatory authorities to achieve optimal results to enhance societal well-being.

Some commenters opposed the requirements for developing a baseline in a BCA in the proposed rule as they argued OMB and EPA policies already establish the process for establishing a baseline, for assuring that benefits will not be double-counted, and for being transparent in those explanations. Creating a new rule for the purpose of preventing an oversight in a pre-existing mechanism for assessing BCA is unnecessarily “reinventing the wheel.” The commenters further argued the proposed requirements for developing a baseline bias the analyses against regulations that

otherwise meet statutory requirements and provide important environmental benefits, in contravention of the CAA's public-health protective mandate.

Other commenters opposing the proposed requirements contended that the EPA provides no specific cases to support its assertion that there is a risk of “double-counting.” Some of the commenters contended that recent research indicates some claimed mechanisms of “double-counting” are either inaccurate or can be addressed by the EPA following its own guidelines on BCA baselines assuming full compliance with existing rules. The commenters added that the proposed rule provides no evidence that there is a gap that needs to be filled in this regard beyond its existing guidance, and, in fact, adds no additional insight into these issues.

None of the comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's *Circular A-4* (OMB 1993) and EPA's *Guidelines* (EPA 2010), which are the existing peer reviewed guidance documents implementing E.O. 12866. Nothing in the public comments have suggested specific additional factors that should be codified into the final rule as factors to be considered when developing the baseline in a BCA. Therefore, the EPA is finalizing the requirement to develop a suitable baseline as proposed, as described below.

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 final rule requires the BCA to provide a reasoned explanation for the baselines used and to identify the key uncertainties in the forecast(s). These requirements for developing a baseline are consistent with best practices as outlined in OMB's *Circular A-4* (1993) and EPA's *Guidelines* (2010).

5. *Measuring Benefits and Costs.* Some commenters contended that the proposal identifies the willingness to pay (WTP) metric as the “correct measure” of changes from the baseline, but the proposal fails to acknowledge the existence of other metrics and does not justify their exclusion in favor of WTP. One commenter further argued the proposal also fails to acknowledge or consider the greater difficulty in estimating willingness-to-pay for non-market goods, such as air quality and associated health risk. Another commenter further added that WTP studies are helpful, but not the only source of information for monetizing benefit and WTP studies are particularly helpful in estimating the value of mortality risk reduction, which typically comprise the bulk of monetized benefits in CAA rules.

Several commenters opposed including the WTP concept in the proposed rule.

The commenters expressed concern that the proposed rule will continue practices to propagate the understatement of CAA benefits, to the detriment of all, but particularly to low-income and minority communities. Several commenters stated that WTP is strongly affected by factors such as ability to pay and by the awareness of the respondent of the harms being inflicted or avoided. A commenter then asserted that a WTP analysis will lead to higher measured monetary benefits for wealthier communities than for poorer communities for the same level of health and wellbeing benefit. At least two commenters focused on particular methods used for estimating WTP. These commenters advised EPA against using survey approaches to estimate WTP because they contend that such studies often overstate WTP that does not align with reality.

None of the comments received have led the EPA to materially change its views from the proposal on the appropriate measure of benefits and costs in a BCA. The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's *Circular A-4* (OMB, 1993) and EPA's *Guidelines* (EPA, 2010), which are the existing peer reviewed guidance documents implementing E.O. 12866. As discussed in Section V.B of this Preamble, the EPA agrees with the SAB's recommendation, per their review of the proposed rule, to provide more clarity in the definition of Benefit-Cost analysis and the measurement of benefits and costs. Therefore, in this final rule EPA has provided a more fulsome definition of BCA to clarify that it is consistent with OMB Circular A-4. The EPA disagrees with commenters who stated that the proposed rule did not acknowledge the existence of metrics other than willingness-to-pay, as discussed below. In addition, the EPA disagrees with commenters who advised to include more discussion in the rule about particular methods for estimating WTP. The EPA's *Guidelines* and

OMB's *Circular A-4* include discussion of particular methods for estimating WTP, which can generally be broadly categorized as either revealed preference or stated preference methods. As described in these guidance documents and standard textbooks on BCA, some methods will be more suitable than others in a given scenario for a variety of reasons, and some will be better able to capture certain types of benefits than others. Since research on all of these methods is ongoing, the limitations and qualifications of each method is best described in guidance and the EPA has decided not to include any requirements related to particular valuation methods in this final rule.

A BCA evaluates the social benefits and social costs of a policy action. The social benefits of a policy are measured by society's willingness-to-pay for the policy outcome. The social costs are measured by the opportunity costs of adopting the policy. Opportunity cost is the value of the next best alternative to a particular activity or resource.<sup>32</sup> A BCA 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. Where all benefits and costs can be quantified and expressed in monetary units, BCA provides decision makers with a clear

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<sup>32</sup> Opportunity cost need not be assessed in monetary terms. It can be assessed in terms of anything that is of value to the person or persons doing the assessing. For example, a grove of trees used to produce paper may have a next-best-alternative use as habitat for spotted owls. Assessing opportunity costs is fundamental to assessing the true cost of any course of action. In the case where there is no explicit accounting or monetary cost (price) attached to a course of action, ignoring opportunity costs could produce the illusion that the action's benefits cost nothing at all. The unseen opportunity costs then become the implicit hidden costs of that course of action.

indication of the most economically efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects).

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 opportunity costs, or reductions in well-being. WTP is the correct measure of these changes in BCA.

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 EPA's *Guidelines* (2010).

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), this

final rule requires a robust explanation for doing so. For further discussion, see OMB's *Circular A-4* (specifically, see section E. Identifying and Measuring Benefits and Costs, General Issues, 2. Developing a Baseline and *Guidelines* (2010), 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.

6. *Methods for Estimating Benefits and Costs.* The EPA received a range of comments on the proposed requirements regarding the methods for estimating benefits and costs. Comments were divided on the idea of codifying best practices, with many commenters supporting codification in a procedural regulation, but others noting possible inconsistency when practices are updated in the future.

Many comments pertained to whether more specific or additional best practices should be codified as requirements in the final rule. For example, when estimating costs, some recommended that the final rule be expanded to include procedural requirements for determining whether an engineering base cost estimation, partial-equilibrium model, general equilibrium model, or a combination of these models should be used. One commenter argued that when a regulation will affect a sector that supplies a wide swath of the economy, then the final rule should specify that the

presumptive cost evaluation method be a general equilibrium model, and if a general equilibrium model is not used, then the BCA should be accompanied by a detailed explanation of why small price effects in the affected sector's outputs would not be expected to have economy-wide effects. Others pointed out that systems are so large and complex that evaluative tools are not adequate for these types of analyses to be accurate and useful for decision-making. Another of these commenters said that although the EPA is correct to highlight the potential value added to be gained by using general equilibrium models, there still are a number of reasons why general equilibrium models may not yet be ready to be used as a principal analytic framework for undertaking cost-benefit analysis of environmental regulations. The commenter argued that general equilibrium models provide insights rather than answers about the economic effects of policies; for example, general equilibrium models are calibrated using parameter estimates to "fit" predetermined values providing a certain degree of "realism" but only up to a point.

Finally, some commenters argued that the proposed rule provided an unbalanced treatment of benefits and costs by setting more stringent standards for benefit estimation than cost estimation, and therefore, aside from being unnecessary and unjustified, they stated the proposed requirements were also biased and arbitrary. These commenters' recommended solution to the proposed rule's problem of treating costs and benefits differently is simply to withdraw the proposed rule and revert to relying on existing guidance, like OMB's Circular A-4 and the EPA's *Guidelines*, which already offer a more balanced treatment to both costs and benefits. Other commenters stated the proposed rule arbitrarily fails to address the likelihood that compliance costs

will be overestimated and benefits will be underestimated.

None of the public comments received have led the EPA to materially change its views from the proposal. The EPA disagrees with the comments that more specific procedures should be codified into regulation pertaining to the use of particular estimation methods or models. The EPA also disagrees with commenters stating that the rule imposes uneven requirements. The EPA is codifying into regulation procedures that are consistent with best practices for estimating both benefits and costs as discussed at length in OMB's *Circular A-4* (OMB 1993) and the EPA's *Guidelines* (EPA 2010), which are the existing peer reviewed guidance documents implementing E.O. 12866. In this final rule, the EPA is codifying these best practices as proposed, as described below.

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. With this final rule, the EPA requires that all BCAs 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, the final rule requires analysts to 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 EPA's *Guidelines* (2010), 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,<sup>33</sup> or benefit endpoints, that can be meaningfully expected as a result of those requirements. 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

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<sup>33</sup> 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.

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.<sup>34</sup>

Once benefit endpoints are identified, analysts need to decide whether and how to quantify changes in each endpoint. From among the endpoints identified above, the EPA will 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 final rule requires the Agency to provide a reasoned explanation for that decision. Additional requirements for choosing and quantifying health endpoints are 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 OMB's *Circular A-4* and the EPA's *Guidelines*. 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, the 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, the EPA will try to measure it in terms of its physical units. If it is not

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<sup>34</sup> 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."

possible to measure the physical units, the EPA will describe material benefits or costs qualitatively.

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, this final rule requires 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, appropriate data and/or studies; and (3) BCAs will qualitatively characterize benefits that cannot be quantified or monetized. In addition, the final rule requires the Agency to 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 OMB's *Circular A-4* and the

EPA's *Guidelines*, and the literature cited therein.

7. *Selecting and Quantifying Health Endpoints in a BCA.* The EPA received numerous comments on the proposed requirements for selecting and quantifying health endpoints in a BCA. Many public commenters were critical of the lack of definitions for key terms in this section, especially “causal” and “likely causal” though some of these commenters supported the proposed requirements while providing more specific definitions that could improve the terms. Other commenters were generally critical of the proposed requirements that any linkage between regulatory requirements and benefits be based on “a clear causal or likely causal relationship” and argued such requirements will restrict the assessment of the health benefits of proposed CAA regulations. With respect to determining what concentration-response functions to use to quantify changes in the selected endpoints, some commenters argued that the proposed criteria for selecting studies from the literature are too restrictive. Others recommended that the EPA consider different criteria entirely or require a more systematic review approach for evaluating the scientific literature to quantify health impacts. For example, one commenter noted that while the list of proposed criteria referred to study features that should be evaluated under a systematic review framework, it was not exhaustive or complete and does not provide a systematic approach for the integration of this evidence to prioritize studies that provide the accurate characterization of health impacts. Some commenters stated that the rule would contradict advice the EPA has received from the National Academies and SAB and/or questioned why, in their view, the EPA is re-inventing the wheel. Some commenters emphasized that best practices for characterizing uncertainty should reflect more probabilistic techniques and that EPA

should also use a risk of bias approach when selecting among studies.

In their review of the proposed rule, the SAB also provided recommendations related to the selection and quantification of health endpoints. First, the SAB recommended that the EPA clarify the requirements for estimation of benefits to incorporate systematic review approaches, better define causality, and include effects for which causal or likely causal relationships may be less certain. In particular, the SAB advised that no “one size fits all” approach to causality should be mandated because a variety of approaches may need to be taken (some data driven, some based on systematic review of the biology, toxicology and epidemiology). Instead, the SAB recommended that the EPA should include reference to and support for relevant guidance from current best Agency practices for evaluating causality. The SAB also advised that the EPA modify the proposed requirement to include in the benefits analyses the effects for which causal or likely causal relationships may be less certain, but the impact would be substantial.

Second, the SAB provided recommendations for how the EPA could adjust the proposed requirements for selection of health endpoints to provide greater clarity and transparency, especially with regard to the selection of concentration response functions. The SAB recommended that the final rule should clarify the specific scientific rationale for endpoint selection and promote transparency by defining specific terms used in the requirements, or the Agency should replace all of the specific criteria on the selection of health endpoints with “an overall framework outline of the systematic review principles it would follow for the evaluation of human health hazard data for the purposes of concentration-response selection and quantification of benefits.” The SAB

also advised the Agency to discuss how relevant advice from the National Academies and the SAB on systematic review as well as the approaches under development by the EPA in the Consolidated Human Toxicity Assessment Guidelines<sup>35</sup> will be evaluated and incorporated. The EPA agrees with the recommendations from the SAB and commenters on the importance of using a systematic review process to evaluate the scientific literature for the purposes of determining which health endpoints to include in a BCA and what concentration-response functions to use to quantify changes in these endpoints. Therefore, the EPA is revising the requirements in this section of the rule as described below.

It is essential for analyses to characterize health effects for which the science indicates the likelihood that changes in exposure would provide positive benefits. The EPA requires that BCAs performed under this final rule will include benefit endpoints for which the scientific evidence indicates there is (a) a causal or likely causal relationship between pollutant exposure and effect, and subsequently, (b) sufficient data and understanding to allow the agency to reasonably model the anticipated change in that effect in response to changes in environmental quality or exposures expected as a result of the regulation under analysis.

As stated in the proposal, decisions about whether and which changes in the health endpoints should be quantified should be informed by an evaluation of the relevant scientific literature studying the strength of the association between exposure to a pollutant and the health endpoint and the nature of the concentration-response

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<sup>35</sup> For more information about the development of the Consolidated Human Toxicity Assessment Guidelines, see: <https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/DF0F42C34645448685258570005ADFFF?OpenDocument> .

function (i.e., the amount of change in the frequency or severity of the health endpoint expected as the distribution of air quality changes). Benefits may be quantified for associations that meet the criteria for causality, considering, for example, the biologic plausibility, consistency, temporality, strength, and specificity of the effect.

In this final rule, the EPA is clarifying that for human health endpoints, a systematic review process must be used to evaluate the hazard data for the purposes of determining which endpoints to include in a BCA and what concentration-response functions to use to quantify changes in these endpoints. As described by Institute of Medicine (IOM), “systematic review is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent” (IOM, 2011).

The systematic review process, at a minimum, consists of: problem formulation and protocol development, evidence identification, evidence evaluation, and evidence integration (National Research Council, 2014). Problem formulation should identify the specific question to be addressed in the review and the protocol should specify the methods used to address the question, making these methods and the review process transparent. Evidence identification should follow a search strategy written into the protocol that explicitly states the inclusion and exclusion criteria for studies. Importantly, a study’s inclusion in the review should not depend upon that study’s findings. When feasible, the evidence evaluation should include a risk of bias assessment to determine how confidently conclusions can be drawn from the data. For example, the EPA began

incorporating a risk of bias assessment into its Integrated Science Assessments (ISAs), starting with the recently published ozone ISA (EPA, 2020).<sup>36</sup> Finally, evidence integration should provide a structured approach to drawing conclusions considering all appropriate and available lines of scientific evidence, including epidemiologic, toxicologic, and mechanistic lines of evidence.

Applying the systematic review process described above, the final rule requires the EPA to identify concentration-response relationships from the scientific literature that take into account the breadth and quality of the available evidence regarding the nature and magnitude of the risk to the populations affected by the regulation. More weight should be given to higher quality studies or analyses that have been peer reviewed. To the extent possible, the studies or analyses should: (1) be based upon human data when available; (2) specify the exposure route, duration, and levels, with preference given to those studies assessing exposure similar to those experienced by the general population; (3) employ a design or analysis that adequately addresses relevant sources of potential critical confounding; (4) consider how exposure is measured, particularly those that provide measurements at the level of the individual and that provide actual measurements of exposure; and (5) be able to reliably distinguish the presence or absence (or degree of severity) of health outcomes. Studies demonstrating more of the attributes listed above, and those which demonstrate the considerations to a greater extent, are expected to provide more accurate

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<sup>36</sup> The EPA prepares ISAs to provide the scientific foundation for setting standards for the 6 criteria air pollutants under the National Ambient Air Quality Standards program. This assessment is a comprehensive review, synthesis, and evaluation of the most policy-relevant science, including key science judgments that are important to inform the development of the risk and exposure assessments, as well as other aspects of the NAAQS review. The preamble to the ISAs describes the five-level causal framework for evaluating weight of evidence and drawing scientific conclusions and causal judgments. See <https://www.epa.gov/isa>.

concentration-response relationships and associated risk estimates. Consistent with the general process of systematic review, the evaluation should emphasize transparency and replicability in the evaluation process.

When utilizing multiple concentration-response functions to estimate impacts on a single health outcome, the BCA must quantify risks in such a way that the heterogeneity in the estimated health impacts is clearly characterized. The EPA will present results in a manner that promotes transparency in the assessment process by selecting and clearly identifying concentration-response functions best characterizing risk for affected populations, 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. 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, abiding by the overall framework of the systematic review process.

In cases where existing Agency documents (e.g., ISA for criteria pollutants) provide the review and synthesis consistent with the process described above, the final rule allows a BCA to reference this synthesis.

Conceptually, BCA requires a comparison of expected costs and expected benefits, so BCA for CAA regulations should include the determination of expected benefits. When sufficient data exist, 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, measures of the central tendency of risk may be used. Upper-bound risk estimates must not be used without also presenting lower bound and central tendency estimates.

8. *Uncertainty Analysis.* Many public commenters supported the proposed rule's codification of best practices for uncertainty analysis and further contended that the EPA's past uncertainty analyses in CAA BCA vary in their quality, scope, and rigor. Some of these commenters provided additional recommendations for uncertainty analyses in the BCA including using probability distributions of risk when calculating benefits. For example, one commenter recommended that the EPA analyze assumptions embedded in the EPA's environmental Benefits Mapping and Analysis Program (BenMAP) tool<sup>37</sup> in its uncertainty assessment as well as further aligning with numerous EPA recommendations from the SAB and the National Academies. Some commenters recommended that the EPA should also quantify the effect of the major sources of uncertainty and variability on the risk estimates, benefit estimates, and cost estimates as well as transparently documenting key assumptions that drive uncertainty analyses.

Some commenters opposed the EPA's proposed requirements for an uncertainty analysis in the BCA, stating that these proposed provisions are arbitrary, capricious and not appropriate. One of these commenters said that the EPA unjustifiably weights the burden of uncertainty assessment on benefits rather than costs by placing more prescriptive requirements on the analysis of the uncertainty of benefits, thus skewing the assessment of uncertainty towards benefits more than costs, and by depicting

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<sup>37</sup> <https://www.epa.gov/benmap>.

benefits as more uncertain than costs. Additional commenters opposed to the EPA's proposal argued that the proposed requirements add seemingly endless layers of analyses and potentially import substantive constraints and judgments under the guise of characterizing uncertainty.

The SAB also made several recommendations related to the proposed requirements for uncertainty analysis. First, the SAB recommended that the preamble of the final rule discuss the broader purposes of uncertainty analysis beyond simple transparency. Second, the SAB explained that because best practices require that the analysis be appropriate for the policy context, uncertainty analysis should only be required to the extent feasible "and appropriate". Third, the SAB advised that the discussion in the final rule be broadened to reflect the fact that outcomes other than the expected value may be very important for policies involving low-probability, high consequence hazards. Also, when presenting quantitative results, the SAB recommended that the final rule require the EPA to clearly note when there are unquantified benefits or costs that could be significant. Finally, the SAB recommended that the EPA acknowledge in the final rule that uncertainty analysis will not correct errors resulting from the inclusion of "poor science", which arguably has a greater impact on policy choices than the lack of uncertainty analysis.

None of the public comments received have led the EPA to materially change its views from the proposal. The EPA disagrees with the comment that the requirement to conduct uncertainty analysis is arbitrary, capricious and not appropriate. The EPA is codifying into regulation procedures that are consistent with the principle of transparency discussed at length in OMB's *Circular A-4* (OMB, 1993) and the EPA's

*Guidelines* (EPA, 2010), which are the existing peer reviewed guidance documents implementing E.O. 12866. The EPA agrees with the principles emphasized in the SAB's comments on the proposed rule. The Agency has reviewed the discussion of uncertainty analysis below to ensure it is consistent with these principles and has made clarifying revisions in this preamble and final regulatory text where helpful. The final rule includes requirements pertaining to uncertainty analysis as provided below.

For various reasons, including the reason that the future is unpredictable, the benefits and costs of future regulatory options are not known with certainty. The EPA is finalizing requirements for BCAs to identify uncertainties underlying the estimation of both benefits and costs and, to the extent feasible and appropriate, quantitatively analyze those that are most influential. Specifically, the final rule requires the EPA to 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 will be required to also present benefit and cost estimates in ways that convey their uncertainty, including acknowledging unquantified benefits and costs, where appropriate. Because information on the range of outcomes from policy may be an important consideration in decision-making, the final rule requires EPA to also characterize the range of likely outcomes. BCAs will be required to include a reasoned explanation for the scope of the uncertainty analysis and to 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 rule requires BCAs to consider sources of uncertainty both

independently and jointly. The BCA should also discuss the extent to which qualitatively assessed costs or benefits are characterized by uncertainty.

Probabilistic uncertainty analysis involves greater effort than other quantitative characterizations of uncertainty but can add insights into the role of uncertainty in a BCA. When simpler quantitative analysis may not sufficiently describe uncertainty, and where probability distributions for relevant input assumptions are available and can be feasibly and credibly combined, BCAs should 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. In instances when calculating expected values is not feasible or appropriate due to data or other limitations, the EPA should strive to present a 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 the EPA's *Guidelines*.

9. *Principle of Transparency.* Several commenters supported the general concept of transparency in conducting BCA, because transparency improves the quality of regulatory decision-making. Some commenters further stated that providing information on the data, models, assumptions, and uncertainties will increase public participation by improving the dialog between the EPA and stakeholders and creating a better-informed public.

Several commenters objected to the transparency provisions of the rule with one commenter stating that it is unclear what is meant by the statement that the EPA's presentation of BCA results should be "reproducible to the extent reasonably possible." Commenters argued that the preamble offers no basis for concluding that the EPA in the past has not been transparent in presenting the results of their analysis of regulatory options. Other commenters further contended that the proposed requirements would obscure the basis for the EPA's decisions and the proposal is inappropriate to require "consistency across the Clean Air Act" given the differences in statutory obligations for different pollutants. Several of these commenters claimed that the EPA's regulatory assessments already are transparent, and the proposed rule would lead to confusion on the regulatory analysis and not increase transparency. One of these commenters further claimed that BCA does not increase transparency because it can distract from the statutory basis of regulations, since most CAA standards are health-based or technology-based standards, which involve a unique set of factors to consider.

None of the comments received have led the EPA to materially change its views from the proposal. The EPA disagrees with the comment that it is inappropriate to impose consistent requirements related to transparency across the CAA given the differences in statutory obligation for different pollutants in various provisions of the Act. The requirements in this final rule aimed at providing transparency do not bar the Agency from complying with any requirements of the Act. The EPA is codifying into regulation procedures that are consistent with the principle of transparency discussed at length in OMB's *Circular A-4* (OMB, 1993) and the EPA's *Guidelines* (EPA, 2010), which are the existing peer reviewed guidance documents implementing E.O. 12866.

For example, the practice of ensuring that results are reproducible is taken directly from OMB's *Circular A-4*. Therefore, after reviewing public comments, the EPA is finalizing the transparency requirements as proposed.

This final rule provides that BCA of significant CAA regulations will include, at a minimum, a detailed and clear explanation of:

- The overall results of the BCA. The benefits, costs, and net benefits of each regulatory option evaluated in the BCA will 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 must 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.
- A description, consistent with the best available scientific information, of the non-monetized and non-quantified benefits and costs of the action. The description must include available evidence on all non-monetized and non-quantified benefits and costs, including explanations as to 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 Agency must ensure that all information (including data and models) used in the development of the BCA is publicly available while consistent with protections for privacy, confidentiality, confidential business information (CBI), and national and homeland security. If data and models are proprietary, the Agency must make available, to the extent practicable, the underlying inputs and assumptions, equations, and methodologies used by EPA.

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

#### *F. Requirements for the presentation of BCA results*

In the proposed rule, the EPA proposed to codify a standardized presentation of the results of the BCA in the preamble of significant regulations. Regarding these presentational requirements, many commenters supported providing additional details and disaggregated data with a focus on the specific objective of the CAA provision or provisions under which the rule is promulgated. These commenters supported the increased transparency that this presentation of BCA results in the preamble will provide to the public on an EPA rulemaking action. Some commenters were supportive of adding even more requirements to enhance transparency (e.g., to include a

disaggregation of impacts on small entities).

Other commenters opposed the proposal's presentational requirements, especially the requirement to provide an additional reporting in the preamble of the public health and welfare benefits that pertain to the specific objective of the CAA provision under which the rule is promulgated. Commenters interpreted this proposed requirement as barring consideration of all benefits that do not stem directly from the statutory objective and they argued that such ancillary benefits developed for a BCA are important for the EPA to take into consideration. Some commenters stated that distinguishing between benefits "targeted by the statutory provision" versus "other welfare effects" can be a complex, controversial, and ultimately fruitless endeavor, and that analysts should not assume, absent explicit statutory language, that any statute has the objective of barring consideration of important indirect effects. For example, any broad statutory language, like "reasonable" or "appropriate," should be read broadly to authorize consideration of all important effects, whether direct or indirect. The SAB did not comment on this element of the proposed rule.

The proposed rule also solicited comment as to whether non-domestic benefits and costs of regulations, when examined, should be reported separately from domestic benefits and costs of such regulations, analogous to the proposed requirement for a separate presentation of benefits limited to those targeted by the relevant statutory provision or provisions. The EPA received wide ranging comments on this issue. Many commenters voiced support for separately reporting, or only reporting, domestic benefits and costs. These commenters stated that separate reporting of domestic and non-domestic benefits and costs would allow stakeholders to better understand who would

experience the costs and benefits before regulatory action is taken. Several commenters also stated that a disaggregated reporting would be consistent with guidance in OMB *Circular A-4* that states that the “...analysis should focus on benefits and costs that accrue to citizens and residents of the United States;” and in the case where a regulation is evaluated that “is likely to have effects beyond the borders of the United States, these effects should be reported separately.” One commenter stated that separate reporting of domestic impacts would assist EPA in transparently fulfilling the CAA’s primary purpose “to protect and enhance the quality of the Nation’s air resources.” Many other commenters were opposed to disaggregated reporting of domestic and non-domestic benefits and costs. Some stated that separate reporting is unnecessary and counterproductive. For example, one commenter stated that identification and communication of subcategories of benefits (such as benefits accruing outside the United States), where practical, is already accommodated and frequently done under existing procedures. Others stated that a policy of breaking out non-domestic benefits only “when examined” de-values non-domestic benefits and ignores the impacts that occur outside of the United States but that harm individuals in and outside of the United States directly and indirectly. Others emphasized that certain classes of effects cannot be meaningfully disaggregated. Some argued that a BCA which does not allow for benefits and costs to be calculated outside of the United States fails to include the “best available science”. These commenters stated that EPA’s request for comment on separate presentation of domestic benefits and costs vs. non-domestic benefits presumes, wrongly, that “non-domestic” benefits and costs can be accounted separately while meeting the agency’s obligations to use the “best available

science” and reasoned decision-making. One commenter pointed to recent National Academies findings that the calculation of a domestic benefit in the case of greenhouse gas emissions reductions cannot be credibly done using current models, as they ignore important spillover effects given the global nature of climate change (National Academies 2017).

None of the comments received pertaining to the proposed additional presentation of benefits limited to those targeted by the relevant statutory provision have led the EPA to materially change its views from the proposal. The EPA disagrees with the comment that distinguishing the benefits pertaining to the CAA statutory objective means that other benefits (or disbenefits) are not to be considered. The proposed presentational requirements do not bar consideration of any part of the BCA. As described in Section V.D of this preamble, the final rule requires that the Agency consider the BCA in the decision-making process when permitted to do so. However, the EPA declines to formulate a specific test or mandate of how to consider the BCA or what weight the BCA, or particular elements of it, should be given in such a future rulemaking. The precise details of what test would be appropriate could differ from one CAA provision to another, and the EPA has not proposed or requested comment on how such tests would be formulated under those specific provisions.

On the issue of separate reporting of domestic and non-domestic benefits and costs, the EPA agrees with commenters who stated that this disaggregation would enhance transparency. Separate reporting is consistent with both guidance in OMB’s *Circular A-4* and with the CAA which is concerned with “enhanc[ing] the quality of the Nation’s air resources so as to promote the public health and welfare and the productive

capacity of its population” (CAA 101(b)). The EPA disagrees with commenters who stated that a disaggregation would de-value non-domestic benefits and ignore the impacts that occur outside of the United States but that harm individuals in and outside of the United States directly and indirectly. A separate reporting does not prohibit calculating or considering non-domestic benefits, but rather helps to allow costs and benefits to be compared in an apples-to-apples manner, whether domestic or not.

Aside from separate reporting of domestic impacts, the EPA disagrees with commenters who stated that additional disaggregation of benefit and cost results in the preamble presentation are needed to enhance transparency. For example, CAA rules will continue to comply with the requirements of the Regulatory Flexibility Act so it is unclear why an additional requirement to discuss or present impacts to small entities is needed in this final rule. Therefore, the EPA is finalizing the presentational requirements as proposed, as described in detail below, along with two additional requirements. First, the final rule requires that any benefits and costs accruing to non-U.S. populations be reported separately to the extent possible in the summary of BCA results in the preamble. Second, the final rule requires that the BCA include a description in the preamble of how the Agency considered the results of the BCA.

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 hazardous air pollutants 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.

In this final rule, the EPA is codifying into regulation several 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 is codifying into regulation the requirement to present a summary in the preamble of the overall BCA results, including total benefits, costs, and net benefits. Within this summary presentation, if any benefits and costs accrue to non-U.S. populations they must be reported separately to the extent possible.

Second, to enhance transparency about the extent to which a rule is achieving its statutory objectives, the EPA is required to provide, 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 final rule requires the EPA to report the quantified estimates of these benefits to the extent practicable and to provide a qualitative characterization if they cannot be quantified. Similarly, if the statute directs or allows the Agency to consider costs, the EPA should also provide a disaggregation of all relevant cost categories to the extent feasible in this section. This requirement would serve as a supplement to the BCA that is developed and presented according to best practices as outlined in Section V.E of this preamble. 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.

Finally, as described in Section V.D of this Preamble, to provide the public with as much information and transparency as possible, the EPA will be required per the final rule to identify when the CAA provision or provisions under which the future rule is promulgated permit consideration of the BCA, and if so, the Agency is required to provide a description in the preamble of how the results of the BCA were considered. If the provision or provisions under which the rule is promulgated prohibit the consideration of the BCA, the final rule requires the Agency to identify the specific provision which bars such consideration. The presentational requirements described above should be provided in the same section of the preamble of future CAA significant rulemakings.

#### *G. Additional Comment Responses*

1. *Planning for Retrospective Analysis.* As discussed in the ANPRM, a lack of data, and a lack of a regularized process for ongoing or retrospective review after

rules have been implemented, inhibits the EPA's ability to gain insights about the realized costs and benefits of actions that may help inform how the Agency designs future regulations and conducts prospective BCA of future rules. Many previous administrations have periodically undertaken programs of retrospective review or issued executive orders urging or requiring 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 within the EPA. When they occur, these reviews rarely involve ex post BCA of the original EPA regulations. The EPA received many comment letters on the ANPRM voicing support for increased retrospective analysis of Agency rules or programs to evaluate the effectiveness of regulations, to design future improvements to increase efficiency, and to improve methods of ex ante analysis. In the proposed rule, the EPA requested comments on this issue, including whether EPA should include a requirement for conducting retrospective analysis of significant CAA rulemakings and how the Agency can overcome the challenges for 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.

The EPA received comments from a variety of stakeholders supporting the idea of conducting more retrospective analysis. Many commenters emphasized that retrospective analyses could provide useful data to help the EPA improve environmental outcomes while minimizing regulatory burdens, promulgate better regulations, and improve the analytical framework the Agency uses to make regulatory decisions. However, some questioned the need and appropriateness of a rule-based approach to

institutionalizing the practice of retrospective analysis of existing regulations. Some commenters stated that the Agency should not compel companies to provide information necessary to conduct high quality retrospective analysis unless the impacted industry is interested and willing to participate in a retrospective review prior to beginning the information collection process. Others recommended that the EPA adopt specific guidance establishing a retrospective analytic process within its rulemaking procedures. One commenter specified that this guidance should include criteria for selecting the set of rules to be studied and establishing at the outset a rule design that facilitates such analyses; that the plan for ex post review should identify at the time of rulemaking the measurable outcomes to be chosen for retrospective analysis, the data needs, the time period for evaluation, and set out and justify a specific plan for data collection. Others stated that any potential requirements regarding retrospective analysis should be concretely proposed in a separate notice that fully explains the need for a rule-based solution to this issue and that allows a new and adequate opportunity for public comment. Finally, some commenters voiced concern that retrospective economic analyses have always been problematic and have many practical challenges. These commenters noted the difficulty in obtaining updated, accurate data for use in retrospective analyses and believe the EPA should focus its efforts to invest in high-quality, robust economic analyses using best-available science and following best economic practices in BCAs prepared for current rulemakings. Additionally, some commenters argued that retrospective analyses could lead to unacceptable regulatory and legal uncertainty especially should previously implemented regulations be undone and past investments based on those regulatory decisions be undermined or reversed.

The EPA agrees with commenters that conducting retrospective analyses of an implemented regulation can provide valuable information that, if considered, can more fully inform public decision-making. In many cases, retrospective analysis provides an opportunity to understand whether a regulation achieved its objectives – for example, whether the regulation, once implemented, promoted economic efficiency as expected compared to a baseline without the regulation. Retrospective analyses may also lead to improved methods for prospective analysis and ultimately improvements in regulatory design. The Agency also agrees with those commenters that said guidance was a more appropriate way to better institutionalize best practices when planning for and conducting retrospective analysis. This approach is also consistent with recent recommendations the EPA received from the SAB during the course of their review of the forthcoming update of the EPA's *Guidelines*. In that review, the SAB recommends that the EPA should consider expanding discussion in the *Guidelines* of how regulatory approaches can be designed to promote effective retrospective analysis and, in the future, possibly devote a chapter to best practices for conducting such analysis.

Given this advice, the EPA is not including a requirement in this final rule that retrospective analysis be undertaken for all significant regulations. Instead, EPA is committing to taking additional steps to better institutionalize the practice of conducting high quality retrospective review and analysis, which could be accomplished through the development of guidance on best practices for conducting retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures including how to address data needs. This guidance could, for example, include criteria for identifying rules that might be most amenable to retrospective analysis and direction

on how to identify analytic requirements for such analysis at the outset when a regulation is promulgated. Data needs could be identified and avenues for ex post data collection integrated into the regulation (while also accounting for the cost and time needed for firms to collect such information). In this way, the EPA could learn from past experience and improve both policy designs and analytic approaches to prospective benefit and cost estimation. Regardless of the specific administrative procedure pursued for institutionalizing retrospective analysis at the EPA, it is the intention of the Agency to engage experts, including academics and practitioners, and to ultimately peer review any guidance that is developed.

2. *Comments pertaining to Executive Order 12898.* Numerous commenters contended that the EPA's proposed rule did not consider EO 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations) and commenters stated that the proposal language incorrectly asserts that "this proposed action is not subject to Executive Order 12898 . . . because it does not establish an environmental health or safety standard." Commenters further stated that air pollution disproportionately impacts minority communities and the proposed rule would obstruct efforts to address this disparity. Commenters further argued the proposed rule was unclear on how the proposal's BCA analysis requirements would ascribe benefits to communities of color that frequently bear the brunt of environmental risks. One of these commenters contended that, although the list of elements to consider in the BCA includes vulnerable and highly impacted communities, the proposal failed to describe how these communities are to be "considered."

The EPA considered these comments but reiterates that this rule, as a

procedural rule, is focused on best practices for conducting BCA analysis for CAA rulemaking with an aim to increase consistency and transparency for these BCA analyses. As such, it does not establish an environmental health or safety standard and is not subject to EO 12898. However, the EPA asserts that with the focus on increased transparency and providing access to the underlying data as provided in this final rule's provisions, the requirements will increase the consistency and transparency of EO 12898 analyses. The additional information available as a result of compliance with this final rule's requirements will provide a better foundation for upcoming EO 12898 analyses of future CAA rulemakings and will improve the understanding of the underlying issues highlighted by the commenters.

## **VI. References**

The following is a listing of the documents that are specifically referenced in this document. 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.
7. Institute of Medicine (IOM). 2011. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press. <https://www.nap.edu/catalog/13059/finding-what-works-in-health-care-standards-for-systematic-reviews>.
8. National Research Council. 2014. Review of EPA's Integrated Risk Information System (IRIS) Process.

## **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 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 action is not subject to Executive Order 13771 because this final rule is a rulemaking of agency organization, procedure, or practice.

*C. Paperwork Reduction Act (PRA)*

This 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 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 and is a rule of agency procedure and practice.

*E. Unfunded Mandates Reform Act (UMRA)*

This 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 imposes no enforceable duty on any state, local or tribal governments or the private sector.

*F. Executive Order 13132: Federalism*

This 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 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 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 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 and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

*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 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.

### *L. Congressional Review Act (CRA)*

This rule is exempt from the CRA because it is a rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.

**List of Subjects in 40 CFR Part 83**

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

Andrew Wheeler,  
Administrator.

For the reasons set forth in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

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

Sec.

83.1 What definitions apply to this subpart?

83.2 How do the provisions of this subpart apply?

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

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

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

**Subpart A - Analysis of Air Regulations**

**§ 83.1 What definitions apply to this subpart?**

*Baseline* means the best assessment of the way the world would evolve absent the regulation. It is the primary point of comparison for assessing the effects of the regulatory options under consideration.

*Benefit-cost analysis* (BCA) means an evaluation of the social benefits and social costs of a policy action and other policy alternatives. The social benefits of a policy are measured by society's willingness-to-pay for the policy outcome. The social costs are measured by the opportunity costs of adopting the policy. BCA addresses the question of whether the benefits for those who gain from the action are sufficient to, in principle, compensate those burdened by costs such that everyone would be at least as well off as

before the policy. The calculation of net benefits (benefits minus costs) answers this question and helps ascertain the economic efficiency of the policy. Where all regulation attributable benefits and costs can be quantified and expressed in monetary units, BCA provides decision makers with a clear indication of the most economically efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects).

*Compliance cost* means the private cost that a regulated entity incurs to comply with a regulation, such as through planning, design, installation, and operation of pollution abatement equipment.

*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 both the original researcher and an independent party.

*Endpoint* is the specific manifestation of the documented effect that is to be quantified for the benefits analysis. It is a metric (e.g., number of hospital admissions) that acts as a surrogate for some aspect of a health or public welfare effect (e.g., respiratory system effects).

*Expected value* is the probabilistically weighted outcome that defines a statistical mean and a measure of the central tendency of a set of 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.

*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.

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

*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.

*Regulatory options* means:

- (1) The proposed or finalized option, and at a minimum the following;
- (2) A more stringent option which contributes to 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
- (3) A less stringent option which contributes to the stated objectives of the Clean Air Act and that costs less (and presumably generates fewer benefits) than the proposed or finalized option.

*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.

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

*Social benefits, or benefits*, means the sum of all positive changes in societal well-being experienced 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. These opportunity costs consist of the value lost to society of all the goods and services that will not be produced and consumed as regulated entities reallocate resources to comply with the regulation.

*Systematic Review Process* is the process for evaluating the scientific literature that includes: (a) identification of the specific question to be addressed in the review; (b) pre-specified methods used to address the question, making these methods and the review process transparent); (c) a search strategy written into the protocol that explicitly states the inclusion and exclusion criteria for studies; and (d) a description of the structured approach used to draw conclusions considering all appropriate and available lines of evidence, including epidemiologic, toxicologic, and mechanistic lines of evidence.

### **§83.2 How do the provisions of this subpart apply?**

(a) After **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, the Agency must prepare a benefit-cost analysis (BCA) for all significant proposed and final regulations, except that the requirement to prepare a BCA for significant final regulations does not apply to final regulations proposed on or before **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. 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 actions taken in permit proceedings.

(b) Except where the provision or provisions under which a significant regulation is promulgated prohibit the consideration of the BCA, the Agency must consider the BCA in promulgating the regulation.

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

(a) A BCA prepared pursuant to this subpart must be developed by the Agency in accordance with best available scientific information and best practices from the economic, engineering, physical, and biological sciences according to paragraphs (a)(1) through (12) of this section.

(1) The BCA must include the following information:

(i) A statement of need as defined in paragraph (a)(2) of this section;

(ii) An examination of regulatory options as defined in paragraph (a)(3) of this section; and

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

(2) The BCA 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 private markets or public institutions causing this problem, and the compelling need for federal government intervention in the market to correct the problem.

(3) The BCA must include an analysis of the benefits and costs of regulatory

options, which would contribute to the stated objectives of the Clean Air Act and an explanation as to why these regulatory options were selected.

Where there is a continuum of options (such as options that vary in stringency), the regulatory options must include at a minimum (as provided in section 83.1): 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. When a continuum of options is not applicable, the regulatory options can include variation of key parameters, such as different compliance dates, enforcement methods, standards by size or location of facilities, and regulatory designs. If fewer than three options are analyzed relative to the baseline, 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 Agency must provide an explanation of why it is not appropriate to analyze more options.

(4) The BCA must include a baseline that appropriately considers relevant factors and relies on transparent and reasonable assumptions. The baseline must account for, but is not limited to, the following factors:

- (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 BCA must include a reasoned explanation for the selection of 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) The BCA must include an estimation of benefits that links regulatory requirements to the value that individuals place on the change in benefit endpoints that can be meaningfully attributed to those requirements.

(8) The BCA must include, to the extent supported by scientific literature as well as practicable in a given rulemaking:

(i) A quantification of all benefits;

(ii) A monetization of all the benefits that follows well-defined economic principles using well-established economic methods, appropriate data and/or studies; and

(iii) A qualitative characterization of benefits that cannot be quantified or monetized.

(9) The process of selecting and quantifying human health benefit endpoints in the BCA must be conducted according to paragraphs (i) through (vii) in this section:

(i) The process of selecting human health benefit endpoints will be based upon

scientific evidence that indicates there is:

(a) a clear causal or likely causal relationship between pollutant exposure and effect, and

(b) sufficient data and understanding to allow the agency to reasonably model the anticipated change in that effect in response to changes in environmental quality or exposures expected as a result of the regulation under analysis.

(ii) For human health endpoints, a systematic review process must be used to evaluate the hazard data for the purposes of determining which endpoints to include in a BCA and what concentration-response functions to use to quantify changes in these endpoints. A study's inclusion in the review must not depend upon that study's findings. More weight should be given to higher quality studies or analyses that have been peer reviewed.

(iii) The studies or analyses used to quantify the concentration-response relationships should take into account the breadth and quality of the available evidence regarding the nature and magnitude of the risk to the populations affected by the regulation. To the extent possible, the studies or analyses should be:

(a) based upon human data when available;

(b) specific to the exposure route, duration, and levels, with preference given to those studies assessing exposure similar to those experienced by the general population;

(c) employ a design or analysis that adequately addresses relevant sources of potential critical confounding;

(d) consider how exposure is measured, particularly those that provide measurements at the level of the individual and that provide actual measurements of exposure; and

(e) reliably distinguish the presence or absence (or degree of severity) of health outcomes.

(iv) When utilizing multiple concentration-response functions to estimate impacts on a single health endpoint, the BCA must quantify risks in such a way that the heterogeneity in the estimated health impacts is clearly characterized.

(v) The presentation of results should characterize the sensitivity of the choice of the concentration-response function on the magnitude and the uncertainty associated with estimated benefits.

(vi) When sufficient data exist, 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, measures of the central tendency of risk may be used. Upper-bound risk estimates must not be used without also presenting lower bound and central tendency estimates.

(vii) Consistent with the general systematic review process, the evaluation and model specification processes conducted under all subsections of (9) must emphasize transparency and replicability. This includes:

(a) An explanation of the basis for significant judgments, assumptions, data, models, and inferences used or relied upon in the assessment and decisions regarding the selection and quantification of health endpoints; and

(b) A description of the sources, extent and magnitude of significant uncertainties

associated with the assessment.

(10) The BCA must include an identification of uncertainties underlying the estimation of both benefits and costs and, to the extent feasible and appropriate, quantitatively analyze those that are most influential; and must present benefits and cost estimates in ways that convey their uncertainty, including acknowledging unquantified benefits and costs, where appropriate. The BCA must include a reasoned explanation for the scope and specific quantitative or qualitative methods chosen to analyze uncertainties. Specifically, the explanation must include the following:

(i) To the extent feasible and appropriate, the BCA must apply quantitative methods to analyze uncertainties that have the largest potential effect on benefits or cost estimates and include a description of such methods.

(ii) The BCA 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. For example, the BCA could characterize statistical, model or parameter uncertainty.

(iii) Where data are sufficient to do so, the BCA must include a consideration of sources of uncertainty both independently and jointly.

(iv) To the extent feasible and appropriate, the BCA must also include a consideration, and transparent acknowledgement of, the extent to which qualitatively-assessed costs or benefits are characterized by uncertainty.

(v) When simpler quantitative analysis may not sufficiently describe uncertainty, and where probability distributions for relevant input assumptions are available and can be feasibly and credibly combined, the BCA must include a characterization of 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 BCA must include a characterization of the range of likely outcomes, including 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 or appropriate, the BCA must present a range of benefits and costs.

(11) The BCA must include a presentation that includes the following elements:

(i) A presentation of 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.

(ii) A description of how the benefits and costs were estimated in the BCA, including the assumptions made for the analysis. The description must include the models, data, and assumptions used to estimate benefits and costs, and the evaluation and selection process for these analytical decisions. The description must also include 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.

(iii) A description, consistent with the best available scientific information, of the non-monetized and non-quantified benefits and costs of the action. The description must include 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.

(iv) A presentation of the results of an assessment of 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 presentation must identify any data and models used to analyze uncertainty in the BCA, and the quality of the available data shall be discussed.

(v) 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.

(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 while consistent with protections for privacy, confidentiality, confidential business information (CBI), and national and homeland security. If data and models are proprietary, the Agency must make available, to the extent practicable, the underlying inputs and assumptions used, equations, and methodologies used by EPA.

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

(a) The Agency must provide a summary in the preamble of each significant regulation of the overall BCA results, including total benefits, costs, and net benefits. Within this summary, if any benefits and costs accrue to non-U.S. populations they must be reported separately to the extent possible.

(b) The Agency must provide an additional presentation in the preamble of each significant regulation 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 significant regulation is promulgated.

(1) 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.

(2) 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 significant regulation is promulgated require 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) When the CAA statutory provision or provisions under which the significant regulation is promulgated does not prohibit the consideration of the BCA, the Agency must provide a description in the preamble of how the Agency considered the BCA. If the provision or provisions under which the significant regulation is promulgated prohibit the consideration of the BCA, the Agency must identify the specific provision which bars such consideration.

(e) The summary, description and presentations specified in paragraphs (a), (b), (c), and (d) of this section must be placed in the same section in the preamble of the regulation.