
# Summary of Public Comments and Responses for Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process

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December 2020

# Summary of Public Comments and Responses for Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process

U. S. Environmental Protection Agency
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Washington D.C. 20460

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## List of Acronyms and Abbreviations

| Acronym | Definition |
|---|---|
| ABR | Association of Battery Recyclers |
| ACA | American Coatings Association |
| ACE | Affordable Clean Energy |
| ADEQ | Arizona Department of Environmental Quality |
| AFP | Americans for Prosperity |
| AFPA | American Forest & Paper Association |
| AGU | American Geophysical Union |
| AIF | Auto Industry Forum |
| ALA | American Lung Association |
| ANPR | The Agricultural and Natural Resources Policy |
| ANPRM | Advance Notice of Proposed Rulemaking |
| AOP | Adverse Outcome Pathway |
| APA | Administrative Procedures Act |
| APF | Air Permitting Forum |
| APPA | American Public Power Association |
| AQMD | Air Quality Management District |
| ARTBA | American Road & Transportation Builders Association |
| ATS | American Thoracic Society |
| AWC | American Wood Council |
| AWEA | American Wind Energy Association |
| AXPC | American Exploration and Production Council |
| BACT | Best Available Control Technology |
| BenMAP | EPA's Benefits Mapping |
| BCA | Benefit-cost Analyses |
| BCAC | Beneficiary Counseling and Assistance Coordinator |
| BCI | Battery Council International |
| BIO | Biotechnology Innovation Organization |
| BRT | Business Roundtable |
| CAA | Clean Air Act |
| CABA | Colorado Aviation Business Association |
| CAC | Clean Air Carolina |
| CAGW | Citizens Against Government Waste |
| CAMRO | Colorado Alliance of Mineral and Royalty Owners |
| CAP | Clean Air Project |
| CARB | California Air Resources Board |
| CASAC | Clean Air Science Advisory Committee |
| CBA | Cost Benefit Analysis |
| CBI | Confidential business information |
| CBO | Congressional Budget Office |
| CEA | Cost Effective Analysis |
| CEG | The Clean Energy Group |
| CEI | Competitive Enterprise Institute |
| CFR | Code of Federal Regulations |

| Acronym | Definition |
|---|---|
| CLF | Clean Air and Water Program, Conservation Law Foundation |
| CMA | Colorado Mining Association |
| $CO_2$ | Carbon dioxide |
| COVID | Corona Virus Disease |
| CPP | Clean Power Plan |
| C-R | Concentration-response |
| CRA | Congressional Review Act |
| CRFs | Concentration-response Functions |
| CSAFs | Chemical-Specific Adjustment Factors |
| DDEFs | Data-Derived Uncertainty Factors |
| EDF | Environmental Defense Fund |
| EDT | Eastern Daylight Time |
| E-EEAC | External-Environmental Economics Advisory Committee |
| EGUs | Electric Utility Steam Generating Units |
| EIA | Economic Impact Analysis |
| EMA | Truck & Engine Manufacturers Association |
| EO | Executive Order |
| EPA | U.S. Environmental Protection Agency |
| EPN | Environmental Protection Network |
| ERDDAA | Environmental Research, Development, and Demonstration Act of 1976 |
| FIP | Federal Implementation Plan |
| FPA | Flexible Packaging Association |
| FRL | Federal Register Log |
| GAO | U.S. Government Accountability Office |
| GHG | Greenhouse Gas |
| HAP | Hazardous Air Pollutant |
| HISA | Highly Influential Scientific Assessment |
| HONEST | Honest and Open New EPA Science Treatment |
| iMSA | Illinois Mathematics and Science Academy |
| ICCT | International Council on Clean Transportation |
| IOM | Institute of Medicine's |
| IPAA | Independent Petroleum Association of America |
| IPM | Integrated Planning Model |
| IRIS | Integrated Risk Information System |
| ISA | Integrated Science Assessment |
| IUA | Integrated Uncertainty Analysis |
| IWG | Interagency Working Group |
| KBIC | Keweenaw Bay Indian Community |
| LCRA | Lower Colorado River Authority |
| LML | Lowest Measured Level |
| MACT | Maximum Achievable Control Technology |
| MATS | Mercury and Air Toxics Standard |
| MDE | Maryland Department of Environment |
| MECA | Manufacturers of Emission Controls Association |

| Acronym | Definition |
|---|---|
| MOA | mode of action |
| MPCA | Minnesota Pollution Control Agency |
| NAAQS | National Ambient Air Quality Standards |
| NACAA | National Association of Clean Air Agencies |
| NADCA | North American Die Casting Association |
| NAFEM | North American Association of Food Equipment Manufacturers |
| NAS | National Academies of Sciences |
| NCASI | National Council for Air and Stream Improvement |
| NCDEQ | North Carolina Department of Environmental Quality |
| NCEE | National Center for Environmental Economics |
| NEDA | National Environmental Development Association |
| NESCAUM | Northeast States for Coordinated Air Use Management |
| NESHAP | National Emission Standards for Hazardous Air Pollutants |
| NLA | National Lime Association |
| NOPR | Notice of Proposed Regulation |
| NPRM | Notice of Proposed Rulemaking |
| NPV | Net Present Value |
| NRDC | Natural Resources Defense Council, Inc. |
| NRECA | National Rural Electric Cooperative Association |
| NSPS | New Source Performance Standard |
| NSSGA | National Stone, Sand & Gravel Association |
| NTAA | National Tribal Air Association |
| OAR | Office of Oceanic and Atmospheric Research |
| OBRT | Ohio Business Roundtable |
| OECD | Organisation for Economic Co-operation and Development |
| OIRA | Office of Information and Regulatory Analysis |
| OMB | Office of Management and Budget |
| OSHA | Occupational Safety and Health Administration's |
| PA | Policy Assessment |
| PABC | Palmetto AgriBusiness Council |
| PACA | Pennsylvania Aggregates and Concrete Association |
| PBPK | Physiologically-based Pharmacokinetic |
| PCBI | Pennsylvania Chamber of Business and Industry |
| PII | Personally Identifiable Information |
| $PM_{2.5}$ | Particulate Matter |
| PMA | Pennsylvania Manufacturers' Association |
| PMPA | Precision Machined Products Association |
| PRA | Paperwork Reduction Act |
| PRHE | Program on Reproductive Health and the Environment |
| PSD | Prevention of Significant Deterioration |
| RACM | Reasonably Available Control Measures |
| RACT | Reasonable Available Control Technology |
| RCS | Report of Five Case Studies (EPA, March 2012) |
| RFA | Regulatory Flexibility Act |
| RFF | Resources for the Future |

| Acronym | Definition |
|---|---|
| RFS | Renewable Fuel Standards |
| RHR | Resources for the Future |
| RIA | Regulatory Impact Analyses |
| RRC | Rate of Return to Capital |
| RVO | Renewable Volume Obligation |
| SAB | Science Advisory Board |
| SAFE | Safer Affordable Fuel-Efficient |
| SBA | U.S. Small Business Administration |
| SBE | Small Business & Entrepreneurship Council |
| SCAQMD | South Coast Air Quality Management District |
| SCC | Source Code Control |
| SCMA | South Carolina Manufacturers Alliance |
| SDWA | Safe Drinking Water Act |
| SIP | State Implementation Plan |
| SITLA | Utah School and Institutional Trust Lands Administration |
| SPC | Shadow Price of Capital |
| SRTP | Social Rate of Time Preference |
| STRS | Strengthening Transparency in Regulatory Science |
| TCEQ | Texas Commission on Environmental Quality |
| TMDL | Total Maximum Daily Load |
| UIUC | University of Illinois at Urbana-Champaign |
| UMRA | Unfunded Mandates Reform Act of 1995 |
| USDA | United State Department of Agriculture |
| USEPA | U.S. Environmental Protection Agency |
| VOC | Volatile Organic Compounds |
| VSL | Value of Statistical Life |
| VSLY | Value of Statistical Life-Years |
| WDEQ | Wyoming Department of Environmental Quality |
| WOE | Weight-of-evidence |
| WTA | Willingness to Accept |
| WTP | Willingness to Pay |

## 1.0 Introduction

The U.S. Environmental Protection Agency (EPA) promulgated this rule to establish processes that the 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.

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 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.

EPA extended the comment period by 8 days (from a July 27, 2020 closing to an August 3, 2020 closing) to allow for a public comment period of 30 days following the public hearing that took place on July 1, 2020. In total, the EPA provided the public with a 53-day comment period for the proposed rulemaking from June 11, 2020 – August 3, 2020. A few commenters requested the EPA hold additional public hearings while a few others requested an extension of the comment period beyond August 3, 2020. However, the EPA considered the 53-day comment period was appropriate, met CAA obligations for this rulemaking, and denied these requests.

EPA held a virtual public hearing via teleconference on the Proposed Rule: Increasing Consistency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process. Attendees, both speakers and those listening, participated via a telephone conference call as announced in the Federal Register Notice for the public hearing (85 FR 37057, June 19, 2020). The hearing took place on July 1, 2020 at 9:00 a.m. - 4:00 p.m. (Eastern Daylight Time (EDT)) with a lunch break from noon to 1:00 p.m. (EDT). In total, fifty speakers registered for the public hearing to provide testimony. The statements are considered comments on the proposed rule and the public hearing's transcript is available in the rule's docket.

Some significant comments and EPA's responses appear in the preamble to the final rule. This document contains summaries of public comments that the EPA received on the proposed standards and EPA's responses. Copies of all comments submitted are available electronically through http://www.regulations.gov by searching Docket ID No. EPA-HQ-OAR-2020-0044.

## 2.0 List of Commenters

The EPA received 17,589 comment letters after August 3, 2020, on the proposed Benefits and Costs rulemaking. Of these, 513 were unique comment letters. All comment letters received on the proposed rulemaking are contained in Docket ID No. EPA-HQ-OAR-2020-0044. The commenter, affiliation, and item number are listed in Table 2-1. The comment letters are identified by their entry in Docket ID No. EPA-HQ-OAR-2020-0044 for convenience.

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0002 | T. Olmstead | None |
| EPA-HQ-OAR-2020-0044-0003 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0004 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0005 | R. Stein | None |
| EPA-HQ-OAR-2020-0044-0006 | Various | Allergy & Asthma Network et. al |
| EPA-HQ-OAR-2020-0044-0010 | R. Bartzatt | None |
| EPA-HQ-OAR-2020-0044-0011 | E. Sheffield | None |
| EPA-HQ-OAR-2020-0044-0012 | D. Elland | None |
| EPA-HQ-OAR-2020-0044-0013 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0014 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0015 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0016 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0017 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0018 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0039 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0040 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0041 | Anonymous public comment | Anonymous |
| EPA-HQ-OAR-2020-0044-0052 | Various | Environmental Defense Fund (EDF), Clean Air Task Force et al. |
| EPA-HQ-OAR-2020-0044-0053 | Gretchen Goldman, and Rachel Cleetus | Union of Concerned Scientists |
| EPA-HQ-OAR-2020-0044-0054 | L. Everett | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0055 | L. Tosi | None |
| EPA-HQ-OAR-2020-0044-0056 | P. DiFiore | None |
| EPA-HQ-OAR-2020-0044-0057 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0058-A1 | C. Frey | Department of Civil, Construction, and Environmental Engineering, NC State University |
| EPA-HQ-OAR-2020-0044-0059-A1 | Dan Byers | US Chamber of Commerce, Global Energy Institute |
| EPA-HQ-OAR-2020-0044-0062 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0063 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0066 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0068 | E. Cameron | None |
| EPA-HQ-OAR-2020-0044-0069-A1 | Chad Vorthman | Colorado Farm Bureau |
| EPA-HQ-OAR-2020-0044-0071 | David T. Stevenson | Caesar Rodney Institute |
| EPA-HQ-OAR-2020-0044-0072 | Paul Campbell | Agriculture & Natural Resources Committee, South Carolina Senate |
| EPA-HQ-OAR-2020-0044-0073 | Cam Crawford | Forestry Association of South Carolina |
| EPA-HQ-OAR-2020-0044-0078 | Ike Brannon | Jack Kemp Foundation |
| EPA-HQ-OAR-2020-0044-0079 | D. Wallace | None |
| EPA-HQ-OAR-2020-0044-0080 | G. Wolfram | None |
| EPA-HQ-OAR-2020-0044-0081 | Chris Swathwood | Colorado Aviation Business Association (CABA) |
| EPA-HQ-OAR-2020-0044-0082 | H. C. Frey et al. | Department of Civil, Construction, and Environmental Engineering North Carolina State University |
| EPA-HQ-OAR-2020-0044-0083 | Patrick J. Tiberi | Ohio Business Roundtable (OBRT) |
| EPA-HQ-OAR-2020-0044-0085 | Karen Kerrigan | Small Business & Entrepreneurship Council (SBE) |
| EPA-HQ-OAR-2020-0044-0086 | Ronald L. Summers | Palmetto AgriBusiness Council (PABC) |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0088 | Thomas A. Schatz | Citizens Against Government Waste (CAGW) |
| EPA-HQ-OAR-2020-0044-0089 | T. Royal | None |
| EPA-HQ-OAR-2020-0044-0090 | Daniel Czecholinski | Arizona Department of Environmental Quality (ADEQ) |
| EPA-HQ-OAR-2020-0044-0091 | James Broughel | Mercatus Center - George Mason University |
| EPA-HQ-OAR-2020-0044-0092 | Jerry Sonnenberg, State Senator District 1 | Colorado Senate |
| EPA-HQ-OAR-2020-0044-0093 | Stephanie Kromer | Ohio Chamber of Commerce |
| EPA-HQ-OAR-2020-0044-0094 | S. S. G. Wierman | None |
| EPA-HQ-OAR-2020-0044-0095 | Mark DeLaquil and Roger Miksad | Association of Battery Recyclers (ABR) and Battery Council International (BCI) |
| EPA-HQ-OAR-2020-0044-0096 | Bernard L. Weinstein | Cox School of Business, Southern Methodist University |
| EPA-HQ-OAR-2020-0044-0097 | Anne Bradbury | American Exploration and Production Council (AXPC) |
| EPA-HQ-OAR-2020-0044-0098 | Charlie Souhrada | North American Association of Food Equipment Manufacturers (NAFEM) |
| EPA-HQ-OAR-2020-0044-0099 | Eddie Bernice Johnson | US House of Representatives |
| EPA-HQ-OAR-2020-0044-0102 | E. R. Ware | None |
| EPA-HQ-OAR-2020-0044-0103 | Burnet R. Maybank III | Nexsen/Pruett Attorneys and Counselors At Law |
| EPA-HQ-OAR-2020-0044-0104 | Richard G. Newell | Resources for the Future (RFF) |
| EPA-HQ-OAR-2020-0044-0105 | B. Zycher | American Enterprise Institute |
| EPA-HQ-OAR-2020-0044-0106 | M. L. Krancer | Silent Majority Strategies |
| EPA-HQ-OAR-2020-0044-0107 | Timothy A. French | Truck & Engine Manufacturers Association (EMA) |
| EPA-HQ-OAR-2020-0044-0108 | Students | iMSA program, UIUC |
| EPA-HQ-OAR-2020-0044-0109 | Joy Wieck | Fond du Lac Band of Lake Superior Chippewa |
| EPA-HQ-OAR-2020-0044-0110 | Mary J. Norris | Cahto Tribe of the Laytonville Rancheria |
| EPA-HQ-OAR-2020-0044-0111 | T. K. Thorne | None |
| EPA-HQ-OAR-2020-0044-0112 | Warren C. Swartz | Keweenaw Bay Indian Community (KBIC) |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0113 | Laura C. Perrotta | American Highway Users Alliance |
| EPA-HQ-OAR-2020-0044-0114 | P. T. Prentice | Independence Institute |
| EPA-HQ-OAR-2020-0044-0115 | William C. Herz | National Lime Association (NLA) |
| EPA-HQ-OAR-2020-0044-0116 | Miles E. Keogh | National Association of Clean Air Agencies (NACAA) |
| EPA-HQ-OAR-2020-0044-0117 | Wayne Nastri | South Coast Air Quality Management District (South Coast AQMD) |
| EPA-HQ-OAR-2020-0044-0118 | Todd Parfitt | Wyoming Department of Environmental Quality (WDEQ) |
| EPA-HQ-OAR-2020-0044-0119 | Kevin Sunday | Pennsylvania Chamber of Business and Industry (PCBI) |
| EPA-HQ-OAR-2020-0044-0120 | Major L. Clark, III | US Small Business Administration (SBA) |
| EPA-HQ-OAR-2020-0044-0121 | David N. Taylor and Carl A. Marrara | Pennsylvania Manufacturers' Association (PMA) |
| EPA-HQ-OAR-2020-0044-0122 | Bill La Marr | California Small Business Alliance |
| EPA-HQ-OAR-2020-0044-0123 | G. Hess | None |
| EPA-HQ-OAR-2020-0044-0124 | Daniel Chartier | American Public Power Association (APPA) and National Rural Electric Cooperative Association (NRECA) |
| EPA-HQ-OAR-2020-0044-0125 | Daniel T. Naatz | Independent Petroleum Association of America (IPAA) |
| EPA-HQ-OAR-2020-0044-0126 | Michael A. Abraczinskas | North Carolina Department of Environmental Quality (NCDEQ) |
| EPA-HQ-OAR-2020-0044-0127 | Aladdine Joroff, et al. | Chesapeake Bay Foundation and National Parks Conservation Association |
| EPA-HQ-OAR-2020-0044-0128 | Michelle Roos | Environmental Protection Network (EPN) |
| EPA-HQ-OAR-2020-0044-0129 | Devin Hartman | R Street Institute |
| EPA-HQ-OAR-2020-0044-0130 | Paul Griffin | Energy Fairness |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0131 | Daniel Savickas and Luke Hogg | FreedomWorks Foundation |
| EPA-HQ-OAR-2020-0044-0132 | Heidi K. McAuliffe | American Coatings Association (ACA) |
| EPA-HQ-OAR-2020-0044-0133 | Ram Singhal | Flexible Packaging Association (FPA) |
| EPA-HQ-OAR-2020-0044-0134 | Laura Watson | Washington State Department of Ecology |
| EPA-HQ-OAR-2020-0044-0135 | Robert Wolcott and Roy Gamse | Environmental Protection Network |
| EPA-HQ-OAR-2020-0044-0137 | David Bauer | American Road & Transportation Builders Association (ARTBA) |
| EPA-HQ-OAR-2020-0044-0138 | Kathleen M. Sgamma | Western Energy Alliance |
| EPA-HQ-OAR-2020-0044-0139 | Liz Mueller | American Lung Association (ALA) et al. |
| EPA-HQ-OAR-2020-0044-0140 | Matthew Soper | District 54, Colorado House of Representatives |
| EPA-HQ-OAR-2020-0044-0141 | Paul J. Miller | Northeast States for Coordinated Air Use Management (NESCAUM) |
| EPA-HQ-OAR-2020-0044-0142 | John F. Wall IV | South Carolina Manufacturers Alliance (SCMA) |
| EPA-HQ-OAR-2020-0044-0143 | American Thoracic Society (ATS) | American Thoracic Society (ATS) |
| EPA-HQ-OAR-2020-0044-0144 | W. O. Berry | None |
| EPA-HQ-OAR-2020-0044-0145 | Giffe Johnson | National Council for Air and Stream Improvement (NCASI) |
| EPA-HQ-OAR-2020-0044-0146 | Rachel McIntosh-Kastrinsky | Clean Air Carolina (CAC) |
| EPA-HQ-OAR-2020-0044-0147 | Gene Grace | American Wind Energy Association (AWEA) |
| EPA-HQ-OAR-2020-0044-0148 | D. R. Hill | None |
| EPA-HQ-OAR-2020-0044-0149 | Emily W. Coyner | National Stone, Sand & Gravel Association (NSSGA) |
| EPA-HQ-OAR-2020-0044-0150 | Jonathan Berry | Boyden Gray & Associates, PLLC |
| EPA-HQ-OAR-2020-0044-0151 | Frank L. Kohlasch | Minnesota Pollution Control Agency (MPCA) |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0152 | Various | Center for Progressive Reform et al. |
| EPA-HQ-OAR-2020-0044-0153 | W. R. Hafker | None |
| EPA-HQ-OAR-2020-0044-0154 | Various | Alaska Community Action on Toxics, et al. |
| EPA-HQ-OAR-2020-0044-0155 | Josie Gaskey | Pennsylvania Aggregates and Concrete Association (PACA) |
| EPA-HQ-OAR-2020-0044-0156 | Omar Nashashibi | North American Die Casting Association (NADCA) |
| EPA-HQ-OAR-2020-0044-0157 | Joseph J. Cordes | George Washington University |
| EPA-HQ-OAR-2020-0044-0158 | Stan Dempsey, Jr. | Colorado Mining Association (CMA) |
| EPA-HQ-OAR-2020-0044-0159 | Business Roundtable (BRT) | Business Roundtable (BRT) |
| EPA-HQ-OAR-2020-0044-0160 | George (Tad) S. Aburn | Maryland Department of Environment (MDE) |
| EPA-HQ-OAR-2020-0044-0161 | Richard W. Corey | California Air Resources Board (CARB) |
| EPA-HQ-OAR-2020-0044-0162 | W. Mason Emnett | Exelon Corporation |
| EPA-HQ-OAR-2020-0044-0163 | D. Bakst | None |
| EPA-HQ-OAR-2020-0044-0164 | Paul R. Noe | American Forest & Paper Association (AFPA) & American Wood Council (AWC) |
| EPA-HQ-OAR-2020-0044-0165 | Toby Baker | Texas Commission on Environmental Quality (TCEQ) |
| EPA-HQ-OAR-2020-0044-0166 | Mark N. Templeton | University of Chicago Law School et al. |
| EPA-HQ-OAR-2020-0044-0167 | David Ure | Utah School and Institutional Trust Lands Administration (SITLA) |
| EPA-HQ-OAR-2020-0044-0168 | Mary F. Evans, et al. | Claremont McKenna College |
| EPA-HQ-OAR-2020-0044-0169 | Chris Bliley | Growth Energy |
| EPA-HQ-OAR-2020-0044-0170 | M. Hudson | None |
| EPA-HQ-OAR-2020-0044-0171 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0172 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0173 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0174 | S. J. Drysdale | None |
| EPA-HQ-OAR-2020-0044-0175 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0176 | T. P. Sheahen | None |
| EPA-HQ-OAR-2020-0044-0177 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0178 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0179 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0180 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0181 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0182 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0183 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0184 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0185 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0186 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0187 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0188 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0189 | W. Johnson | None |
| EPA-HQ-OAR-2020-0044-0190 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0191 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0192 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0193 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0194 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0195 | Anonymous public comment | None |

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| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0196 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0197 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0198 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0199 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0200 | Matthew J. Kotchen | Department of Economics, Yale University |
| EPA-HQ-OAR-2020-0044-0201 | R. Michael Johnson, Jr. | York County Council South Carolina |
| EPA-HQ-OAR-2020-0044-0202 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0203 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0206 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0207 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0208 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0209 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0210 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0211 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0212 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0213 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0214 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0215 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0216 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0217 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0218 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0219 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0220 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0221 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0222 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0223 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0224 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0225 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0226 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0227 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0228 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0229 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0230 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0231 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0232 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0233 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0234 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0235 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0236 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0237 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0238 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0239 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0240 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0241 | M. Poppa | None |
| EPA-HQ-OAR-2020-0044-0242 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0243 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0244 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0245 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0246 | C. Luhrsen | None |
| EPA-HQ-OAR-2020-0044-0247 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0248 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0249 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0250 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0251 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0252 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0253 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0254 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0255 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0256 | J. Trulio | None |
| EPA-HQ-OAR-2020-0044-0257 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0258 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0259 | M. Bons | None |
| EPA-HQ-OAR-2020-0044-0260 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0261 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0262 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0263 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0264 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0265 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0266 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0267 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0268 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0269 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0270 | E. King | None |
| EPA-HQ-OAR-2020-0044-0271 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0272 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0273 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0274 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0275 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0276 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0277 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0278 | F. Zipperer | None |
| EPA-HQ-OAR-2020-0044-0279 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0280 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0282 | D. DePrez | None |
| EPA-HQ-OAR-2020-0044-0284 | C. Southbury | None |
| EPA-HQ-OAR-2020-0044-0299 | P. Zimmerman | None |
| EPA-HQ-OAR-2020-0044-0313 | R. Sheets | None |
| EPA-HQ-OAR-2020-0044-0317 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0319 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0320 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0321 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0334 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0338 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0340 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0342 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0344 | D. Neff | None |
| EPA-HQ-OAR-2020-0044-0345 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0346 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0349 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0350 | J. Brink | None |
| EPA-HQ-OAR-2020-0044-0351 | C. Lish | None |
| EPA-HQ-OAR-2020-0044-0352 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0353 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0354 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0356 | Martin Rodriguez | Americans for Prosperity (AFP) |
| EPA-HQ-OAR-2020-0044-0357 | Policy committee | GeoHealth Section Policy Committee of the American Geophysical Union (AGU) |
| EPA-HQ-OAR-2020-0044-0358 | Leslie Ritts | National Environmental Development Association's Clean Air Project (NEDA/CAP) |
| EPA-HQ-OAR-2020-0044-0359 | Senator Ray Scott | CO State Senate |
| EPA-HQ-OAR-2020-0044-0360 | Hilary Meltzer | New York City Law Department |
| EPA-HQ-OAR-2020-0044-0361 | John Cooke | CO State Senate |
| EPA-HQ-OAR-2020-0044-0362 | Gavin G. McCabe | Environmental Protection Bureau, Office of the Attorney General, New York |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0363 | Lisa Piering | Town of Rangley, CO |
| EPA-HQ-OAR-2020-0044-0364 | Governor Mark Gordon | State of Wyoming |
| EPA-HQ-OAR-2020-0044-0365 | Brent A. Fewell | ConservAmerica |
| EPA-HQ-OAR-2020-0044-0366 | Shannon S. Broome | Air Permitting Forum and the Auto Industry Forum (APF and AIF) |
| EPA-HQ-OAR-2020-0044-0367 | B. Mannix | |
| EPA-HQ-OAR-2020-0044-0368 | Various | Regulatory Improvement Council et. Al |
| EPA-HQ-OAR-2020-0044-0369 | S. Hess | None |
| EPA-HQ-OAR-2020-0044-0370 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0371 | Reed Williams | Wilsource Enterprise |
| EPA-HQ-OAR-2020-0044-0372 | Neil Ray | Colorado Alliance of Mineral and Royalty Owners (CAMRO) |
| EPA-HQ-OAR-2020-0044-0373 | Chelsea Kendall | Clean Air and Water Program, Conservation Law Foundation (CLF) |
| EPA-HQ-OAR-2020-0044-0374 | K. Sloan | None |
| EPA-HQ-OAR-2020-0044-0375 | Marlo Lewis | Competitive Enterprise Institute (CEI) |
| EPA-HQ-OAR-2020-0044-0377 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0378 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0379 | J. Lee | None |
| EPA-HQ-OAR-2020-0044-0380 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0381 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0382 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0383 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0384 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0385 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0386 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0387 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0388 | T. Hansen | None |
| EPA-HQ-OAR-2020-0044-0389 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0391 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0392 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0393 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0394 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0395 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0396 | W. Alber | None |
| EPA-HQ-OAR-2020-0044-0397 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0398 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0399 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0401 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0402 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0403 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0404 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0405 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0406 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0407 | Julie Gros | Clean Air Carolina |
| EPA-HQ-OAR-2020-0044-0409 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0410 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0411 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0412 | S. Milnes | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0413 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0415 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0416 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0417 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0418 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0419 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0420 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0421 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0422 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0423 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0424 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0425 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0426 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0427 | Kathleen D. (no surname provided) | None |
| EPA-HQ-OAR-2020-0044-0428 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0429 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0430 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0431 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0432 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0433 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0434 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0435 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0436 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0437 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0438 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0439 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0440 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0441 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0442 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0443 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0444 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0445 | W. Slater | None |
| EPA-HQ-OAR-2020-0044-0446 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0447 | J. and K. Lorensen | None |
| EPA-HQ-OAR-2020-0044-0448 | Bob (no surname provided) | None |
| EPA-HQ-OAR-2020-0044-0449 | B. Adams | None |
| EPA-HQ-OAR-2020-0044-0450 | T. Moore | None |
| EPA-HQ-OAR-2020-0044-0453 | B. Foster | None |
| EPA-HQ-OAR-2020-0044-0454 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0455 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0456 | J. and V. Albanese | None |
| EPA-HQ-OAR-2020-0044-0457 | Bryan (no surname provided) | None |
| EPA-HQ-OAR-2020-0044-0459 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0460 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0468 | Dwayne Paul and Rachel Lea Scott | Collaborative Center for Justice, Inc. |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0469 | Ted Pitts | South Carolina Chamber of Commerce |
| EPA-HQ-OAR-2020-0044-0470 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0471 | Carrie Jenks | The Clean Energy Group (CEG) |
| EPA-HQ-OAR-2020-0044-0472 | Various | EDF, et al. |
| EPA-HQ-OAR-2020-0044-0474 | Patti Hershey | Lower Colorado River Authority (LCRA) |
| EPA-HQ-OAR-2020-0044-0475 | Various | CALSTART, et al. |
| EPA-HQ-OAR-2020-0044-0481 | Leslie Sue Ritts | National Environmental Development Association's Clean Air Project (NEDA/CAP) |
| EPA-HQ-OAR-2020-0044-0482 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0483 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0484 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0485 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0486 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0487 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0488 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0490 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0491 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0492 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0493 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0494 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0495 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0496 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0497 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0498 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0499 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0500 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0501 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0502 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0503 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0504 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0505 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0506 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0507 | B. Jones | None |
| EPA-HQ-OAR-2020-0044-0508 | Miles Free | Precision Machined Products Association (PMPA) |
| EPA-HQ-OAR-2020-0044-0509 | A.G. Randol III | None |
| EPA-HQ-OAR-2020-0044-0510 | Stephanie Batchelor | Biotechnology Innovation Organization (BIO) |
| EPA-HQ-OAR-2020-0044-0511 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0512 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0514 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0515 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0516 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0517 | Rasto Brezny | Manufacturers of Emission Controls Association (MECA) |
| EPA-HQ-OAR-2020-0044-0518 | Swati Rayasam | Program on Reproductive Health and the Environment (PRHE), University of |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| | | California, San Francisco et al. |
| EPA-HQ-OAR-2020-0044-0519 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0521 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0522 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0523 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0524 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0525 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0526 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0527 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0528 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0529 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0530 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0532 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0533 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0534 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0535 | Cherie (no Surname provided) | None |
| EPA-HQ-OAR-2020-0044-0536 | L. Baldasare | None |
| EPA-HQ-OAR-2020-0044-0537 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0539 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0540 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0542 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0543 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0545 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0546 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0548 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0549 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0550 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0551 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0552 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0553 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0554 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0555 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0557 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0558 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0562 | R. J. Bertozzi | None |
| EPA-HQ-OAR-2020-0044-0563 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0565 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0566 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0567 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0568 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0569 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0570 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0571 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0572 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0573 | J. Pennington | None |
| EPA-HQ-OAR-2020-0044-0578 | C. E. Ward | None |
| EPA-HQ-OAR-2020-0044-0579 | Janzen Family | None |
| EPA-HQ-OAR-2020-0044-0580 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0581 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0582 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0583 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0589 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0591 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0593 | K. Evans | None |
| EPA-HQ-OAR-2020-0044-0594 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0595 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0596 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0603 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0604 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0605 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0606 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0607 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0608 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0610 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0611 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0612 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0613 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0614 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0615 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0616 | Various | Institute for Policy Integrity, EDF, Union of Concerned Scientists, et al. |
| EPA-HQ-OAR-2020-0044-0617 | Various | ACC, API, NAM, US Chamber of Commerce |
| EPA-HQ-OAR-2020-0044-0618 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0620 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0621 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0622 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0623 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0624 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0625 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0627 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0629 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0630 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0631 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0632 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0633 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0635 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0638 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0639 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0641 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0642 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0643 | D. Mulcihy | None |
| EPA-HQ-OAR-2020-0044-0645 | R. Mezzavilla | None |
| EPA-HQ-OAR-2020-0044-0646 | E. Petersen | None |
| EPA-HQ-OAR-2020-0044-0647 | K. Kite-Powell | None |
| EPA-HQ-OAR-2020-0044-0649 | J. Dahlman | None |
| EPA-HQ-OAR-2020-0044-0650 | G. Lee | None |
| EPA-HQ-OAR-2020-0044-0651 | N. Poenisch | None |
| EPA-HQ-OAR-2020-0044-0652 | C. Noble | None |
| EPA-HQ-OAR-2020-0044-0653 | C. Mendez | None |
| EPA-HQ-OAR-2020-0044-0654 | C. Ellis | None |
| EPA-HQ-OAR-2020-0044-0655 | R. M. Deems | None |
| EPA-HQ-OAR-2020-0044-0656 | S. Collins | None |
| EPA-HQ-OAR-2020-0044-0657 | S. Roller | None |
| EPA-HQ-OAR-2020-0044-0658 | A. Mellinger-Birdsong | Mothers & Others for Clean Air |
| EPA-HQ-OAR-2020-0044-0659 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0660 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0661 | D. McLinko | None |
| EPA-HQ-OAR-2020-0044-0662 | George D. Thurston | International Society for Environmental Epidemiology |
| EPA-HQ-OAR-2020-0044-0663 | Various | Earth Justice, CA Communities Air Toxics, Sierra Club |
| EPA-HQ-OAR-2020-0044-0664 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0665 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0670 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0671 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0673 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0674 | Anonymous public comment | None |

**Table 2-1. Public Comments Received After the Proposed Benefits and Costs Rulemaking**

| Commenter Number | Commenter Name | Commenter Affiliation |
|---|---|---|
| EPA-HQ-OAR-2020-0044-0675 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0676 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0677 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0678 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0679 | Anonymous public comment | None |
| EPA-HQ-OAR-2020-0044-0680 | Jim Ketcham-Colwill | Save EPA |
| EPA-HQ-OAR-2020-0044-0681 | J. E. Enstrom | None |
| EPA-HQ-OAR-2020-0044-0682 | Alan Wilson | Office of the Attorney General, State of South Carolina |
| EPA-HQ-OAR-2020-0044-0683 | Wilfred J. Nabahe | National Tribal Air Association (NTAA) Executive Committee |
| EPA-HQ-OAR-2020-0044-0685 | Professor Melissa J. Luttrell | The University of Tulsa College of Law |

# 3.0 Background

## 3.1 Need for the Rule

### *3.1.1 Support/Opposition of the Proposed Action*

Support

**Comment:** Commenters supported EPA's proposed action. Several of these commenters contended that a BCA is an essential tool for rational decision making and supported EPA's proposed action for at least one of the following reasons:

- EPA's proposed action ensures that best practices are being upheld throughout the regulatory process and requires the EPA to adopt these best practices on how it assesses the risks, benefits, and costs and conduct a systematic review of all evidence.
- EPA's proposed action requires the EPA to conduct existing studies and models using clear criteria to prevent focusing disproportionately on one study alone.
- EPA's proposed action is within EPA's authority to ensure BCAs are not conducted under arbitrary standards and subjective factors.
- EPA's proposed action provides more clarity and transparency, makes common sense, enhances public accountability, engagement, and understanding of the scientific and other inputs that drive EPA's decisions, improves the integrity of the rulemaking process, and leads to better public policy.
- EPA's proposed action will deliver continued environmental improvement as well as a more predictable and achievable set of outcomes for manufacturers and the regulated community.
- EPA's proposed action helps ensure rules deliver on the outcomes Congress expected and that this progress maximizes cost-effective environmental improvement.
- EPA's proposed action will establish safeguards against regulators acting on a political agenda.
- EPA's proposed action addresses the lack of accountability amongst bureaucrats.
- EPA's proposed action will help Americans get back on their feet from an economy that is teetering towards recession due to COVID-19.
- EPA's proposed action will help ensure existing law is enforced with clarity, precision, and predictability.
- EPA's proposed action prioritizes fairness.
- EPA's proposed action will instill uniformity in the assessment of the impact of proposed regulations.
- EPA's proposed action will ensure EPA's regulations do more good than harm.

- EPA's proposed action creates a process that will balance legitimate and practical questions about the economic and the environmental factors to evaluate.
- EPA's proposed action will help avoid unreasonable burdens on business and the general public at little or no marginal benefit.
- EPA's proposed action is a sound approach for balancing the public's dual interest in environmental protection and economic vitality. It will not harm the environment, will bring more jobs, and will save local and state tax dollars.
- EPA's proposed action removes all political bias to the process.
- EPA's proposed action furthers the ambitions of all previous administrations in the past 46 years to adequately assess the costs and benefits of new rules[1] and this administration's directive to accurately estimate benefits and costs and identify regulations where costs exceed benefits.[2]
- EPA's proposed action will help the federal government become more of a partner rather than an adversary to American agriculture, manufacturing, transportation, and other sectors.

A commenter recommended that EPA's proposed action supersede, rather than duplicate, existing non-justiciable, non-statutory sources of guidance for Agency analysis, including Executive Orders (e.g., EO 12866), Office of Management and Budget (OMB) Circulars (e.g., OMB Circular A-4 (OMB, 1993)), and EPA documents (e.g., Guidelines for Preparing Economic Analyses (EPA, 2010)). The commenter stated that if the EPA does not intend to finalize the proposed action, then the Administrator or their designee must provide rationale in statutorily-relevant terms.

Oppose

Commenters opposed EPA's proposed action. In general, these commenters said the proposal weakens pollution protection and ignores longstanding economic best practices and the latest peer-reviewed science. Several of the commenters opposed EPA's proposed action for at least one of the following reasons:

- EPA's proposed action, if finalized, will encourage litigation to block CAA rules on grounds that they do not follow those procedures, despite the EPA's statement (85 FR 35613) that the rule "would not affect the rights ... of outside parties." The litigation will consume significant resources at the federal and state level to address a problem that does not exist.
- EPA's proposed action creates an elaborate and excessively burdensome set of procedures for completing BCA that would be practically impossible for the EPA to satisfy and would be prohibitively costly to complete. Instead, maximum flexibility is

[1] President Ford's 1974 Executive Order (EO) 11821; President Carter's 1978 EO 12044, Improving Government Regulations; President Reagan's EO 12291, Federal Regulation; and President Clinton's EO 12866, Regulatory Planning and Review; and President Obama's EO 13563.

[2] President Trump's EO 13777.

needed to enable the EPA to fit the analysis to the unique circumstances presented by each rulemaking.

- EPA's proposed action would result in a disproportionate impact on disadvantaged communities (including people of color and tribal communities) that are already suffering from poorer health which are more likely to have new pollutant emitters in their area. It would average benefits across society thereby undervaluing the health benefits from reductions in harmful air pollution in locally and specifically-impacted communities.
- EPA's proposed action would make it harder to support stronger regulations, and allow the Administrator to voluntarily delay and burden minor regulations by applying the proposed requirements at will.
- EPA's proposed action cherry-picks "stakeholder" comments and defers to regulated industries. It favor polluters over well/documented, science-based negative consequences. It would skew the results toward industry at the expense of people.
- EPA's proposed action would significantly limit the scientific studies that could inform CAA BCAs, explicitly targeting limitations on the use of epidemiological studies.
- EPA's proposed action would confuse regulatory decision-making by requiring unjustified emphasis on normal scientific uncertainty.
- EPA's proposed action would put Americans at greater risk for negative health impacts of air pollution such as increased incidence of aggravated asthma, lung cancers, ischemic heart disease, and chronic obstructive pulmonary disease.
- EPA's proposed action ignores the successful track record of the CAA and seeks to defeat the effective implementation of CAA rules in the future by subtly and insidiously rigging the BCAs that the EPA performs so that they are even more biased against the kind of robust environmental and public health protections that Congress charged the EPA with implementing under the CAA.
- EPA's proposed action defies logic and common sense because many key stakeholders, including scientists and public health experts are overburdened due to the COVID-19 pandemic. A commenter added that it is unconscionable for the EPA to be focused during the COVID-19 pandemic on making it easier to undo existing public health protections and harder to put new ones in place.
- EPA's proposed action creates additional government bureaucracy.
- EPA's proposed action ignores the full range of public health benefits of air pollution regulations and manipulates how public health impacts are quantified. It conflicts with the basic purpose of the CAA and undermines the existing flexibility that is essential for us to achieve EPA's core mission to protect Americans' health and the environment. It deemphasizes the benefits of clean air safeguards, adds new hurdles for issuing clean air protections, and disregards the scientific basis for clean air rules.

For example, it would allow the EPA to disregard benefits such as fewer premature deaths and fewer childhood asthma attacks in its rulemaking.

- EPA's proposed action fails to comply with CAA section 103 that requires the Administrator to develop "effective and practical" methods to prevent and control air pollution.
- EPA's proposed action transforms the BCA into a rigid, impractical, and cost-ineffective impediment to reasoned decision making.
- EPA's proposed action is an example of overregulation.
- EPA's proposed action requires the EPA to show "a compelling need for federal government intervention in the market" each and every time it undertakes a major CAA rulemaking, but Congress never required such a demonstration and it already found there was a compelling need for federal pollution standards by passing the CAA in the first place.

Commenters opined that the real purpose of the proposal was to weaken the EPA, rather than a good faith effort to improve the EPA's Regulatory Impact Analysis (RIA) procedures. A commenter said that, at best, the preamble alluded indirectly to the 2016 "appropriate and necessary" finding for the EPA's Mercury and Air Toxics Standard (MATS) rule in which the EPA relied in part on the significant enormous co-benefits of the expected PM emissions reduction from the MATS rule to support its conclusion that the CAA's unique statutory trigger for regulating mercury and other toxic air pollutants from fossil-fueled power plants had been satisfied. The commenter contended that the EPA used co-benefits in this manner consistently and transparently for over a decade.

Commenters said it was concerned that EPA's intent for the proposal was not to create a more open public process and allow for circumstantial flexibility, but to diminish scientific rigor in favor of promoting preferred outcomes. A commenter said EPA's proposed action would likely prevent the EPA from using high-quality, cutting-edge science to support its estimates of public health benefits and would build on a decades' long strategy devised by opponents of regulations to use the BCA methodology as a tool for blocking or weakening vital safeguards. Another commenter noted that the EPA began its section, "Methods for Estimating Benefits and Costs" by acknowledging the importance of flexibility in choosing methods of analysis, but the commenter was concerned that the proposal might limit flexibility, given the necessity to analyze impacts using current methods and the dynamic nature of disciplines which will limit the ability of expert analysts to use comprehensive and up-to-date economic methodologies and guidance.

Another commenter opined that EPA's primary argument for the proposed rule is for the sake of consistency, but this argument is not compelling and is potentially harmful if consistency comes at the cost of sacrificing the flexibility that is needed to promulgate rules that protect human health and the environment.

Commenters opposed EPA's proposed action because they said it does not explain how any of the EPA's previous BCAs have fallen short of any applicable legal requirements or failed to deliver on their purported policy benefits, nor does EPA's proposed action make the case that such shortcomings are so widespread among the EPA's BCA practices that the proposal was

necessary and would succeed as a corrective measure. These commenters said that EPA's proposed action provides nothing beyond a few vague examples in a failed attempt to demonstrate need, does not assess the significance of the alleged problem, does not demonstrate a compelling social purpose, does not avoid unnecessary duplication, does not assess how likely the proposed changes were to address the alleged problem, does not assess the strengths or limitations of the scant evidence of need, and does not identify any deficiencies in existing laws, orders, and guidelines. Commenters argued that, given the clear credibility and reliability of the peer-reviewed and longstanding methodologies (as acknowledged by the EPA itself throughout the proposal), it was arbitrary and capricious for the EPA to constrain its methodologies and depart from previous practice without providing a fact-based and reasoned analysis.

Commenters said that the EPA did not substantiate its contention (85 FR 35617) that the EPA has "underestimated costs, overestimated benefits, or evaluated benefits and costs inconsistently with its rulemakings." A commenter said that an agency must "justify its rule with a reasoned explanation", but the preamble of the proposed rule did not meet the "reasoned explanation" standard. Another commenter added that the examples of damage to the economy provided by the EPA were not backed with examples or research, undermining the scientific purpose of the CAA and the bodies meant to enforce it, and the solutions the EPA suggested miss the key logical steps in problem solving. Another commenter said they are concerned that the proposal completely disregarded the prominent identification in their comments in response to the ANPRM of the EPA's failure to document any concrete inconsistency in how it has conducted BCAs, much less any inconsistency that is not explained by the statute's different requirements for different CAA programs (e.g., NAAQS, NESHAP, and NSPS). Commenters contended that the evidence shows that the benefits of CAA protections have, if anything, been underestimated and costs frequently overestimated and referenced a study (Retrospective Study of the Costs of EPA Regulations: A Report of Four Case Studies). A commenter said the proposal displayed an unexplained, one-sided focus on reducing estimated benefits and increasing estimated costs of clean air protections, entirely failing to assess ways that the EPA has historically underestimated benefits and overestimated costs.

Commenters said that numerous analyses have concluded that CAA regulations are highly cost-effective, and noted that a previous, peer-reviewed study of CAA regulations determined that benefits from 1990 to 2020 would exceed costs by a factor of more than 30 to one. The commenters quoted OMB's conclusion, in a report to Congress published on December 9, 2019: "Across the Federal government, the rules with the highest estimated benefits as well as the highest estimated costs come from the Environmental Protection Agency and in particular its Office of Air and Radiation[,]" and that "the estimated benefits of these rules far exceed the estimated costs[.]"

A commenter noted that the proposal cited Justice Scalia's opinion in Michigan v. EPA (135 S. Ct. 2699, 2706 (2015)) in part to justify its heavy (and disproportionate) consideration of costs in BCAs. However, the commenter contended that this use of Scalia's quote was misleading because Justice Scalia did not accurately characterize every, or even most, of current CAA regulations, and the proposed rule would have an impact on every single regulation going forward. The commenter stated that EPA's suggestion that the majority of CAA regulations "do significantly more harm than good" was inaccurate and the commenter noted that, historically,

these regulations have saved the nation trillions of dollars and these savings are in large part made up by the prevention of premature deaths.

**Response:** We are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in section V.A of the preamble to the final rule, we maintain that codifying the BCA in regulatory decision-making will help ensure that 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 requirements promulgated in this action address the comments, by many, that EPA has not consistently estimated, presented, and considered benefits and costs in line with best practices and principles set forth in long standing executive orders governing regulatory analysis. 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 adequate consideration of, and public accountability concerning, their costs and benefits. Thus, we have determined that the Final Rule is necessary to ensure that BCA practices are implemented in a consistent fashion prospectively.

We disagree with commenters that contended the rule was overly burdensome as the requirements are based on current guidance documents that EPA is following for their BCA analysis, such as OMB Circular A-4. We also disagree with commenters asserting that the BCA rule will result in negative health impacts or ignores the full range of public health benefits. The BCA rule codifies best practices for conducting a BCA and requires that risk assessments used to support BCAs follow best methodological practices for risk characterization and risk assessment; it does not set pollutant standards. Additional discussion is provided is section 3.1.2 of this document. We also disagree with commenters contending that the BCA fails to comply with CAA section 103 because we maintain that the BCA proposal is a procedural rule under CAA section 301 to increase consistency and transparency in the CAA rulemaking process and does not conflict with CAA section 103. Further discussion of our rationale that the BCA is a procedural rule is found in chapter 4. Commenters are referred to Chapter 12 for additional responses regarding executive orders and environmental justice, Chapter 6 for additional responses regarding uncertainty, Chapter 4 for additional responses to legal comments, and Chapter 7 for additional responses regarding requirements for scientific studies.

### *3.1.2 Double Counting and Consideration of Co-Benefits*

**Comment:** Commenters stated that EPA's proposed action does not provide justification for the EPA's concerns over potential "double-counting" of benefits. Many of these commenters said that Agency failed to provide any evidence that double-counting benefits had ever occurred in any previous BCA and/or how the proposed rule would take any further action beyond the existing procedures to prevent double-counting benefits from occurring. Commenters rejected EPA's example in the proposal (85 FR 35617) of a lack of transparency where "some commenters contend that some BCAs have double-counted benefits that arise from another regulation." Another commenter stated that the proposal is arbitrary and capricious since the

occurrence of double counting of benefits is unfounded and because, under the EPA's existing guidance, any economic analysis performed by the EPA assumes full compliance by industry with regulatory requirements, including newly enacted regulations that are in the process of being implemented.

**Response:** We are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. In the proposal we noted that there could be misestimation risks if existing regulations are not carefully accounted for in the analysis. As such, the final rule aims to ensure the consistency and transparency when conducting BCA in CAA rulemakings to ensure best practices are followed in line with those provided in OMB Circular A-4 and EPA's Guidelines for Preparing Economic Analyses (hereafter, Guidelines).

**Comment:** Commenters stated that EPA's proposed action does not provide justification for the EPA's concerns over potential "double-counting" of benefits. Many of these commenters said that Agency failed to provide any evidence that double-counting benefits had ever occurred in any previous BCA and/or how the proposed rule would take any further action beyond the existing procedures to prevent double-counting benefits from occurring. Commenters rejected EPA's example in the proposal (85 FR 35617) of a lack of transparency where "some commenters contend that some BCAs have double-counted benefits that arise from another regulation." Another commenter stated that the proposal is arbitrary and capricious since the occurrence of double counting of benefits is unfounded and because, under the EPA's existing guidance, any economic analysis performed by the EPA assumes full compliance by industry with regulatory requirements, including newly enacted regulations that are in the process of being implemented.

A commenter stated that EPA's proposed action, including the vague examples the EPA offered in the ANPRM (e.g., MATS and the Oil and Gas NSPS), fails to offer any evidence of any historical problems with transparency or consistency in the presentation of co-benefits. The commenter added that the EPA failed to explain how a regulatory requirement for an "additional presentation" featuring only a subset of benefits while excluding co-benefits would reduce "public confusion." Commenters said that, although the EPA alluded to controversy over consideration of co-benefits in the EPA's finding that it is "appropriate and necessary" to regulate toxics from power plants, the BCA for the proposed rule clearly explains which benefits accompany which pollutant reductions and what assumptions and models are used. A commenter suggested that, if the EPA were concerned about ambiguous or misleading impacts from regulations in which co-benefits have the largest monetized effects, the solution would be to correctly characterize the given regulation, rather than discounting the co-benefits.

A commenter said that a shortcoming in EPA's proposed BCA rule is the failure to properly account for categories of significant benefits that can only be described in qualitative terms. The commenter said the MATS rule is a paradigmatic case for this shortcoming and asserted due to the inability of the BCA to quantitatively account for anything but a small fraction of the direct benefits that the rule would generate, the "appropriate and necessary" finding could only account for a tiny subset of the benefits that would result from reduction in mercury pollution, and it would likewise fail to account entirely for the full range of benefits that

would result from reductions in several other non-mercury hazardous air pollutants, including arsenic, lead, and cadmium. Another commenter said the MATS rule did not double-count pollution reduction benefits with regard to the NAAQS.

**Response:** We are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. Our primary reasons for codifying the BCA in regulatory decision-making are to 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. Additionally, codification of best practices for conducting BCA consistent with EPA's Guidelines and the OMB's Circular A-4 will avoid possible misestimations in developing future rules.

The EPA disagrees with the comment that the rule fails to properly account for categories of significant benefits that can only be described in qualitative terms. The final rule requires that BCAs must provide available evidence on all non-monetized and non-quantified benefits and costs, including why they are not being monetized or quantified and what the potential impact of those benefits and costs might be on the overall results of the BCA.

Finally, existing OMB and EPA guidance is clear that a BCA should endeavor to account for all benefits and costs of the regulatory action, including positive and negative welfare effects that do not stem directly from the statutory objective of the CAA provision under which a rule is promulgated. To enhance transparency about the extent to which a rule is achieving its statutory objectives, the final rule includes a requirement that BCAs will 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. Section 11.2 Benefits vs Ancillary Benefits provides additional discussion.

### *3.1.3 Guidelines More Appropriate than Regulation*

**Comment:** Several commenters supported the use of guidelines for the BCA procedures rather than using a rulemaking. Commenters argued that transparency and comprehensiveness of CAA BCAs is already ensured by several laws and policies (e.g., the Unfunded Mandates Reform Act of 1995 (UMRA), longstanding Presidential EOs (e.g., 12866), OMB's Circular A-4, EPA's current Guidelines, and EPA's Plan for Periodic Retrospective Reviews of Existing Regulations). Commenters noted that existing resources (e.g., EO 12866, OMB's Circular A-4, EPA's Guidelines) already provide guidance on conducting BCAs. A commenter pointed out that OMB's 2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act found that, when compared with other rules promulgated throughout the federal government, air quality rules advanced by the EPA boasted the "highest estimated benefits." Commenters questioned why a formal rulemaking was necessary when the EPA is currently updating its existing BCA guidelines in a parallel process (the commenter noted that EPA's National Center for Environmental Economics (NCEE) is updating the EPA's "Guidelines for Preparing Economic Analysis," and the EPA Science Advisory Board (SAB) has released a draft report offering comments and revisions). Commenters urged the EPA to withdraw the rulemaking in its entirety and said that any

improvements in BCA should be adopted in EPA's Guidelines for Preparing Economic Analysis (after public comment and review by the EPA's Economics Advisory Board) and any new procedures should not be embedded in new regulations. In particular, a commenter said that the EPA should update the guidelines to better account for distributional concerns, disproportionate cumulative burdens on historically marginalized communities, and qualitative assessments of non-market goods. A commenter noted that the proposed rule listed only the 2010 version of EPA's Guidelines for Preparing Economic Analyses, seemingly ignoring that the EPA updated various chapters in 2014, 2015, and 2016, and that EPA's Science Advisory Board is currently revising and reviewing the Guidelines. Commenters added that the concerns mentioned in the proposal were better handled through the guidelines because guidelines are better for addressing variations in BCAs, which can be very technical and complex and difficult for a rule or any current commenters to anticipate issues or concerns that could arise in the future, and that guidelines can be clarified much more easily. Commenters also noted that best practices for BCAs are continually evolving as new science and improved methodologies become available, and guidelines rather than regulations allow for approaches that can change to reflect new science and methods as warranted.

Commenters said that the proposed rule would ossify select elements of current guidance, locking the EPA into procedures that will eventually become outdated and/or inconsistent with future EOs and OMB Guidance. A commenter questioned why the EPA pursued an ANPRM where many commenters had specifically pointed to the option of pursuing improved guidance or policies, and the proposed rule remained unclear why that avenue was not acceptable or sufficient. A commenter said that the proposal is puzzling given that this Administration has generally advocated removing regulations and argued that any new regulation must have strong justification. A commenter contended that the RIAs issued by the EPA are both robust and transparent, with all assumptions broken out, total benefits and costs disaggregated, both annualized and 20-year costs and benefits presented with a range of discount rates, alternate regulatory options explored, and underlying methodologies detailed. The commenter stated that the RIAs are also subject to rigorous scrutiny, both by the economists within NCEE, as well as by OMB's Office of Information and Regulatory Analysis (OIRA), which routinely challenges and ground truths assumptions and methodologies in the RIAs and requires that any deficiencies be remedied.

**Response:** The final rule codifies best practices consistent with EPA's Guidelines and the OMB's Circular A-4, and also requires that risk assessments used to support BCAs should follow best methodological practices for risk characterization/assessment. We maintain that codifying the BCA in regulatory decision-making 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.

### *3.1.4 Miscellaneous Comments*

**Comment:** A commenter contended that under no circumstances should the EPA issue a final rule that specifies or limits how BCAs may be used in decision-making. The commenter

noted that this was a complex topic and commenters cannot foresee, much less address, all of the potential positions that the EPA might take.

**Response:** The final rule does not limit how BCA's may be used in decision-making. The final rules only codify the procedures that are already being followed in guidance documents and OMB's Circular A-4.

**Comment:** A commenter said that Congress should codify principles for a BCA. Other commenters noted that Congress prescribed different approaches for the EPA to consider benefits and costs in rulemakings under the various CAA programs (e.g., NAAQS, NESHAP, and NSPS). A commenter asserted that the proposal was based on a false premise that uniformity across the interrelated but distinct CAA programs was lawful and possible. The commenter added that, to the extent that inconsistency is a driving rationale for EPA's proposal, as the EPA asserted, treating costs and benefits differently under distinct programs is in fact appropriate because it is consistent with the variable approach to regulation of distinct CAA programs that is dictated by the statute and interpretive case law. A commenter stated that it was neither desirable nor appropriate to impose a one-size-fits-all approach to CAA provisions because of the diversity of statutory obligations within the CAA. A commenter said that the proposal did not explain why mandated uniformity in the way the EPA evaluates costs and benefits under different CAA provisions was necessary or consistent with EPA's lawful performance of its statutory duties or with the acts of health protection goals. The commenter stated that Congress laid out the factors in the CAA that it wanted the EPA to consider for each health protective program from clean air standards to emission limits for factories and power plants, to protections against health risks from toxic pollutants.

A commenter questioned the benefit of adding administrative burden and wasting taxpayer resources on a rulemaking that could not meaningfully bind the EPA in the future. The commenter added that only new legislation could durably give courts a role in examining BCA in the rulemaking process, and no rulemaking can durably create a commitment to BCA any more than an EPA rulemaking can etch in stone a substantive policy (e.g., a given stringency of emissions standards). The commenter said that a future administrator or administration could simply withdraw or revise any rule, except to the extent such a withdrawal contradicts statutory authority, which a withdrawal or revision of a BCA rule would not (i.e., a rulemaking today cannot be elevated in legal rank above a future rulemaking, at least unless existing legal precedent is changed so as to apply increased scrutiny). The commenter added that a less-formal guidance document would give agency flexibility in seeking public comment and peer review without the relatively costly APA requirements, and no new legal obligations on parties outside the government would be created.

**Response:** The codified procedures are those currently being followed for rulemakings using EPA guidance documents and OMB's Circular A-4. We maintain that codifying the BCA procedures in the regulatory process 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. We recognize that BCA procedures may change in the future, and any changes to BCA procedures codified in this regulation can be addressed in future regulations, if necessary. We also disagree that the BCA rule establishes a one-size-fits-all approach for all rulemakings. The BCA merely identifies procedures to be used when conducting

a BCA, leaves flexibility to follow distinct requirements of specific statutory provisions, and does not institute specific criteria to make decisions. Regulatory decisions will be based on the specific source being regulated, requirements in the relevant laws, and, where not prohibited, the results of the analysis. Additionally, we do not consider the requirements in the BCA to be overly burdensome as the same procedures are in guidance documents that EPA follows for rulemakings. Furthermore, we cannot speculate on the actions of future Administrations at this time.

**Comment:** A commenter said that the entire proposal describes BCAs in terms of "private markets" as factors causing a problem needing regulation, based on EPA's unspoken idea that the market will correct itself to the benefit of all. The commenter said it was concerned that this idea was not based on scientific evidence thereby undermining the credibility of the proposed regulation and describing the health benefits of regulating air pollution in a confusing way.

**Response:** We disagree with the commenters assertion. The intent of the proposal and final rulemaking is to ensure transparency and consistency in benefits-cost analyses conducted for rulemakings.

## 3.2 Guidance Documents

**Comment:** A commenter pointed out that May 13, 2019 memorandum referenced by the EPA in the proposal (85 FR 35617) indicates that the EPA will update its Guidelines for Preparing Economic Analyses, but the most recent version of the guidelines predates the May 13, 2019 memorandum. Thus, the commenter contended that the public cannot ascertain how the EPA was interpreting "stakeholder" comments and, especially, whether the EPA had conducted a critical, fair, and balanced assessment of the stakeholder comments. A commenter said that the reliance in both the proposal preamble and the proposed regulatory requirements of the EPA guidelines that are mid-revision was arbitrary and it also precluded informed comment in violation of the APA because commenters cannot know which "best practices" identified or discussed in the 2010 and 2014 Guidelines may be retained or omitted in the ongoing update.

**Response:** We do not expect the forthcoming update of EPA's Guidelines to include any changes to the elements of BCA included this rule. We are also incorporating recommendations made by the SAB during the course of their review of the update to the Guidelines. For example, we anticipate 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 the update of the Guidelines in general, see: https://yosemite.epa.gov/sab/sabproduct.nsf//LookupWebProjectsCurrentBOARD/30D5E59E8DC91C2285258403006EEE00?OpenDocument.

**Comment:** A commenter noted that OMB's Circular A-4 instructs agencies to use more than one formula for BCA and also sets out a broader objective for agencies to achieve analytical consistency in estimating benefits and costs across regulations. The commenter said that it believes that both requirements create potential points of contention with the proposal, in which the EPA puts forth formulaic criteria and imposes constraints on BCA under the CAA (85 FR 35620-35621). Another commenter stated that the ANPRM did not address how the existing

guidance would relate to the rulemaking in instances where there may be disagreement between the two. The commenter recommended that uncertainty in interpretation between the two should lead to over-consideration of benefits out of an abundance of caution.

Another commenter contended that the EPA was arbitrary and capricious in its disregard for the existing OMB framework. The commenter noted that it appeared that OMB staff made repeated efforts to orient the EPA staff to the OMB's Circular A-4 definitions and practices for delineating between direct costs and benefits and indirect costs and benefits, which were not included. The commenter added that the failure of the proposed rule to engage OMB's directions on this matter constituted a departure from established, peer-reviewed best practices in standards of analysis and the proposed rule's counterproductive disregard for the terms of OMB's Circular A-4 is not in accordance with requirements for reasoned decision-making. Likewise, another commenter questioned if the EPA had the authority to contradict OMB's Circular A-4 in the conduct of BCAs only for regulations written under the CAA and noted that the proposal did not address how this situation fits in with EPA's notion of "consistency" when, theoretically, the EPA would be conducting BCAs using different standards than every other federal agency and even within the EPA (85 FR 35615). The commenter stated that although the proposal claimed that it would "complement" OMB's Circular A-4, the commenter said that there was no discussion of how differences between the two documents might be handled, or of why OMB's Circular A-4 was not being updated.

A commenter supported advancement of provisions that require application of relevant guidance from OMB's Circular A-4, including use of domestic (vs. global) benefit accounting to avoid an apples to oranges scenario that compares domestic costs with international benefits. The commenter also recommended that the EPA require presentation of benefit estimates calculated based on both the Value of Statistical Life (VSL) and Value of Statistical Life-Years (VSLY), consistent with guidance in OMB's Circular A-4. Other commenters encouraged the EPA to maintain the states' flexibility in complying with federal air pollution control program requirements and noted that this flexibility is best served by ensuring that the EPA evaluates and reports all of the co-benefits of regulatory activities, consistent with current OMB guidance outlined in OMB's Circular A-4.

A commenter identified several other cost metrics the EPA has used in the past other than BCA, such as compliance cost as a percent of the power sector sales, annual compliance capital expenditures compared the power sectors annual expenditures. The commenter added that OMB also provides guidance on different viable tools to evaluate costs and benefits as part of rigorous regulatory analyses in OMB's Circular A-4. The commenter explained that OMB's Circular A-4 acknowledges that there are important costs and benefits that cannot be monetized. The commenter added that in this guidance, OMB recognizes cost-effectiveness as an acceptable alternative for BCA in regulatory analyses—and that it may be the only possible method under certain circumstances. The commenter noted that OMB discusses the importance of the cost-effectiveness metric for public health and safety rulemakings, and by the nature of its statutory purpose to protect the public health and welfare, many CAA rulemakings fall under this category. The commenter concluded that the OMB guidelines, and guidance more broadly, provide a much more flexible framework that can guide the EPA in conducting robust analyses through a toolbox of cost metrics that can be tailored to meet a variety of circumstances.

**Response:** The EPA disagrees with commenters that this rule is unnecessary. Commenters are referred to Chapter 3 for additional responses on the background for the rule and Chapter 4 for additional responses to legal comments. 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 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 the BCA of significant CAA regulations follow best practices. The specific requirements in this Final Rule in fact complement more detailed existing guidances the EPA relies upon, such as OMB's Circular A-4 and EPA's Guidelines as commenters referenced, and will allow EPA to develop quality regulations consistent with the CAA.

**Comment:** A commenter advised the EPA to provide the SAB with an opportunity to review the proposed action, consistent with the Environmental Research, Development, and Demonstration Act of 1976 (ERDDAA). The commenter argued that given that the EPA has peer-reviewed procedures for economic analysis, a logical improvement of the RIA process would be for the EPA to assure that BCAs receive expert peer review in which the review criteria include aspects of transparency, consistency, and best practices, and any principles or criteria related to "transparency, consistency, and best practices" should be reviewed by the Science Advisory Board (SAB). The commenter provided the following examples of the types of findings from the SAB's current posted draft report of their review of the EPA guidelines that the EPA should consider:

- "Create a new section 5.1.1 titled Comprehensiveness to clearly emphasize that the dominant guidance is to include all significant and feasible costs and benefits in an unbiased manner."
- "Clearly state the need to consider all benefits, both direct and ancillary."
- "The EPA may consider developing a declining discount rate schedule, which could help address the time horizon problem, for intergenerational policy contexts."
- "The narrative for Chapter 11 should include strong language calling for the analyst to investigate and present information on ancillary benefits (co-benefits) and ancillary costs (including countervailing risks)."

**Response:** We received comments and recommendations on the proposed rule from the 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). We also reviewed comments received from the SAB during the course of its review of the forthcoming update of EPA's Guidelines. We considered the SAB recommendations in finalizing the BCA rulemaking. The preamble to the final BCA rulemaking discusses the many areas where the SAB provide recommendations.

**Comment**: A commenter noted that 40 CFR 83.3(a)(5) of the proposal states that the EPA "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." The commenter stated that the proposed language of this provision did not provide any context or

explanation of what the terms "framework," "characteristics," "appropriate" or "approach adopted" mean or refer to what they refer. The commenter asserted that the language in 40 CFR 83.3(a)(5) did not make it clear that the EPA intended that this provision implement some or all of the discussion under the heading "Methods for Estimating Benefits and Costs" of the proposal (85 FR 35619-35620). The commenter noted that the proposal preamble (85 FR 35619-35620) did not appear to provide any more or different advice or instruction for performing BCA than the existing EPA Guidelines or OMB's Circular A-4. Accordingly, the commenter said that proposed 40 CFR 83.3(a)(5) was arbitrary and capricious and potentially unlawful, and the EPA should not adopt it.

A commenter added that that EPA's proposal left open major questions that the EPA should have concretely addressed, such as how the BCAs would be conducted, what future rulemakings would be subject to the requirements, and how, if at all, the results of the required BCAs would be used to inform regulatory decisions. The commenter stated that, because the EPA failed to provide its views on key aspects of its rulemaking in a "concrete and focused form," commenters lack the ability to present full "criticism or formulation of alternatives," which undercuts the EPA's ability to ensure that it evaluates all necessary aspects of the problem it is considering (see Home Box Office, 567 F.2d at 36).

**Response:** Rulemakings are governed by different statutes with different requirements. The intent of the BCA is to codify general procedures for conducting a BCA for all rulemakings. In order to allow sufficient flexibility for the BCA to apply to all rulemakings, the proposed and final BCA rulemaking does not specify or prescribed specific requirements for the BCA procedures referenced by the commenter.

**Comment:** A commenter contended that reiterating existing requirements in the form of a regulation seemed unlikely to effectively address the problems with the estimates of costs and benefits in previous analyses identified in the preamble. The commenter suggested that the types of problems identified by the EPA appear to require: (1) ensuring that analysts are well-trained; (2) providing adequate time and resources to support careful analysis and detailed checking of the results; and (3) investing in substantial research to provide high quality data for use in these analyses. The commenter added that the analysis should be protected from political interference to ensure its objectivity.

**Response:** We maintain that codifying the BCA in regulatory decision-making will help ensure that the EPA implements its statutory obligations under the CAA and describes in implementing those obligations in a consistent and transparent manner. The suggestions made by the commenter are ones which would need to account for changes to the statutory timeframes and requirements under which the Agency promulgates rulemakings, and not appropriate for this rulemaking.

**Comment:** A commenter suggested that if the EPA modifies the current regulatory guidance on costs and benefits, the modification should only be to increase the comprehensiveness of valuation of costs and benefits which would include emphasis on valuing the co-benefits of mitigation actions and the inclusion and continued refinement of valuation of currently non-monetized impacts, including impacts on natural and working lands, health impacts, and impacts related to active transportation and mobility.

**Response:** The requirements included in this rulemaking are consistent with OMB's Circular A-4 guidance. The intent of codifying the BCA in regulatory decision-making is to ensure consistency and transparency in the procedures that are generally followed in BCA's. The commenter is referred to Section V.A. of the preamble for further discussion on the BCA.

### 3.3 Lack of Administrative Record

**Comment:** A commenter asserted that the proposed rule did not indicate that the EPA had fairly summarized all of the public comments on the ANPRM, including diverse points of view and, more importantly, science- and evidence-based points. The commenter noted that EPA's statement (85 FR 35617) that "based on these public comments, the EPA decided to take further action to evaluate opportunities for reform" requires that the EPA should transparently disclose and provide an administrative record for public review and comment regarding the problem identification, characterization, and analysis upon which this regulatory proposal is founded. The commenter added that the EPA should characterize the record as part of the proposed rule and that the May 13, 2019 memorandum cited by the EPA (85 FR 35617) did not do this. The commenter contended that the EPA only vaguely summarizing unspecified comments, and thus failed to provide an adequate administrative record for public review regarding the underlying basis of this proposal. The commenter questioned who the commenters were, what the content, basis and rationale of the recommendations were, and why the EPA adopted a comment without any critical analysis. The commenter concluded that proposed rules usually have an administrative record that includes background documents that characterize and analyze the needs for the proposed rule and that evaluate regulatory alternatives.

**Response:** We disagree with the commenters assertion that EPA needed to summarize all the comments in the ANPRM. The ANPRM was not a rulemaking, and is therefore, we are not required to summarize and respond to comments. The intent of the ANPRM was to solicit information on some of the aspects of the BCA to further inform EPA. Further, the ANPRM was to solicit comment on a rulemaking which could apply procedures across multiple statutes which inform rulemakings at the agency and was not specific to the CAA.

### 3.4 Cost and Benefits of the Proposal

**Comment:** Commenters, argued that the EPA did not assess and consider the costs of EPA's proposed action in violation of various EOs. Other commenters opined that the proposal itself would not pass a cost-benefit test. Another commenter contended that the EPA had completely disregarded the numerous and substantial costs that the proposed rule would likely impose on the EPA and the public, and any further action on the proposal without such analysis short of withdrawal would be arbitrary and unlawful (see *State Farm*, 463 U.S. at 43). The commenter argued that the EPA cannot finalize the proposal unless it examines the costs to the EPA and the public of conducting superfluous analysis, or selecting less stringent regulatory options. Another commenter contended that the costs of complying with the proposed rule's procedures, including the harms imposed on society by delay of beneficial regulations would far exceed any benefits of the proposed rule.

A commenter stated that EPA's failure to estimate or consider the EPA's costs of implementing the proposal violated EO 12866 and precluded fully-informed public comment, and rendered the proposed rule arbitrary and capricious. The commenter noted that the proposed

rule would apply significant new burdens to the EPA that it has failed to estimate or consider. The commenter cited that 40 CFR 83.3(a)(9)(vii) of the proposal would mandate that each BCA (or related document) characterize: (A) The variability in the concentration-response functions across studies and models, including plausible alternatives; (B) The assumptions, defaults, and uncertainties, their rationale, and their influence on the resulting estimates; (C) The extent to which scientific literature suggests that the nature of the effect may vary across demographic or health characteristics; (D) The potential variability of the concentration-response function over the range in concentrations of interest for the given policy; (E) The influence of potential confounders on the reported risk coefficient; (F) The likelihood that the parameters of the concentration-response differ based on geographic location; and (G) Attributes that affect the suitability of the study or model for informing a risk assessment, including the age of the air quality data, and the generalizability of the study population.

A commenter asserted that the proposal failed to comply with EO 13771 which requires agencies to assess and consider the costs of regulatory actions when making regulatory decisions (82 FR 9339). The commenter noted that the EPA incorrectly claimed that the proposed rule was exempt from EO 13771 because the rule concerned "agency organization, management or personnel." The commenter argued that the proposed rule would require the EPA to spend dollars and staff time on activities such as requesting and getting data from study authors; creating information technology infrastructure and a data management system to manage, store, and archive large volumes of data; making the data available in a format that is useful and accessible to the public; combing through these extensive datasets to identify and redact Personally Identifiable Information and Confidential Business Information. The commenter referred to the estimates prepared by the Congressional Budget Office (CBO) and the EPA to evaluate the potential cost of implementing requirements similar to those in the proposed rule under the Secret Science Reform Act of 2015 and the Honest and Open New EPA Science Treatment (HONEST) Act of 2017. For these regulations, the commenter said that the EPA staff estimated that making underlying data publicly available would cost $10,000 to $30,000 for most studies, but could range up to $1 million for some studies, and the CBO estimated the total cost across the EPA at more than $250 million per year with a significant (if not majority) portion of this cost likely stemming from CAA rulemakings. The commenter acknowledged that, although the number of studies may be smaller than estimated for the 2015 and 2017 bills, the cost and burden of the proposed rule would still be immense.

Aside from additional requirements in conducting BCAs, a commenter stated that the proposal would also entail costs associated with EPA's compliance activities, rulemaking decisions, and defense of its rules from attacks stemming from the proposal and that the EPA must carefully consider the full range of these likely costs before it can finalize any rule along these lines. The commenter contended that the EPA must delineate the effects of its proposal on the established rulemaking process, noting which efforts would be additional and in what types of rulemakings those additional requirements would apply, and assess the costs to the EPA of carrying out the extra steps. Commenters cited as an example EPA's proposed (85 FR 35626) requirement that every rulemaking in which there is a "continuum of options" assess the benefits and costs of at least three regulatory options, with one more stringent and one less stringent than the proposed or finalized option, or alternatively, the EPA may "explain why it is not appropriate to analyze more options"(85 FR 35626, 40 CFR 83.3(a)(3)). The commenters contended that the requirement could impose costs on the EPA of carrying out an unnecessary analysis of a weaker

option, even where the EPA has determined that any lesser level of protection is unlawful or otherwise unacceptable.

A commenter said that the proposed requirements for selecting benefit endpoints and quantifying health benefits are arbitrary and would impose significant unanalyzed costs. The commenter stated that the proposed requirement in 40 CFR 83.3(a)(7) could entail significant costs and needed to be clarified, with key terms (e.g., "robust enough to support . . . quantification") undefined. The commenter asserted that the EPA must assess the costs to the EPA and the public under this provision of failing to regulate pollution that it is statutorily charged with addressing, or conducting superfluous analysis.

The commenter added that the proposed requirement in 40 CFR 83.3(a)(12) for the EPA to disclose all data and models used in the analysis of benefits and costs and to provide "appropriate protection" for proprietary or personal information would result in excessive costs. The commenter stated that the EPA must examine the enormous costs of this requirement to the EPA, as well as its implications for public health and environmental protections.

A commenter stated that the EPA asked in the proposal whether certain, unspecified elements of this proposed rulemaking should consider resource constraints, inquiring whether the decision to undertake BCA for a particular action should depend on EPA resources. The commenter stated that the EPA should not incorporate any such provision in its regulations and the EPA should evaluate the costs of the proposed rulemaking before proceeding further to inform the public of the costs of a rulemaking. The commenter contended that EPA, not commenters, is best situated to explain the potential resource constraints and associated consequences of the proposal. The commenter added that making case-by-case decisions as to whether resources are sufficient to perform BCA for particular projects would likely to lead to inconsistent, arbitrary decision-making.

**Response:** We disagree with the commenters. The BCA rulemaking is intended to codify procedures to conduct BCAs in future significant CAA rulemakings. The procedures are consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines), which are the existing peer reviewed guidance documents implementing EO 12866. This rulemaking does not prescribe compliance requirements, but only procedures on how to conduct an analysis, and therefore, it is not necessary to conduct a BCA for this rulemaking. In addition, since the rule declines to formulate a specific test or mandate of how to consider the BCA or what weight the BCA should be given in such a future rulemaking, it is impossible to predict precisely how decision makers will use this information in the future. However, in theory, BCA provides more information to decision makers which can lead to better decisions that will enhance social welfare.

# 4.0 Legal

## 4.1 Procedural Exception

**Comment:** Several commenters maintained that the proposal is a substantive rule that is subject to notice-and-comment rulemaking requirements and cannot be authorized by the law governing procedural rules. The commenters disagreed with EPA's position that the rule is merely an internal procedural rule that would not regulate any person or entity outside of EPA and, therefore, is exempt from the notice and comment provisions of the Administrative Procedures Act (APA). Commenters stated that the proposed rule is far more than an internal housekeeping action that can be justified under the authority of either CAA section 301 or the Federal Housekeeping Act. To the contrary, commenters argued that an agency action that affects private rights and interests cannot qualify as an agency procedural rule that is exempt from the APA, nor can rules that constrict EPA's discretion in the conduct of rulemaking. *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980). A commenter noted that EPA has stated that this rule would have substantial impact on government and industry's investments, contradicting the claim in the proposal that it would have little impact on any person or entity outside EPA. Another commenter added that the rule is a substantive rulemaking because it would have a binding effect on EPA that would jeopardize the rights and interests of the public by affecting the stringency of clean air and public health protections under the CAA. A commenter added that the proposed rule constitutes a statement of particular applicability, purporting to implement and prescribe law, which is squarely in the compass of the APA definition of a "rule" (5 U.S.C. section 551(4)) that must abide by notice and comment requirements. Commenters stated that the rule does not qualify for the procedural exemption because it would bind EPA legally to conducting BCA even for rules where consideration of cost is not required or even allowed. By specifying or restricting the processes and science that EPA must follow in determining costs and benefits, commenters stated that the rule would limit the types of scientific studies that the public could submit to EPA to demonstrate the benefits of a particular action and, therefore, would directly limit the rights of the public to provide effective comment on future EPA regulatory proposals. A commenter contended that in excluding relevant science from expert consideration, based on factors that Congress did not intend for the EPA to prioritize, the EPA would fail to consider important aspects of the problems under consideration, issue decisions counter to the evidence before the EPA, and commit APA violations with every affected action. The commenter added that in addition to its substantive prohibition on arbitrary and capricious actions, the APA establishes general procedural requirements for agency rulemakings, including a requirement for agencies to consider the relevant information presented via public comment on proposed rulemakings. The commenter stated that by precluding agency economists from incorporating relevant studies raised in public comments on proposed CAA regulations, the proposal would cause future EPA actions to violate the APA's procedural requirements as well.

Commenters provided other examples of case law to demonstrate how the proposed BCA rule qualifies as a substantive action that is subject to notice-and-comment rulemaking. A commenter indicated that in *CropLife America v. EPA*, the D.C. Circuit ruled that an action is a "substantive rule" if it would prescribe practices for weighing data and limiting agency consideration of data that the public might otherwise submit. The commenter cited other court

rulings to support the commenters' contention that the proposed rule is a substantive rule subject to notice and comment rulemaking, and that EPA cannot avoid notice-and-comment rulemaking under the authority of the Federal Housekeeping Act. Another commenter argued that a rule that has a significant impact on substantive public rights and interests falls outside the narrow scope of the APA procedure exception. *See, e.g., U.S. Dep't of Labor v. Kast Metals Corp.*, 744 F.2d 1145, 1153 (5th Cir. 1984); *Pickus v. U.S. Bd. of Parole*, 507 F.2d 1107, 1114 (D.C. Cir. 1974). The commenter stated that courts have repeatedly emphasized that a rule's "effect on those within its regulatory scope" is the critical factor, not an agency's own categorization of a rule as either procedural or substantive. See *Kast Metals*, 744 F.2d at 1153.

Another commenter noted that EPA itself stated in response to a request for comment on identifying regulations that impose costs that exceed benefits, that per Executive Order 13777 and based on these public comments, EPA decided to take further action to evaluate opportunities for reform. The commenter concluded that such decisions and statements undermine EPA's assertion that this a rule of process or procedure that does not require notice and comment under the APA.

**Response:** EPA disagrees with the commenters' assertions that the rule is substantive and cannot be authorized by laws governing procedural rules. EPA notes that it voluntarily took notice and comment on this rule and is providing responses to the comments it received. Thus, EPA did not "set itself up to not have to respond to substantive comments it receives." EPA further notes that the rule was not proposed or finalized pursuant to the Federal Housekeeping Act; thus, any comments regarding such authority are not germane to this final rule. EPA's authority to promulgate this final rule pursuant to section 301 of the Clean Air Act (CAA) is discussed at Section V.B of the preamble to the final rule. Commenters suggested that an agency action that affects private rights and interests cannot qualify as an agency procedural rule that is exempt from the APA and that rules that constrict EPA's discretion in the conduct of rulemaking likewise cannot be procedural. However, even were EPA to accept the premises of this argument, commenters do not identify any impact of the rule on private individuals or their rights or any portion of the rule that constricts EPA's discretion. Commenters assert that the intended effect of "transparency" is upon outside parties and that EPA conceded that outside parties may be interested in the rule to claim it therefore is substantive. The rule addresses transparency achieved via the application of procedure. For example, an internal rule regarding the steps taken to post something to an agency website could achieve transparency. The public's interest in procedure does not render a procedural rule substantive.

Commenters cite statements that are not part of the administrative record in support of the notion that the rule has substantive impact, but they identify no portion of the rule that would affect the stringency of clean air and public health protections under the CAA, would limit agency consideration of data that the public might otherwise submit, or would cause EPA to fail to consider important aspects of the problems under consideration. Nothing in the final rule dictates any given outcome of future rulemakings to which this final rule is applicable, and nothing in the final rule prohibits the public from submitting data and scientific studies to the records of such future proceedings or prohibits the Agency from considering such data and studies. In regard to commenters' claim that the rule is not procedural because it would bind EPA legally to conducting BCA even for rules where consideration of cost is not required or even allowed, EPA notes that the final rule specifically states that the Agency must consider the

BCA in promulgating the regulation except where the provision or provisions under which a significant regulation is promulgated prohibit the consideration of the BCA. In such circumstances, the BCA is provided to the public for the purpose of transparency, as discussed in the preamble at Section V.A. This is consistent with prior agency practice. For example, RIAs are currently produced for CAA rules where the Agency is barred from considering cost in decision making, as discussed in the context of National Ambient Air Quality Standards in the preamble at Section III.A.

Commenters cite *CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003), stating that the D.C. Circuit ruled that an action is a "substantive rule" if it would prescribe practices for weighing data and limiting agency consideration of data that the public might otherwise submit. However, as commenters note, the D.C. Circuit in *CropLife* considered whether an EPA statement that the agency would not consider third-party-controlled human exposure studies was a substantive rule, and the court's holding in that case was based on the determination that the rule barred reliance on third-party human studies. No such restrictions are present in the final rule. EPA again notes that commenters have not identified provisions in the rule that either prescribe practices for weighing data or limit agency consideration of data that the public may submit. Commenters note that under CAA Section 307(d)(4)(B)(i), as well as general principles of administrative law, submitted comments and data are required to become part of the record that must be considered as part of the rulemaking process, but commenters do not identify anything in the rule that changes this aspect of rulemaking. Nothing in the final rule prohibits EPA consideration of studies and data submitted by the public to the agency as part of an administrative record for an agency action, and nothing states that such data and studies must be compliant with any provisions of the rule. The final rule applies solely to the preparation of a BCA by the Agency, which is to be made available to the public.

Commenters also noted that courts have emphasized that a rule's "effect on those within its regulatory scope" is the critical factor to determining if a rule is procedural or substantive. EPA notes that the final rule has no substantive effects on regulated entities or members of the public as it governs internal procedure. Finally, EPA statements that the Agency decided to take further action to evaluate opportunities for reform pursuant to Executive Order 13777 have no bearing on what is contained in this final rule and whether its contents are substantive or procedural, and commenters have not identified any specific portion of the rule they assert is substantive.

**Comment:** A commenter stated that if EPA finalizes action under the proposal, it must add regulatory text to expressly disclaim that the regulation creates any rights that can be enforced at law or in equity against EPA in order to validate the proposals representation that it will not affect the rights or obligations of outside parties. The commenter added that the disclaimer is standard for many actions that purport to be non-substantive, such as Executive Order 12866. The commenter also stated that EPA did not discuss the concept of judicially-enforced consistency, indicating EPA did not mean to advance such a position.

**Response:** As discussed in the preamble in section V.B, EPA disagrees with the commenter's belief that the final rule is not enforceable against the Agency, and, thus, declines to include any such disclaimer.

**Comment:** Commenters requested EPA clarify that it intends to be bound by notice and comment requirements on judicial review. The commenters cited *Morton v. Ruiz*, where the Supreme Court noted "[w]here the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. This is so even where the internal procedures are possibly more rigorous than otherwise would be required." 415 U.S. 199, 235 (1974).

**Response:** EPA disagrees with commenters' suggestion that the final rule alters the rights of individuals outside of the Agency, as discussed in the preamble at V.B and in this RTC. Regardless, EPA has voluntarily followed notice and comment procedures, including conducting a public hearing and responding to relevant comments submitted by the public during the comment period.

## 4.2 Additional Legal Authority

**Comment:** Several commenters stated that EPA cannot base a final action on whatever alternative authorities are identified based on comments received on an open-ended request for alternative authorities without first giving stakeholders the opportunity for comment on a revised proposal. The commenters concluded that this inappropriate solicitation evinces that EPA has a weak and deficient claim to authority under CAA section 301.

A commenter supported the proposed rule but cautioned against adopting the rule under the sole authority of CAA section 301 as a procedural practice. The commenter stated that because EPA stated that a rule adopted under section 301 "would not affect the rights or obligations of outside parties," then the use of BCA in all future significant rulemakings would be at the discretion of EPA and not enforceable by third parties. The commenter stated that in addition to CAA section 301, a second and independent legal basis for establishing an enforceable BCA mandate is EPA's programmatic substantive rulemaking authority. The commenter stated that there is strong precedent under the CAA for EPA to use this approach. For example, EPA has set General Provisions under 40 C.F.R. Parts 60 (New Source Performance Standards), 61 (National Emissions Standards for Hazardous Air Pollutants), and 63 ("MACT" standards) that effectively governed subsequent source-category-specific regulations issued under these programs. The commenter stated that each of these General Provisions includes detailed and prescriptive requirements that apply to subsequent categorical rules unless EPA makes category-specific changes through rulemaking and that these General Provisions were adopted under the CAA provisions that authorize or require EPA to establish emissions limitations and standards under these various programs.

Several commenters stated that the Housekeeping Statute does not provide a legal basis for the proposed rule. The commenters stated that courts have consistently ruled that the Housekeeping Statute was never intended to be used as an authority to justify substantive rules with legal consequences. The commenters explained that a substantive rule has been established to be a rule that has the force of law and affects "individual rights and obligations." The commenters maintain that the proposed rule is substantive because it affects how EPA will implement a Federal law and changes the basis on which regulatory decisions are made. The commenters added that the rule affects individual rights because (1) it would affect the ability of the public to comment effectively on future proposed CAA regulations because EPA could reject comments based on science that does not meet the criteria of the rule and (2) prevents the public

from receiving the benefits of air pollution control because it erodes the value judgments on which regulatory decisions are made (e.g., by devaluing co-benefits of regulations). A commenter cited *Merck vs. HHS*, 962 F.3d 531 (D.C. Cir. June 16, 2020), and *New York Stock Exchange v. SEC*, 962 F.3d 541 (D.C. Cir. June 16, 2020), to illustrate that housekeeping provisions would not apply.

Another commenter cited the series of Supreme Court decisions for the proposition that the "cost-consideration canon" holds that unless Congress explicitly says otherwise, EPA must consider costs in deciding whether and how to proceed. The commenter added that the canon instructs courts to read statutes to require agencies to balance benefits and costs, absent a clear statement in the statute to the contrary.

**Response:** EPA is promulgating the final rule pursuant to authority in Section 301 of the CAA as proposed. EPA solicited comments regarding alternative bases of authority but has not made any changes to the final rule based on the comments it received. Therefore, comments regarding the appropriateness of such a solicitation need not be addressed as the solicitation did not materially affect the final rule. As discussed in the preamble at Section V.B, because this rule covers requirements that apply to EPA's rulemaking procedure and does not impose any obligations or grant any rights to third parties, it is procedural. In this final rule, EPA does not interpret or apply other provisions of the CAA as a source of authority. EPA determined that, given the complexities and established case law regarding cost consideration concerning specific CAA provisions, it was appropriate to establish this procedural rule pursuant to EPA's CAA Section 301 authority. EPA will determine how it considers the resultant BCA in the subsequent rulemakings pursuant to the specifics of the CAA provision under which such a rule is promulgated. In this action, 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.

EPA further notes that the rule was not proposed or finalized pursuant to the Federal Housekeeping Act, thus, any comments regarding such authority are not germane to this final rule. EPA's authority to promulgate this final rule pursuant to section 301 of the Clean Air Act (CAA) is discussed in the preamble in section V.B. Further, EPA discusses in the same section of the preamble its determination that the final rule is enforceable against the Agency. This discussion notes that the enforceability of a procedural rule does not in and of itself render a rule non-procedural. In regard to the "cost-consideration canon" noted by commenters, EPA notes, as discussed in the preamble at Sections III.A and V.D, that the Supreme Court has stated 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).

Finally, EPA does not find the holdings in *Merck vs. HHS*, 962 F.3d 531 (D.C. Cir. June 16, 2020) and *New York Stock Exchange v. SEC*, 962 F.3d 541 (D.C. Cir. June 16, 2020) to be inconsistent with the use of CAA section 301 authority for this procedural rule. In *New York Stock Exchange*, the D.C. Circuit determined that "merely because an agency has rulemaking power does not mean that it has delegated authority to adopt a particular regulation." *New York Stock Exchange,* 962 F.3d at 554. In *Merck*, the D.C. Circuit determined that "for a regulation to be 'necessary'" there must be "an actual and discernible nexus between the rule and the conduct

or management [the program]" and "the rule's effect must be more than tangential." *Merck,* 962 F.3d 537-38. As discussed in the preamble at Section V.B, EPA determined 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 and is clearly more than tangential to the implementation of the CAA.

## 4.3 Background

**Comment:** Many commenters argued that EPA has adequate legal authority for conducting BCA under CAA section 301. The commenters cited numerous court cases defending the ability to conduct BCA even if the statute does not explicitly require one and ruling that silence in a statute does not prohibit the use of BCA. A commenter stated that the Supreme Court in *Whitman* held that although EPA cannot consider cost in setting an NAAQS, EPA can develop and transmit cost information to states to use in developing attainment plans to implement the standards. A commenter added that for NAAQS, the CAA requires the Clean Air Science Advisory Committee to provide the Administrator advice on the economics effects of the standard. The commenters collectively cited a number of court rulings, including the following, that an agency may use BCA whenever the statute is silent on cost or requires a regulatory decision a finding of "reasonable" or "appropriate:"

- *Entergy Corp. v. Riverkeeper, Inc.,* 556 U.S. 208, 222-224 (2009)
- *American Textile Mfrs. Inst. V. Donovan*, 452 U.S. 490 (1981)
- *Whitman v. Am. Trucking Assn's,* 531 U.S. 457 (2001)
- *Sierra Club v. Costle*, 657 F.2d 298, 345 (D.C. Cir. 1981)
- *Michigan v. EPA*, 135 S. Ct. 2699, 2706 (2015)
- *Lignite Energy Council v. EPA*, 198 F.3d 930, 933 (D.C. Cir. 1999)
- *Advocates for Highway and Auto Safety v. FMCSA*, 429 F.3d. 1136 (D.C. Cir. 2005)
- *Public Citizen, Inc. v. Mineta*, 340 F.3d 39 (2nd Cir. 2003)
- *NRDC v. EPA*, 824 F.2d 1258 (1st Cir. 1987)

- *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 222 (2009)

Several commenters stated that even where Congress has granted an agency broad discretion, EPA can place limits on that discretion through rulemaking, citing the following cases:

- *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979)
- *Batterton v. Francis*, 432 U.S. 416, 425 n.9 (1977)
- *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002)
- *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000)
- *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 96 (D.C. Cir. 1997)

Several commenters also explained how the existing CAA provisions allow for consideration of BCA for NAAQS, NSPS, section 111(d), consumer product VOC rules, NESHAP, PSD, Regional Haze, RACM and RACT, and mobile source rules. Other commenters noted that other parts of the CAA require EPA to consider costs and benefits of its actions including CAA sections 302(h), 312, 317, and 321. Another commenter cited CAA sections 101 and 301 justifying a consistent procedure for considering the benefits and costs of future regulations and making the information public.

A commenter contended that even for regulatory programs like the National Ambient Air Quality Standards (NAAQS), for which cost and implementation considerations are prohibited in the standard-setting process, there is Congressional direction to EPA, its science advisors, and state environmental agencies that they heed "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of these standards. (42 U.S. Code § 7409(d)(2)(C)).

Many commenters stated that CAA section 301 does not grant EPA the authority for the proposed BCA rule. The commenters stated that the D.C. Circuit Court has emphasized that section 301 does not provide open-ended authority to develop any rules it chooses on any matter pertaining to the CAA. The commenters maintain that the proposed rule is unnecessary because the CAA provides statutory guidance on cost considerations in each rulemaking section and EPA has 50 years of past legal and policy precedent for CAA implementation. In this circumstance, the commenters stated that the proposed regulation does not meet the statutory requirement as being "…necessary to carry out his [the] functions" of implementing the CAA. Rather, several commenters expressed that the purpose of the proposed regulation appears to be an effort to tie EPA's hands in implementing the goals of the CAA by forcing BCA analysis for all rules that EPA deems to be "significant," even in programs where the consideration of cost is prohibited. A commenter contended that air pollution rules under future administrations could be delayed and blocked by industries that sue EPA – not for violating CAA requirements – but for not producing BCAs that have nothing whatsoever to do with that law.

A commenter opposed only approving a rule if its monetized benefits exceed its costs and noted that Congress did not mandate such a test. The commenter added that the rule is a recipe for biased decision-making because BCA cannot account for benefits that cannot be monetized.

The commenter also pointed out that the rule would allow EPA to inappropriately exclude monetized benefits because the rule uses terms like the use of "robust" science, "degree of compliance by regulated entities with other regulations", and "best available science," which are undefined terms that would allow EPA to exclude certain valid scientific studies in evaluating benefits.

A commenter challenged EPA's claim of authority to issue a rule binding EPA to conduct BCA across all CAA rulemakings, because section 317 evinces Congress' intent that only select, enumerated types of CAA rulemakings (e.g., regulations under section 111) are mandated to have specialized regulatory attention to problems of costs. The commenter also pointed out that in CAA section 317, Congress directed that nothing in section 317 shall be construed to provide that the analysis of the factors (i.e., economic analysis) specified in this subsection affects or alters the factors that the Administrator is required to consider in taking any action under NSPS, ozone and stratospheric protection, PSD, and certain mobile source provisions of Title II. The commenter noted several additional areas where the proposed rule conflicts with section 317 including terminology, and section 317(c)-(g).

Several commenters charged that section 301 provides no basis for the proposed rule because the proposal is not a procedural rule but instead a substantive rule to impose a uniform BCA analysis on CAA rulemaking actions in contradiction to the statutory parameters specified by Congress for implementing the CAA. A commenter stated that the proposed rule violated the CAA because BCA places a heavier reliance on cost than is called for even in sections of the CA where costs can be considered, e.g., NSPS.

A commenter contended that CAA section 307(d) must apply to the proposal but the proposal does not discuss section 307. The commenter added that EPA can either retract the proposal and make a new proposal that identifies it as subject to section 307 or finalize the proposed rule by adding language that expressly excludes all rulemakings under section 307(d) in section 83.2 of the BCA rule.

A commenter stated that it is not always appropriate to base a standard on BCA for three reasons. First, the commenter pointed out that NAAQS are intended to protect the public with an ample margin of safety and that costs are not considered in setting the rule, but are considered only in implementing the rule. Second, the commenter stated that basing a standard on net benefits is not equitable because not all communities are equally affected by air pollution, and the standards are intended to protect the most vulnerable. Third, the commenter pointed out that because not all benefits can be monetized, BCA will not always maximize social benefits.

A commenter charged that the proposed rule is arbitrary and capricious because it is unnecessary and would subvert the purposes of the CAA. The commenter stated that the added BCA requirements would create new and unnecessary burdens on EPA's rulemaking capacity by requiring consideration of at least 3 regulatory options (even when some of the options are not actually under consideration); by requiring BCA in rulemaking where cost is not a consideration; by requiring EPA to publish all underlying data; and requiring analysis of a large number of assumptions, uncertainties, variabilities, influences, and alternatives. Several commenters claimed that the additional burdens on EPA would strain agency resources and undermine the ability to meet statutory deadlines, such as review and revision of NAAQS on a 5-year schedule,

and to respond to new threats to public health. The commenters charged that BCA will result in arbitrary decisions because the proposed BCA requirements will overvalue cost and undervalue benefits by the overemphasis on the uncertainty of regulatory benefits, leading to omission of some benefits. The commenters also pointed out that the rule violates the Administrative Procedures Act because EPA has provided no reasoned basis for the rule other than reliance on concerns raised by an unspecified number of unidentified commenters on an earlier published ANPR.

A commenter cited *Bowen v. Georgetown Univ. Hospital*, 488 U.S. 204, 208 (1988), to inform EPA's power to promulgate legislative regulations is limited to the authority delegated by Congress. The commenter added that EPA must have a defensible basis in law for its regulatory actions, and it is obliged to minimally explain its basis of authority, particularly when, as here, it makes a proposal that is characteristically novel and unprecedented. The commenter concluded that the proposal fails to do this in any way that can survive judicial review. The commenter also contended that the proposal is deficient because it does not consider CAA section 317 requirements. Another commenter noted that Congress deliberately chose to direct EPA to use feasibility studies instead of BCAs to guide regulatory decision-making. A commenter stated that where Congress has not required a formal BCA, EPA is not required to undertake one. *Michigan v. EPA*, 135 S. Ct. 2699, 2711 (2015). Another commenter added that except with respect to power plants, EPA is barred from considering costs when determining which source categories require regulation under Section 112. The commenter cited other examples of the CAA provisions that bars consideration of costs and specifically noted Section 165(e)'s requirement for at least one year of ambient air-quality monitoring prior to an application for a PSD permit and the D.C. circuit has ruled that this mandate cannot be relaxed or modified based on cost-benefit considerations as the proposal attempts to do. The commenter added that EPA has failed to provide section-specific evaluations of whether and how each affected provision and its context allows for consideration of costs and, where cost consideration is permitted, and whether imposing a cost-benefit requirement is consistent that section's language and purpose. The commenter stated that instead, EPA proposes to force a cost-benefit mandate on every provision of the CAA that could be used to authorize a significant rule without having first conducted the section-specific analyses and demonstration that Supreme Court and D.C. Circuit precedent require. The commenter contended that such an approach is unlawful and arbitrary.

A commenter stated that the rule is prescriptive on many of the best practices, which conflicts with provisions of the CAA, such as section 112(d)(2) which requires EPA to consider any non-air quality health and environmental impacts, and is therefore in conflict with the proposed rule practices to not consider them. Another commenter added that the proposals extensive restrictions and limitations to uncertainty, concentration-response relationships, and co-benefits conflict with the requirements in EOs and provisions of the CAA to use the best available science to conduct analyses.

A commenter pointed out that the courts have repealed such open-ended use of this provision repeatedly and that legal justification and authority should be determined prior to rule making and public comment. A commenter noted that Section 301(a)(1) of the CAA only grants EPA the authority "to prescribe such regulations as are necessary to carry out [its] functions." and that this general rulemaking authority is not boundless since it does not enable EPA to undertake any expedient or useful regulatory actions in the name of administration of the CAA

(see *Citizens to Save Spencer Cnty. v. U.S. Envtl. Prot. Agency*, 600 F.2d 844, 873 (D.C. Cir. 1979). A commenter added that, by the terms of the provision itself, rules promulgated under this authority must be "necessary" to EPA's effective administration of the CAA. See *Merck & Co. v. U.S. Dep't of Health & Human Servs*., 962 F.3d 531, 537–38 (D.C. Cir. 2020) (noting the limiting role of key phrases in general rulemaking provisions). The commenter added that, in this instance, as opposed to filling a gap, the proposed regulation replicated EPA's existing Guidelines for Preparing Economic Analyses which EPA periodically updates and, according to the Administrator, the current iteration of revisions "will help clarify best practices for how to conduct benefit-cost analysis, including guidance on key methodological and modeling choices, assumptions, uncertainties and context around benefits and costs." The commenter stated that such duplicative efforts cannot be "necessary," and that EPA did not demonstrate that they are "useful."

**Response:** EPA agrees with commenters asserting that section 301 of the CAA contains adequate authority for this final rule and disagrees with other commenters' assertions that CAA section 301 does not grant EPA the authority for the rule. EPA's authority to promulgate this final rule pursuant to section 301 of the CAA is discussed at Section V.B of the preamble to the final rule. EPA notes the discussion in section III.A of the preamble of the case law history regarding BCA. In regard to comments received in opposition to a mandate that to approve a rule its monetized benefits must exceed its costs, EPA notes it has not adopted such a requirement in the final rule. Regarding comments that terminology such as "robust science" and "degree of compliance by regulated entities with other regulations" would allow EPA to exclude certain valid scientific studies in evaluating benefits, EPA notes that these terms are used in EPA's Guidelines (EPA, 2010).

Regarding comments that Section 317 of the CAA evinces Congress' intent that only select, enumerated types of CAA rulemakings are mandated to have specialized regulatory attention to problems of costs, EPA notes that Section 317 is an independent and distinct requirement from this final rule. While Section 317 requirements and the requirements of this final rule may both include forms of cost analysis, the economic impact analysis conducted pursuant to section 317 of the CAA focuses on cost. It is not a BCA, as required by this final rule, that accounts for both costs and benefits. Furthermore, nothing in Section 317 precludes any additional analysis. Were Section 317 to evince Congress' intent that only select enumerated types of CAA rulemakings are mandated to have specialized regulatory attention to problems of costs, the specific CAA provisions that call for the consideration of cost discussed at Section III.A of the preamble would be superfluous. The need for this final rule is discussed in Section V.A of the preamble. Additionally, as discussed in the preamble at Sections III.A and V.D, the Supreme Court has stated 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) (emphasis added).

As discussed in Section V.B of the preamble and in this RTC at 4.1, EPA disagrees with commenters' assertions that this rule is not a procedural rule. Thus, section 307(d) of the CAA is not applicable and, as noted above, EPA has voluntarily taken comment on the rule. Furthermore, the final rule does not dictate how EPA will consider the BCA in future rulemakings nor does it require that EPA base any regulation on the BCA  Thus, commenters'

assertions that the rule places heavier reliance on cost than is called for even in sections of the CAA where costs can be considered are unfounded.

EPA disagrees that the rule is arbitrary and capricious, unnecessary, violates the Administrative Procedure Act, or lacks a reasoned basis. EPA disagrees with commenters' assertions that EPA has failed to explain its basis of authority per *Bowen v. Georgetown Univ. Hospital*, 488 U.S. 204, 208 (1988). EPA's determination regarding its authority to promulgate the rule is contained in the preamble at Section V.B. EPA's determination in regard to why the rule is necessary is contained in the preamble at Section V.A and in Section 3 of this RTC. EPA has determined that it has sufficient resources to conduct the requirements of the final rule. In regard to commenters' concerns with section 112 and 165(e) of the CAA, EPA notes that the final rule specifically states that the Agency must consider the BCA in promulgating the regulation except where the provision or provisions under which a significant regulation is promulgated prohibit the consideration of the BCA. In such circumstances it is provided to the public for transparency, as discussed in the preamble at Section V.A. Further, in regard to commenters' concerns that EPA is mandating the most cost-effective option on every provision of the CAA, EPA notes that the final rule contains no such mandate, only that when permissible in the context of a significant CAA regulation, the BCA be considered.

Regarding comments that the rule conflicts with provisions of the CAA, such as section 112(d)(2) which requires EPA to consider any non-air quality health and environmental impacts, EPA again notes that the requirements of this final rule do not replace or supplant any analysis required by a specific CAA provision and are additional to such requirements. EPA notes that the final rule specifically states that the Agency must consider the BCA in promulgating the regulation except where the provision or provisions under which a significant regulation is promulgated prohibit the consideration of the BCA. In such circumstances it is provided to the public for the purpose of transparency, as discussed in the preamble at Section V.A. Regarding commenters' assertions that the rule's extensive restrictions and limitations to uncertainty, concentration-response relationships, and co-benefits conflict with the requirements in Executive Orders and provisions of the CAA to use the best available science to conduct analyses EPA notes that the provisions in the rule are based on existing guidance and are not in conflict with that guidance. In regard to the treatment of "co-benefits", the final rule does not preclude the inclusion of this category of benefits in a BCA. Rather, for transparency the rule has a presentational requirement that EPA 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 If these benefit categories cannot be monetized, EPA must present quantified estimates to the extent possible and provide a qualitative characterization if they cannot be quantified.

Finally, as previously discussed, EPA does not find the holding in *Merck vs. HHS*, 962 F.3d 531 (D.C. Cir. June 16, 2020), to be inconsistent with the use of CAA section 301 authority for this procedural rule. In *Merck* the D.C. Circuit determined that "for a regulation to be 'necessary'" there must be "an actual and discernible nexus between the rule and the conduct or management [the program]" and "the rule's effect must be more than tangential." *Merck,* 962 F.3d 537-38. As discussed in the preamble at Section V.B, EPA determined 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 and is clearly more than tangential to the implementation of the CAA.

## 4.4 Other Legal

**Comment:** A commenter stated that the Environmental Research, Development and Demonstration Authorization Act of 1978 requires that any regulation that is provided to another Federal agency for review and comment must be provided to the Science Advisory Board (SAB) for review, but the record does not show that an SAB review was conducted.

Another commenter stated that the proposed rule is inconsistent with the CAA because proposed 40 CFR 83.3(a)(9) constrains the type of scientific materials that EPA can consider in a rulemaking.

A commenter stated that the proposed rule would create an unnecessary risk of increased litigation and as a result diminish the effectiveness of ongoing CAA programs. The commenter pointed out that although EPA claims the rule to be procedural, the BCA analyses for future rules would be subject to court review during litigation and could lead to outcomes contrary to the requirements of the CAA. The commenter stated that the rule would impose burdensome and unnecessary tasks on a rulemaking and protracted interagency review. The commenter claimed that the convoluted requirements of the rule create ample opportunity for excessive litigation and reversible error. The commenter stated that EPA has not provided a reasonable rationale for why this additional cost and litigation risk is necessary and speculated that the purpose was to invite litigation to impede or deter future regulation.

A commenter claimed that the rule is unlawful because EPA has failed to conduct a section by section analysis of the CAA to determine where and how BCA can be mandated. The commenter explained that in *Whitman,* the Supreme Court has made clear that a determination of whether EPA can consider costs—and if so, how—requires an analysis of the statutory language of each section to determine context. According to the commenter, the Court has explained, if Congress directs EPA to "regulate on the basis of a factor that on its face does not include cost, the Act normally should not be read as implicitly allowing EPA to consider cost anyway" (Michigan, 135 S. Ct at 2709). The commenter claimed that nor is it the case, as EPA wrongly seems to assume, that the CAA's use of terms such as "appropriate," "necessary," "reasonable," "requisite," or "adequate" automatically authorizes the consideration of costs. The commenter

concluded that EPA's current policy preference for BCA cannot override the specific statutory directives of the CAA.

**Response:** In response to commenters' statements that the proposed rule must be provided to the Science Advisory Board (SAB) for review, EPA received comments and recommendations on the proposed rule from the 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). EPA also reviewed comments received from the SAB during its review of the forthcoming update of EPA's Guidelines. EPA considered the SAB recommendations in finalizing this rule. The preamble to the final rule discusses the many areas where the SAB provided recommendations.

EPA disagrees with commenters' assertions that the rule provision at 40 CFR 83.3(a)(9) constrains the type of scientific materials that EPA can consider in a rulemaking. This provision governs the creation of the BCA for the purpose of complying with this final rule. As previously noted nothing in the final rule prohibits EPA consideration of studies and data submitted by the public to the agency as part of an administrative record for an agency action and nothing states that such data and studies must be compliant with any provisions of the rule. The final rule applies solely the BCA prepared by the Agency and made available to the public.

In response to commenters' assertions that the rule would create an unnecessary risk of increased litigation and lead to outcomes contrary to the requirements of the CAA, EPA notes its discussion of the enforceability of the final rule against the Agency at Section V.B of the preamble. Further, commenters have not identified how the rule would lead to outcomes contrary to the requirements of the CAA. The Final Rule does not dictate any outcome. EPA notes that the final rule specifically states that the Agency must consider the BCA in promulgating the regulation except where the provision or provisions under which a significant regulation is promulgated prohibit the consideration of the BCA. In such circumstances it is provided to the public for the purpose of transparency, as discussed in the preamble at Section V.A.

In response to commenters' concerns that the rule increases the burden upon the agency and interagency review process and that EPA has not provided a reasonable rationale for why this additional cost and litigation risk is necessary, EPA's discussion of why this rule is necessary and of its benefits, including increased consistency and transparency, is contained in Section V.A of the preamble and in Chapter 3 of this RTC.

## 5.0 Applicability

**Comment:** Several commenters supported the proposal that the definition of "significant regulation" should be the same as the definition of "significant regulatory action" under EO 12866. A commenter stated that the EO 12866 language should be inserted into the BCA rather than referencing EO 12866, because EOs can be changed or withdrawn in the future.

A commenter stated EO 12866 requires BCAs for "significant regulatory actions" and said that, despite the comprehensiveness of this longstanding definition of "significant regulatory actions", the EPA proposed in section 83.1 to apply the requirements not only to significant regulatory actions, as defined by EO 12866, but to any CAA action "otherwise designated as significant by the Administrator." The commenter noted that the EPA cited as ostensible justification in the proposal preamble (85 FR 35618) potential regulations "that are important to analyze for other policy reasons. For example, a rule projected to have less than a $100 million annual effect on the economy could disproportionately affect a single industry, population subgroup, or geographic area." The commenter contended that such rules would already be covered by the definition under EO 12866, which includes rules that may "adversely affect in a material way" a sector of the economy or local communities. The commenter said that neither the proposal preamble nor regulatory text contains any parameters or guidelines for the administrator to apply the proposed rule to additional CAA regulations. The commenter asserted that this unjustified and arbitrary provision would allow the administrator to selectively delay and burden minor regulations with the mandatory process now proposed.

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." A commenter argued that such inclusion is important to avoid adverse impacts on small businesses. Another commenter argued that the $100 million threshold was too restrictive and would eliminate BCA affecting rural communities, advocating for BCA for any rule that affects the economy in a "material way." Another commenter stated that the rulemaking should apply to any rule projected to have an effect on the economy of $100 million or more in a given year, or otherwise projected to adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

Commenters advocated using the definition of "significant" from the Congressional Review Act (CRA). The CRA defines a "major" rule as having:

(A) an annual effect on the economy of $100,000,000 or more;

(B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(C) 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 and export markets.

The commenters argued that adopting a definition from U.S. law is preferable to one from an EO. 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 stated that 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. The commenters added that to address any concerns that the resource demands for a BCA would be great, the EPA should tailor the amount of indirect quantitative analysis of the estimated impact to the action's likely magnitude of effect.

Several commenters objected to giving the Administrator the discretion to decide what constitutes a significant regulation, because with no specific decision criteria specified the rule, the decisions would be arbitrary and contrary to the stated goals of the BCA rule for consistency and transparency.

Several commenters objected to the concept of adjusting the $100 million applicability criteria for inflation. A commenter stated that it is not sensible to adopt a provision that could lead to fewer regulations being analyzed for BCA. Several commenters argued that inflating the threshold would create confusion by diverting from the threshold used by other agencies under EO 12866 and OMB's Circular A-4. A commenter stated that the EPA can adjust the threshold by changing the rule at a later date, if appropriate. The commenter stated that the rule should not "consider resource constraints" once a rulemaking is otherwise applicable, and the EPA should allocate its resources appropriately so that all significant rulemakings receive full and robust BCA. Another commenter opposed the adjustment because an inflation adjustment would give the EPA and other agencies incentive for inflationary monetary, fiscal, and regulatory policies.

A commenter advocated to include in the definition of "significant regulation" any notice-and comment rulemaking for any application for a preemption waiver under CAA section 209(b), where the aggregate impact of the California mobile-source regulations at issue could have an annual nationwide impact of $100 million or more. As justification, the commenter attached their comments previously submitted on the ANPRM.

Some commenters argued not to limit BCA only to those actions that are economically significant. Some commenters stated that BCA should be required for any rule for which the EPA must conduct a Regulatory Flexibility Analysis, arguing for the importance of protecting small businesses. A commenter added that a BCA would provide a consistent framework for the evaluation of the costs imposed on small entities and for demonstrating that the benefits to be gained by regulating small entities accomplish the stated objectives of the applicable section of the CAA. A commenter advocated that to consider an action to be not economically significant should require a signoff by the Small Business Administration or the Department of Commerce. Another commenter stated that BCA should be required for all rules imposing costs on the public and that the EPA should commit to a schedule for lowering the threshold in the future.

Some commenters supported the proposal to conduct BCA for only the most significant regulations, and another commenter stated that BCA should not be required for minor rule updates.

A commenter advocated that in deciding if the EPA will conduct a BCA for a rule that falls below the $100 million impact, the decision should consider the impact that the potential

regulation will have on a state's economy, pointing out that some industries have an outsized economic impact on a state. The commenter added that states are sensitive to additional delegated demands with limited or no associated federal funding, so it is also important that state agency resources are not considered uniformly in the BCA, but rather, relatively. The commenter suggested that the EPA could issue an Advanced Notice of Proposed Rulemaking if the EPA is uncertain of the significance of a proposal on a certain industry or entity. A commenter opposed expanding the BCA because it would deplete EPA's analytic, financial, and expertise resources without providing any benefit to public health or the environment.

**Response:** In the final rule we are promulgating the proposal definition of significant regulation as "a proposed or final regulation that is determined to be a "significant regulatory action" pursuant to EO 12866 or is otherwise designated as significant by the Administrator." We have reviewed the commenters suggestions, but we believe the definition of significant regulatory action in EO 12866 is the most appropriate definition for the BCA rulemaking; it applies to rulemakings where EPA believes it is necessary to conduct BCA analysis providing increased coverage of future rulemakings without being overly expansive such that an unnecessary number of additional rulemakings would be required to conduct a BCA where it is not necessary. In addition, the requirement also provides additional flexibility to the Administrator to require a BCA analysis for instances when the rulemaking does not meet the significant regulatory action definition in EO 12866, but may be warranted such as when a rulemaking affects a substantial number of small businesses or entities. We also note that "significant regulatory action" in EO 12866 is not limited to actions that have an effect on the economy of $100 million or more. Significant regulatory action also applies to regulations that:

- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

We also maintain that the requirement provides adequate protections for small businesses when combined with the regulatory Flexibility Act, and as discussed, the Administrator also has discretion to require a BCA for rulemakings that may affect small entities and businesses, if needed.

Additionally, we agree with the commenters on not adjusting the $100 million applicability level criteria for inflation and have not included that requirement in the final rule. As some of the commenters have noted, adding such a requirement would create consistency issues with OMB's Circular A-4 and EO 12866.

**Comment:** A commenter asked the EPA to clarify the definition of "significant regulation" to exclude actions to approve a State Implementation Plan (SIP), because the CAA specifies that the EPA must approve a SIP if it meets all of the applicable requirements. The commenter added that if the EPA is unwilling to do this, it cannot credibly state EO 13132 on

Federalism is inapplicable. The commenter stated that the interests of states in the development, adoption, and ultimate enforceability of their SIPs will be implicated if the regulatory text is not changed. The commenter argued that if the SIP meets CAA requirements, it would be inappropriate to second-guess a state's decision because the EPA thinks it is too costly. The commenter stated that the EPA may not consider cost in acting upon a SIP revision. The commenter argued that the exclusion should extend also to the EPA actions taken instead of a state, e.g., a source specific FIP action or an action under CAA section 126 for interstate air pollution abatement. The commenter pointed out that the EPA has a long record of ruling that such actions are not subject to EO 12866 because they are not a "rule" under the meaning of the EO because they are not "of general applicability." The commenter added that since EO12866 is inapplicable—and because the proposal already accepts the logic that permitting determinations are excluded (which are an analytically and formally similar kind of source-specific control determination)—this type of EPA action must also be excluded from the proposed regulation. The commenter concluded that because the need for this exclusion also directly or indirectly bears on the rights of states (as exemplified by the reference to section 126), this change is also needed for the rule to be consistent with the proposal's representation and conclusion regarding federalism.

**Response:** We view the BCA rule as only applying when the OAR branch of EPA issues a rulemaking. As such, we do not develop a BCA for state SIP submittals. However, we also note that if a state does not submit transport SIPS, OAR has issued transport FIPS, such as the Cross-State Air Pollution Rule and completed BCA's for such rulemakings.

# 6.0 Best Practices

## 6.1 Key Elements

**Comment:** A commenter supported EPA's proposed "key elements", including: (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 regulatory options relative to the baseline (no action) scenario.

**Response:** We are finalizing the three key elements as proposed.

## 6.2 Statement of Need

**Comment:** Some commenters opposed the EPA requiring a statement of need (as a factor in the BCA) for at least one of the following reasons:

- A statement of need would be in conflict with many, if not most, of EPA's rulemaking responsibilities under the CAA. Where a rule is required by Congress, Congress has itself determined that sufficient market failure or other valid lawmaking reasons exist to justify government intervention (e.g., CAA sections 101(a)(2), 109, 111, and 112); therefore, the EPA lacks the authority to refuse to adopt most rules based on the content of a statement of need, and it would be a waste of time and resources to spend a great deal of effort justifying taking an action that Congress has required to be taken. A citation to the provision of the CAA statute that requires the rulemaking should be sufficient for any statement of need.
- A statement of need deprives the person of freedom to invest and determine growth and expansion on its own.
- A statement of need will give rise to endless litigation over business needs of a particular applicant, risking breach of confidential business information and strategies currently protected from disclosure.

A commenter said that the requirement to include a statement of need (as a factor in the BCA) should only apply to regulations that are not legally required. The commenter also argued that the EPA cannot apply the "statement of need" requirement to rulemakings subject to CAA section 307(d) requirements since 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."

Some commenters supported the EPA requiring a statement of need (as a factor in the BCA). A commenter said that the requirement is consistent with agency guidance detailed in OMB's Circular A-4 and EO 12866. The commenter 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. Another commenter said the requirement would help ensure that the EPA carefully considers the basis for action.

**Response:** The EPA disagrees with the comment that a statement of need would conflict with the EPA's rulemaking responsibilities under the CAA. As discussed in Section V.E.2 of the preamble to the final rule, 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 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. EO 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people…" (emphasis added). The Office of Management and Budget's guidance for how to comply with EO 12866, OMB's Circular A-4, provides recommendations to federal agencies on the development of economic analyses supporting regulatory actions. OMB's Circular A-4 (specifically, see pg. 2) states that "a statement of the need for the proposed action" is a "key element" of a regulatory analysis, and that "an agency must demonstrate that the proposed action is necessary". 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 (specifically, see B. Introduction, The Need for Federal Regulatory Action) and EPA's Guidelines (specifically, see Chapter 3 "Statement of Need for Policy Action").

**Comment:** A commenter urged the EPA to remove any reference to market failures from its requirements relating to the preparation of a statement of need for BCAs. The commenter argued that the proposed statement of need forces the EPA to identify a market failure as a precondition to regulating under the CAA which could serve to artificially circumscribe the authority delegated to the EPA by Congress.

**Response:** We disagree with the commenter's assertion. Requiring the statement of need is in no way a precondition for conducting a rulemaking. As discussed in Section V.E.2 of the preamble to the final rule, an articulation of the statement of need does not bar the Agency from complying with any requirements of the CAA. The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. EO 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people…" (emphasis added). The Office of Management and Budget's guidance for how to comply with EO 12866, OMB's Circular A-4, provides recommendations to federal agencies on the development of economic analyses supporting regulatory actions. OMB's Circular A-4 (specifically, see pg. 2) states that "a statement of the need for the proposed action" is a "key element" of a regulatory analysis, and that "an agency must demonstrate that the proposed action is necessary". 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 (specifically, see B. Introduction, The Need for Federal Regulatory Action) and EPA's Guidelines (specifically, see Chapter 3 "Statement of Need for Policy Action").

## 6.3 Number of Regulatory Options

**Comment:** Some commenters opposed the requirement to analyze the benefits and costs of at least three regulatory options for at least one of the following reasons:

- The EPA incorrectly assumes that a continuum of options is possible; and it is unclear how the EPA will determine that a continuum of options exists. For toxic or other particularly harmful pollutants, there may be no exposure level that is safe for public health.
- Requiring three regulatory options may lead to patently inappropriate or otherwise unacceptable options, as might be the case in the control of pollutants that have the potential to cause extreme health impacts at very low doses.
- Requiring three regulatory options may lead the EPA to put forward intentionally poor choices, making the desired choice appeared better by comparison.
- Requiring three regulatory options pushes the EPA toward "middle ground" measures, where the EPA must justify requiring more aggressive actions.
- Requiring three regulatory options will result in an arbitrary diversion of resources and delay important rules to protect human health and the environment.
- Requiring three regulatory options may lead to unintended consequences such as leading the EPA to evaluate options that are infeasible and impractical.
- Existing structures already allow for alternatives to be presented when viable.

A commenter supported the requirement to analyze the benefits and costs of at least three regulatory options. The commenter 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. The commenter said that this perspective adds granularity to complex, nuanced decisions and helps stakeholders better understand the direction and magnitude of alternatives to the preferred option. The commenter suggested that the EPA also consider a fourth option, the implementation of voluntary programs; however, such an approach would need to be appropriate to the circumstances.

**Response:** We disagree with the commenters. As discussed in Section V.E.4 for the preamble to the final BCA rule, the EPA is codifying into regulation a procedure that is already

prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 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 about their opportunity costs 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 described in the preamble discussion. 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, or other notable deviations from the proposed or finalized option. 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 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).

## 6.4 Baseline

**Comment:** Some commenters opposed the requirements for developing a baseline in a BCA for at least one of the following reasons:

- OMB and EPA policies[3] 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."
- EPA's proposed rule erroneously treats double-counting as though it were a part of the existing framework, rather than a potential error. Double-counting is analytically never appropriate, and it should never occur under the current BCA framework.

[3] See OMB's Circular A-4 (pages 38-42) and multiple chapters of the EPA's 2020 Draft Guidelines for Preparing Economic Analysis

Although the EPA implies in the proposal that double-counting currently takes place as a deliberate strategy to further environmental goals, this is not the case. In fact, double-counting often harms environmental and conservation goals.[4]

- The proposed requirements for developing a baseline will be impossible to satisfy in practice. No matter how many resources the EPA expends on its pursuit, and no matter how long its future CAA rulemakings become delayed, regulated industries will still likely be able to find defects in the EPA's analytical baseline. This will give them seemingly endless opportunities to tie up future rules in endless litigation.
- The proposed requirements for developing a baseline biases the analyses against regulations that otherwise meet statutory requirements and provide important environmental benefits, in contravention of the CAA's public-health protective mandate.

Some commenters supported the requirements for developing a baseline in a BCA for at least one of the following reasons:

- A BCA is useless if not compared to the baseline of taking no action.
- The proposed requirements for developing a baseline address consistency and best practices.
- The proposed requirements for developing a baseline allows the EPA to use one baseline based solely on current standards and another based on the EPA's reasoned assumptions regarding the effect of all related pending regulations; and this is consistent with OMB's Circular A-4.

**Response:** None of the comments received have led the EPA to materially change its views from the proposal. As discussed in Section V.E.4 of the preamble to the final BCA rule, the EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 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. Further discussion is provided in Section V.E.4 of the final rule. Additionally, see OMB's Circular A-4 (specifically, see section E. Identifying and Measuring Benefits and Costs).

**Comment:** A commenter said that to the extent that the EPA wishes to ensure a proper baseline analysis in its BCA, it would be better achieved through discretionary terms presented in the form of a guidance document that would permit the EPA to adjust the analysis to the unique characteristics of the particular pollutant and CAA rule at issue.

**Response:** None of the comments received have led the EPA to materially change its views from the proposal. As discussed in Section V.E.4 of the preamble to the final BCA rule,

[4] See Alex Hanafi, 7 Reasons Avoiding Double Counting of Emissions Reductions Helps Countries and the Environment, Climate 411, Environmental Defense Fund (2018)

the EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. We maintain that codifying the BCA in regulatory decision-making 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.

**Comment:** 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 noted one report[5] found that the simultaneous advancement of multiple CAA-related rulemakings resulted in changes between proposed and final RIAs' baseline assumptions about implementation of other regulations that created inconsistencies in BCA estimates between the proposed and final stages and revealed examples of double-counting. A commenter recommended that the EPA add specific language to proposed 40 CFR 8.3(a)(4) to forbid "double-counting" and prescribe specific steps to prevent it.

Other commenters 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 addressed by the EPA following its own guidelines on BCA baselines assuming full compliance with existing rules.[6] The commenters added that to the extent that double-counting is currently occurring, the EPA should instead address this error by correcting existing processes. 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 See, e.g., Fed. Communications Comm 'n v. Fox Television Stations, Inc., 556 U.S. 502, 513, 515 (2009) (agency must show that there are "good reasons" and "reasoned explanation" for action); State Farm, 463 U.S. at 42-43 (agency must provide a "satisfactory explanation" for action).

**Response:** 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. Developing and clearly specifying the baseline can only help the BCA process. EPA does not consider it a detriment to do this. These requirements for developing a baseline are consistent with best practices as outlined in OMB's Circular A-4 and EPA's Guidelines. Additional discussion of avoiding double counting in baselines can be found in OMB's Circular A-4 (specifically, see E. Identifying and Measuring Benefits and Costs) and EPA's Guidelines (specifically, see Chapter 5).

**Comment:** A commenter said that the EPA should avoid counter-productive "co-benefits" by requiring a robust regulatory baseline that reflects all projected federal and state emissions reductions, as well as a robust alternatives analysis including the opportunity costs of pursuing "co-benefits" through sub-optimal or even unwarranted actions. The commenter

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

[6] "Co-Benefits and Regulatory Impact Analysis," p. 22. http://conference.nber.org/conf_papers/f136946.pdf.

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.

**Response:** 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). These requirements for developing a baseline are consistent with best practices as outlined in OMB's Circular A-4 and EPA's Guidelines. Regarding the commenter's concern about so-called "co-benefits", existing OMB and EPA guidance is clear that a BCA should endeavor to account for all benefits and costs of the regulatory action, including positive and negative welfare effects that do not stem directly from the statutory objective of the CAA provision under which a rule is promulgated. To enhance transparency about the extent to which a rule is achieving its statutory objectives, the final rule includes a requirement that BCAs will 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.

**Comment:** A commenter recommended that the EPA expand on the required baseline scenarios to better understand and evaluate the changes of a proposed or final regulation. The commenter said that in doing so, the EPA should account for reductions that occur because of regulations promulgated under other parts of the CAA, the evolution of markets absent regulation, subnational policies, and other relevant factors.

**Response:** 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. 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 and EPA's Guidelines.

**Comment:** Commenters recommended that the EPA improve this rulemaking by establishing a best practice for identifying a baseline before it regulates. The commenters argued that establishing a clear baseline also allows the EPA to use evidence-based evaluation techniques to identify ways to reduce regulatory burdens by removing regulatory requirements that turn out to be less effective than first envisioned. The commenters also stated that

establishing a clear baseline helps identify regulatory gaps that can provide opportunities for additional, cost-effective regulation, while also avoiding counting benefits that already have been counted elsewhere. The commenters contended that dedicating more analytical resources at the front end of a BCA will fortify the EPA's regulatory alternatives analysis, if it is to have any meaning and impact on selecting the most cost-effective regulations.

**Response:** The EPA agrees with commenters asserting the need for best practices to develop a baseline which the final rule establishes in section V.E of the preamble. The final BCA rulemaking requirements are consistent with best practices as outlined in OMB's Circular A-4 and EPA's Guidelines.

**Comment:** A commenter recommended that the EPA account for a the regulatory rebound effect in the baseline, which refers to the shift in compliance behavior tied to a policy targeting a co-pollutant—or, in other words, a new policy that indirectly reduces emissions covered under a pre-existing policy can result in a change in the pre-existing policy.[7] The commenter said that for the original MATS rule, the rebound effect caused the BCA to overstate the co-benefits of fine particulate matter ($PM_{2.5}$), which is already regulated under NAAQS and was the primary benefit driver of the rule.[8] The commenter said that reductions in $PM_{2.5}$ from MATS would allow states in NAAQS attainment to relax regulations on other $PM_{2.5}$ sources; and this would offset the effect of MATS on $PM_{2.5}$ as other areas could reduce standards stringency on new sources. The commenter said that the rebound effect for $PM_{2.5}$ dominates BCA results for many CAA rules and, in fact, constitutes two of three categories that drive the vast majority of total benefits of various regulations the last two decades.[9]

**Response:** 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). In addition, 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. These requirements are consistent with best practices as outlined in OMB's Circular A-4 and EPA's Guidelines. Finally, the EPA disagrees with the comment that suggests the rebound effect is a baseline issue. The rebound effect is usually used to describe a situation where an improvement in the efficiency of a service (such as lighting, cooling, or driving) makes it cheaper, normally leading consumers to

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7 See, e.g., Meredith Fowlie, "Declining Power Plant Emissions, Co-benefits, and Regulatory Rebound," American Social Science Association Meeting, 2020. https://www.aeaweb.org/conference/webcasts/2020.

8 Devin Hartman, "Comments of the Electricity Consumers Resource Council," Feb. 7, 2019, p. 2. https://elcon.org/wp-content/uploads/ELCON-MATS-Comments-FINAL.pdf.

9 See, e.g., Susan E. Dudley, "Perpetuating Puffery: An Analysis of the Composition of OMB's Reported Benefits of Regulation," Business Economics 47 (2012), pp. 165–76. https://link.springer.com/article/10.1057/be.2012.14.

demand more of it. EPA regularly evaluates the influence of possible rebound effects on the benefits and costs of a rule.

**Comment:** A commenter contended that because CAA regulations, cost incrementally more per unit of benefit today than they did when the EPA was established in 1970, it is appropriate to evaluate those incremental benefits and costs, against a baseline that ensures progress at an acceptable cost. The commenter explained that if the cost is greater than the benefits, that may be justifiable on some other basis, but everything will be analyzed the same way. The commenter stated that it is appropriate to choose a method for allowing people, other than theoretical economists, to see what is happening in analyses. The commenter supported an EPA toolbox on BCA, and that there is a commitment in writing (e.g., codification of the procedures and requirements for CBA) for this rulemaking, but first the EPA needs a "best practice" for defining the baseline.

**Response:** None of the comments received have led the EPA to materially change its views from the proposal. EPA agrees with the commenter that incremental cost and benefits are different today than when EPA was established, and that it is appropriate that analyses allow readers to fully understand the analysis. The final BCA rulemaking includes provisions to promote transparency of BCA. Regarding baseline, best practices for defining the baseline are given by OMB's Circular A-4 and EPA's Guidelines. As discussed in the preamble to the final BCA rulemaking, EPA is codifying into regulation procedures that are already prescribed as a best practice in those documents.

## 6.5 Multiple Baselines

**Comment:** Commenters supported the EPA following existing guidelines to address issues related to sequencing rules. A commenter) stated that if the EPA follows existing guidelines for transparently defining the baseline for analysis, including the proper consideration of other rules simultaneously under development, then the sequencing of rules often will not affect the estimation of benefits and costs, and, as such, the proposed rule is unnecessary. A commenter noted that on the issue of the costs and benefits of sequential rules: as compared to sequential rulemakings that each individually address a single pollutant, addressing multiple pollutants through a single rulemaking may reduce administrative and paperwork costs and may create cost-minimizing opportunities for multi-pollutant and novel compliance strategies, and these considerations counsel in favor of fully weighing important indirect benefits from the reduction of co-pollutants Another commenter stated that decisions related to the sequencing of linked and unlinked rules can have a significant impact on BCA analyses and the promulgation of regulations, and thus, the EPA should also consult with experts, including SAB, to understand the impacts of sequencing in the context of specific rulemakings. The commenter added that doing so will help ensure that proper baselines are used which factor in evidence of full compliance, under-compliance, or over-compliance within a sequence of emissions tightening rules. The commenter stated that "a proposed regulation that can be justified from a net benefit perspective under full compliance can also be justified under any baseline compliance rate. The commenter added that if non-compliance with previous regulation occurs selectively when compliance costs are high, then the benefit-cost ratio will decline as higher rates of compliance are assumed [given the cost per unit of benefit], and net benefits could potentially switch from positive to negative for a proposed regulation." The commenterconcluded that it is crucial that

any consideration of the sequence of rulemakings include carefully incorporating analysis of different compliance rates for each rule involved to avoid producing deflated or inflated net benefits.

**Response:** 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 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. 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. 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 and EPA's Guidelines.

## 6.6 Measuring Benefits and Costs

**Comment:** A commenter supported a final rule with a thorough and upfront description of how benefits and costs were estimated, key assumptions concerning the models, data, and assumptions used, and the evaluation and selection process for these decisions, disaggregation of social benefits attributable to the targeted statutory provisions underlying the regulation, and other benefits that give rise to the regulation, and other welfare effects.

A commenter stated that the EPA should continue forward on instituting summaries of the results of BCAs, including relevant ranges and ancillary benefits that are also worth considering. The commenter stated that the EPA can also improve its position as an authority on regulations by being clear about key assumptions that drive these analyses as well as a frank disclosure of uncertainty or risk in the models used and how that may influence decision making.

A commenter contended that without this rule, EPA does not need to consider costs and benefits resulting in overall economic health discrepancies being commonplace. The commenter contended that this new regulation would have fixed and likely negated the Clean Power Plan idea from ever taking root, which would have been disastrous to minorities.

**Response:** 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. As discussed in Section V.E 5 of the preamble to the final BCA rulemaking, we are codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866.

**Comment:** Several commenters opposed including the willingness to pay (WTP) concept in the rule. The commenters expressed concern that rule will continue to propagate the understatement of CAA benefits, to the detriment of all, but particularly to low-income and minority communities. The commenters added that, in so doing, the proposal may perpetuate structural discrimination in CAA rulemaking. 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. The commenters added that those with less ability to pay may set their willingness within different competing constraints than those for whom money is more readily available. A commenter explained that when someone has greater economic means, they will likely be willing to pay more than a poorer person would be willing to pay for the same environmental benefit. The commenter 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. A commenter contended that WTP underestimates the value of regulatory benefits because it is constrained by the individuals ability to pay. The commenter added that the WTP bias is even more pronounced for regulations that uniquely benefit low-wealth individuals, and especially those from historically marginalized communities, and thus results in introducing social injustice and structural racism into the results of BCA. A commenter contended that if the "benefits" of pollution limits are determined based on the wealth of the people they protect, any regulation that safeguards low income communities will be devalued—making it more likely that air-quality protections will be weakened or eliminated in light of compliance costs.

A commenter contended that WTP does not consider the fact that many Americans do not get the opportunity to make these "choices" to pay more to live in a clean area, or to agree on what value to put on a clean environment but rather live where they must, due to economic realities, or in contaminated homelands defined by Reservation boundaries, even if these areas are contaminated or receive higher amounts of pollution than others. The commenter asserted that the concept of WTP fails these individuals, as the people with the power to vote with their checkbooks may not be willing to pay more for their neighbors to also live in a clean area. The commenter contended that the EPA fails to consider whether the cost and/or 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." The commenter added that the market cannot always produce these protections on its own, and costs may need to increase to protect the vulnerable. The commenter also stated that some groups will balk at being asked to pay more so other groups (e.g. those already carrying a heavier body burden of pollution) can benefit. The commenter acknowledged it may be inevitable that some groups lose monetarily so others can have better health outcomes. The commenter stated that inability to monetize certain benefits may lead to ignoring these benefits and raises equity issues. The commenter concluded that overly prescriptive regulations on BCA could serve to obstruct the control of emissions that may is proportionately affect EJ communities, who have historically borne a heavier burden of exposure.

A commenter contended that proposal identifies the WTP metric as the "correct measure" of changes from the baseline, but fails to even acknowledge the existence of other metrics, and does not justify their exclusion in favor of WTP. 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 added that WTP studies are helpful, but not the only source of information for monetizing benefits. The commenter stated WTP studies are particularly helpful in estimating the value of mortality risk reduction, which typically comprise the bulk of monetized benefits in CAA rules. The commenter added that for this reason they supported the EPA continuing to rely on WTP studies when monetizing benefits. However, the commenter also added that the EPA should not limit benefits transfer analyses to WTP

studies. The commenter identified several studies in the past decade have shown ozone and PM pollution reductions improve educational attainment, labor-force participation, later-life earnings, and worker productivity. The commenter concluded that these studies show there are meaningful and at least partially monetizable societal benefits from air pollution reductions even in cases where a formal WTP study has not been published and peer-reviewed. A commenter contended that studies often overstate willingness to pay that does not align with reality, and provided an example of increased costs for renewable energy. The commenter added that effort should be made in finding real world willingness to pay data, rather than using surveys.

Some commenters supported a willingness to accept (WTA) measure. A commenter added that under the "willingness to accept" approach, the EPA would instead assess how much people would demand to be paid in order to give up the benefits of specific air-quality protections. The commenter added that the difference between a person's "willingness to accept" and "willingness to pay" can be significant. The commenter concluded that given that the CAA grants members of the public a right to air that's safe to breathe, moreover, it is the "willingness to accept" approach that would most accurately reflect the relevant legal entitlements.

A commenter recognized that reduction of pollutants and protection of natural resources may not always have a direct market value and if the EPA is to conduct a rigorous economic analysis, it must monetize or derive a value for such action. The commenter cautioned the EPA about using WTP as studies have demonstrated inherent bias in its use and is subject to producing significant errors. The commenter contended that it has been well documented that individuals being surveyed and asked hypothetical questions are far more likely to exaggerate their stated value versus true values and what they actually are willing to pay. The commenter added that bias can also result from poorly designed questions and deficiencies involving the implementation of the surveys.

A commenter supported the WTP criteria. The commenter added that the EPA should also address potential discrepancies between WTP methodologies and implementation of proposed rules. The commenter provided an example of WTP literature for visibility improvements may not be adequate to quantify benefits of Regional Haze Regulations, because the metric for tracking progress under the Regional Haze Rule (RHR) is the 20% most anthropogenically impaired days, and visitors to national parks and wilderness areas may not visit on this subset of days.

Another commenter contended that the proposal does not discuss how data is acquired for "willingness to pay" and how data for it are weighed.

A commenter stated that WTP is based on an economist's computer model of an unrealistic situation or an extrapolation from data obtained from another group entirely. The commenter added that it assumes knowledge of the thought processes of people in poverty and this is unjust and inequitable as it is not based on reality or scientific evidence. The commenter added that the proposed requirements cannot provide consistency because the social costs and social benefits are not comparable on the same basis.

**Response:** As discussed in the Section V.E.5 of the preamble to the final BCA rule, we maintain that WTP is the correct measure of assessing social benefits 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 Guidelines (2010/14).

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 (for example, 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) and EPA's Guidelines (specifically, see 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.

**Comment:** A commenter expressed concern that the "fitness for purpose" standard as the method for prioritizing inputs and assumptions within economic analyses may not be appropriate in issues for which there may be disparities in impact and in the value of protection. The commenter suggested, another standard such as the "precautionary principle" may be more appropriate and more consistent with the federal guidance cited in EPA's NPRM (OMB Circular M-19-15). The commenter cited one study that defined the precautionary principle as four central components: taking preventive action in the face of uncertainty; shifting the burden of proof to the proponents of an activity; exploring a wide range of alternatives to possibly harmful actions; and increasing public participation in decision making.

**Response:** 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. As discussed in the preamble to the final BCA rule, we recognize 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 quantified. As further discussed in OMB's M 19-15, this concept is referred to as "fitness for purpose," whereby information anticipated to have a higher impact must be held to higher standards of quality. 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 quantify the estimated benefit or cost it in terms of its risk, frequency, and scope. If it is not possible to measure these characteristics, the EPA will describe material benefits or costs qualitatively.

**Comment:** A commenter contended that many environmental and public health benefits cannot easily be quantified in monetary terms. The commenter added that it is difficult, if not impossible, to calculate with precision all of the benefits that accompany cleaner, less polluted air for a community and an improved quality-of-life for its residents. The commenter asserted that this dynamic is even more profound for vulnerable communities. The commenter explained that the greater pollution burden endured by these communities both enhances the difficulty of quantifying the benefits that would result from clean air regulations targeted to address them, and heightens the risk of distortion should environmental regulations fail to comprehensively account for those benefits. The commenter stated that the proposed rule offers an ambiguous treatment of non-monetary benefits within CAA BCAs that calls their value into question. The commenter contended that the proposed rule asserts that if the "comparison of benefits to costs in the net benefit calculation" is difficult to measure in monetary terms, the EPA must provide a "robust explanation" in order to justify deviating from a simple monetary calculation. The commenter added that any diminishment of the role or influence of non-monetary benefits in clean air regulations would carry significant EJ implications by risking the systematic underestimation of social benefits for vulnerable communities. The commenter stated that the EPA should clarify how the rule proposes to change its consideration of non-monetary benefits in order to reassure low-income communities, Tribal and indigenous communities, and communities of color and that clean air regulations will continue to fully account for all potential benefits, including those not easily quantified.

**Response:** The EPA disagrees with commenters who stated that the proposed offers an ambiguous treatment of non-monetary benefits within CAA BCAs that calls their value into question. The rule codifies into regulation BCA procedures consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866). The final rule requires that BCAs must provide available evidence on all non-monetized and non-quantified benefits and costs, including why they are not being monetized or quantified and what the potential impact of those benefits and costs might be on the overall results of the BCA. Furthermore, EPA acknowledges the need to analyze distributional impacts consistent with OMB's Circular A-4, particularly in the economic impact analysis (EIA) for a rulemaking. However, this rulemaking is focused on BCA, and does not address EIA or other types of analysis conducted pursuant to executive orders or statutory requirements

OMB's Circular A-4 contains procedures for addressing non-monetized benefits.

**Comment:** A commenter asserted that to meet statutory requirements to develop many types of environmental controls by definition the EPA must impose certain costs on polluting sources as necessary to produce the desired statutory result. The commenter contended that a discretionary rule of agency practice cannot alter these types of statutory demands.

A commenter stated that flexibility is essential in the analysis to support standards under the CAA because not all sources of air pollution respond to the same control technologies, nor do all types of air pollution cause the same types of harms, and not all public health impacts are evenly distributed across all communities. The commenter stated that increasing transparency and consistency in the analysis upon which regulatory decisions are based cannot 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 stated in the NPRM are already being met through existing EPA practices, particularly RIAs required by EO 12866. The commenter contended that setting a prescriptive process for conducting BCAs will lead to inflexibility that could prove detrimental to public health and the environment. The commenter concluded that the flexible approaches in the BCA framework that account for the multiplicity of harms from and solutions to air pollution – as currently utilized in RIAs – are essential to producing high quality standards to protect human health and the environment.

**Response:** We disagree with commenters assertion. The commenter is misinterpreting the proposal rule. The proposed and final rule codifies into regulation procedures that are consistent with the best practices discussed at length in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The rule does not and cannot prevent EPA from conducting analysis with the flexibility and accuracy needed for regulatory decision making on the wide variety of air pollutants and sources regulated under the CAA.

**Comment:** Several commenters contended that the proposal only impacts changes to the calculation of benefits, but none to the calculation of costs. The commenter contended that any changes to calculating BCA's should be applied to both benefits and costs to ensure consistency and transparency. A commenter added that these detrimental impacts will be felt most significantly by our communities of color, who already disproportionately suffer from respiratory illnesses caused by high levels of air pollution.

Commenters contended that the proposal does not address the tendency of the EPA to overestimate costs and underestimate benefits. The commenter cited one study that showed that the EPA's pre-implementation estimates of environmental compliance costs were more than double the after-the-fact compliance costs in eleven out of twelve cases. The commenter added that given the documented disparities between predicted and actual economic costs, the EPA would be well-served to focus on improved analytics that are not considered in this proposal. Another commenter contended that the under the proposal, the EPA's BCAs would likely understate the benefits of clean air while overstating the costs of pollution limits, and in focusing on the "net benefits" of air quality regulations, the proposed rule would ignore the disproportionate harms that have long fallen on the nation's frontline communities.

A commenter expressed concern that the rule will continue to propagate the understatement of CAA benefits, to the detriment of all, but particularly to low-income communities, minority communities, children, and other vulnerable populations. The commenter contended that the EPA did not consider the impact of this proposal on EJ communities, Native American communities, or on children. In the proposal, the EPA dismissed EO 13175, 13045,

and 12898 as not relevant, although this is in fact a substantive rulemaking that would impact these populations.

A commenter noted that the solution to this problem of the proposed rule treating costs and benefits differently is not to "apply" similar "requirements . . . to all risk assessments but to withdraw the proposed rule and revert to relying on existing guidance, like OMB's Circular A-4 and EPA's Guidelines, which already offer a more balanced treatment to both costs and benefits.

The commenter contended that the EPA misleadingly implies in the proposed rule that health benefits are more likely than costs to be uncertain, by calling out specifically the need to "report probability distributions for each health benefit" without similarly highlighting the best analytical tools for disclosing the uncertainty around cost estimates. The commenter stated that by repeatedly setting more stringent standards for benefit estimates than for cost estimates, the proposed rule reveals itself to be an arbitrary distortion of existing guidelines and not a mere codification.

The commenter added that while the proposed rule would require that analysts "must" engage in line-drawing exercises in every rulemaking to exclude co-benefits from an additional required presentation, the proposed rule only requires similar treatment of indirect costs "to the extent possible" and when the statute provides a specific listing of costs. The commenter stated that giving relatively less weight to indirect benefits while giving full weight to indirect costs is yet another way of arbitrarily treating costs and benefits differently. The commenter contended that indirect benefits "are simply mirror images" of indirect costs. The commenter added that this becomes especially apparent when deregulating: the benefits of the original action become the costs of the rollback. More generally, agencies are required by the courts to treat costs and benefits alike and consider each with comparable analysis, and may not "put a thumb on the scale by undervaluing the benefits and overvaluing the costs."

A commenter expressed concern that the EPA has continued to refuse using a scientifically credible social cost of carbon estimate in its regulatory analyses. The commenter contended that EPA's distortion of this key metric in its analyses belies any intent to improve the quality of regulatory BCAs.

A commenter contended that the proposal failed to mention several of the recent changes or proposed changes to formulas associated with the calculation of benefits. The commenter expressed concern that the methods being proposed by the EPA will weigh too heavily for the purported cost of potential regulations while failing to adequately capture the potential benefit from those same regulations. The commenter added that the standard of data integrity is two tiered, making it more difficult to introduce robust scientific and health data. The commenter expressed concern that the EPA will overweight the costs of regulations by adjusting the calculation methodology within the "Impacts on Employment" in the forthcoming revision to the Guidelines for Performing Regulatory Impact Analysis. The commenter added that it appears that through this action and other rules recently promulgated by the EPA that the EPA is consistently attempting to limit the calculated benefit by significantly reducing the social cost of carbon. The commenter noted that the social cost of carbon dropped from $45 per metric ton of $CO_2$ to $1-$7 per metric ton of $CO_2$ which is far lower price for $CO_2$ that currently exists in

nearly all existing carbon markets. The commenter added that the lower prices fail to meet the mark of using the 'best available science', a stated goal of this rulemaking.

**Response:** 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. We disagree with the commenters' assertions that the proposal BCA rulemaking only affected the calculation of benefits and not costs. We did not propose to change the calculation of benefits. We proposed, and are finalizing, codifying into regulation general procedures that are already prescribed as a best practice in existing guidance documents (e.g., OMB's Circular A-4 and EPA's Guidelines), which are the existing peer reviewed guidance documents implementing EO 12866). The final rule does not replace any detailed recommendations for Agency analysis included in existing guidance. Detailed recommendations on issues relevant to estimating the social cost of carbon is one example of a topic that is discussed in existing guidance documents and not addressed in the final rule.

Regarding comments on the social cost of carbon, to estimate the climate benefits associated with changes in CO2 emissions, the EPA applies a measure of the domestic social cost of carbon (SC– CO2) to value the climate impacts of a rulemaking, and presents results based on a measure of the global SC-CO2 in sensitivity analysis. The SC–CO2 is a metric that estimates the monetary value of impacts associated with marginal changes in CO2 emissions in a given year. The BCA rulemaking only codifies the BCA procedures as provided in OMB's Circular A-4 and EPA's Guidelines, and this rulemaking does not directly address the social cost of carbon as identified by the commenter.

**Comment:** A commenter opposed framing the concept of regulatory costs in terms of opportunity costs. The commenter contended that EPA's conception of opportunity costs assumes that businesses spared regulatory costs will make productive use of that money such as investments in capital or hiring instead of using the money for noninvestment purposes, such as stock buybacks or corporate mergers. However, the commenter stated that recent experience provides ample evidence of how unrealistic this assumption is. The commenter added that where compliance costs are passed on to consumers, those costs do not impact investments. The commenter also stated that the extent to which regulations or taxes impair total private investments is sensitive to assumptions made in macroeconomic modeling. The commenter concluded that the practical effect of this false assumption is to systematically overestimates regulatory costs by making the opportunity costs look bigger than they really are. In turn, overestimates of regulatory costs would skew the results of the EPA's BCA against stronger CAA rules.

**Response:** We proposed, and are finalizing, codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines. In OMB's Circular A-4, the social costs are measured by the opportunity costs of adopting the policy. These opportunity costs consist of the value lost to society of all the goods and services that will not be produced and consumed if firms reallocate resources in order to comply with the regulation. We note that the same concepts and definitions are used widely in economic literature. Further discussion of opportunity cost and how to measure it is provided in section V.E.5 of the final rule's preamble.

**Comment**: Commenters supported the inclusion of the effects of unemployment in the BCA. Commenters added that some effects include numerous stress-related health effects from unemployment which have not been considered by the EPA in the past.

A commenter stated that job gains and losses can serve as an indicator of potential overall efficiency gains and losses, especially those associated with increasing-returns phenomena in industry and may capture effects that are missed by the general-equilibrium analyses the EPA usually performs. The commenter added that adequately considering employment effects is necessary for the EPA to achieve its stated goal of considering "all benefits and costs" from a given regulation. The commenter also opposed EPA's arguments that the EPA need not consider employment effects. The commenter stated that EPA's assumption that any unemployment resulting from regulation will merely be transitional is inappropriate in the context of the manufacturing jobs affected by CAA regulation. The commented added that the industries that the EPA regulates most heavily under the CAA are, in fact, often characterized by the lack of "mediating mechanisms" that "ensure that affected workers generally do not have lowered employment prospects years after the initial dislocation." The commenter provided an example where empirical research suggests that adverse employment effects from the decline in manufacturing jobs since 2000 have lasted far longer than similar effects in other sectors, and that these effects have significantly contributed to the persistent aggregate decline in the workforce over the United States as a whole. The commenter stated that related research suggests that environmental regulation under the CAA has been a major factor in the decline in those manufacturing jobs.

A commenter stated that the EPA already has the tools it needs to consider employment effects of proposed regulations in BCAs. The commenter explained that although agencies are not currently required to consider job losses and gains in formal BCAs, "the vast majority of regulations" already "include some assessment of the regulation's effect on employment." The commenter added that EPA's own guidelines for economic analyses state that "if desired, the analyst can assess the employment impacts of a regulation as part of" an EIA, and the EPA provides guidance on what factors to consider when conducting such an analysis, and EPA's current guidance states, however, that these impacts "[in most situations] should not be included in the formal BCA." The commenter explained that because these employment-effects analyses are not actually incorporated into the EPA's formal BCA, they currently tend "merely [to serve] as a check on the practicability of the regulatory option the agency ha[s] already chosen on other grounds—and a standardless check at that." The commenter concluded that to capture the full societal impact of its proposed regulations more accurately, the EPA should incorporate these estimates into the formal BCAs, recognizing that the particular employment analyses required may vary based on the regulation being considered.

A commenter stated that meaningful consideration of employment effects in the regulatory decision making process involves at least three steps: (1) clearly relocating evaluation of job gains and losses from EIAs and feasibility analyses only, into formal BCAs; (2) identifying regulations with potentially significant employment impacts; and (3) balancing employment effects against the other costs and benefits of a given regulation. The commenter added that within that first step towards including employment effects in formal BCAs, the EPA could, potentially in collaboration with other agencies, (1) establish "the value of a statistical job," (2) estimate "multipliers to translate compliance costs into reduced investment," and (3)

derive "a direct relationship between the sheer volume of regulation and rates of investment and productivity growth." The commenter noted that multiple researchers have attempted to establish empirically the relationship between increased regulation and job losses, and there is a substantial literature that aims to specifically "examine[] whether environmental regulation has caused job loss." The commenter concluded that regulators as well as government scientists and economists can build on this research to establish statistical job values, estimate the correct multipliers, and derive the relationships most appropriate for the CAA regulatory context.

**Response:** We thank the commenters for their suggestions. We typically analyze employment impacts and other distributional impacts for rules that warrant this type of analysis, particularly in the EIA for a rulemaking. However, this rulemaking is focused on BCA, and does not address EIA or other types of analysis conducted pursuant to executive orders or statutory requirements.

**Comment**: A commenter supported a BCA for the entire time horizon that costs and benefits will accrue instead of snapshot of what it look like in a given year within a range to support pre-determined conclusions.

**Response:** The EPA is codifying into regulation general best practices consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866). The final rule does not replace any detailed recommendations for Agency analysis included in these existing guidances. Detailed recommendations regarding the appropriate time horizon to use in the analysis is one example of a topic that is discussed in the existing guidance documents and not addressed in the final rule.

**Comment**: A commenter supported modeling the benefits and costs on the whole economy and not just part of it.

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The final rule 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. 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.

**Comment:** A commenter contended that because costs are not to be considered in setting the NAAQS, it would be irregular and illogical for the EPA to provide a justification of net

societal benefits in explaining why an established cost per ton threshold is reasonable and achievable. The commenter stated that it is arbitrary for the EPA to fail to engage in these structural considerations, specifically in relation to how setting NAAQS without regard to costs drives the interrelated adoption of federal rules needed to achieve the NAAQS. The commenter added that State and local regulators, as with EPA, have conventionally and regularly examined "costs" under a cost effectiveness framework that looks at costs per ton of pollutant removed. The commenter contended that the proposal substitutes a different conception and requirement for presentation of "costs," even as the conventional metric is in many contexts supported and required by judicial precedent. The commenter concluded that there may be responsible ways to present added analysis, but the proposed rule never considers whether the added analysis might be redundant, illogical or confusing to the public, or wasteful of agency and judicial resources.

**Response:** The commenter is incorrect. The proposed and final BCA rule does not require justification of net societal benefits. The EPA is codifying into regulation general best practices consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866). The EPA has regularly prepared BCA for NAAQS rulemakings when they meet the criteria for conducting such analysis under Section 3(f)(1) of EO 12866.

**Comment:** A commenter requested that state-level and state-specific economic impacts of rulemakings are considered in BCAs, as a "one-size-fits-all" approach to the benefits and costs associated with implementing a rulemaking does not reflect how a rulemaking may affect certain states differently than others. The commenter also requested that exogenous impacts arising from the implementation of or interrelationship with other rulemakings be considered in BCAs.

**Response**: None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. As such, the commenter's request is inappropriate for the BCA. We note that EPA regularly includes economic impact analyses in the RIAs for rulemakings, and EO 13132 requires that rules that have federalism implications due to either substantial compliance costs must submit a Federalism Summary Impact Statement and conduct consultation with elected officials of affected state and local governments.

**Comment:** A commenter requested the EPA present mortality benefits separately, including countervailing changes in mortality. The commenter stated that EPA should clearly break down how many lives are expected to be saved from its rules and present this number unconcealed by factors such as discounting, and present the "gross" and "net" mortality reduction, where the net mortality reduction accounts for countervailing risk increases (or decreases) owing to income losses (or gains) induced by the regulation that state-level and state-specific economic impacts of rulemakings.

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-

4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. We note that EPA does already calculate mortality benefits in the RIAs for each rulemaking.

**Comment:** A commenter supported delineating between benefits and costs that are consumed and those that come in the form of investment. The commenter added that the proper way to conduct BCA is to separate consumption and investment, since these different benefits and costs have different rates of return associated with them. The commenter concluded that if an analyst does not discern which benefits and costs are invested and which are consumed, he or she can have little confidence that the opportunity cost of capital has been accounted for in analysis.

**Response:** The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. We refer the commenter to these documents for questions related to displacement of consumption vs. investment in the discounting discussion.

**Comment:** A commenter requested the EPA disaggregate benefits and costs by geographical area, allowing the determination of whether there is a disproportionate cost to one population, with a disproportionate benefit to another.

**Response:** The EIA and distributional outcomes focus on disaggregating effects in various ways (e.g., income groups, race, sex, industrial sector, geography) to show impacts separately for the groups and sectors of interest. Depending on the rulemaking and the underlying data, presenting results in disaggregated form (e.g., by geographic area) can provide important information to policy makers that may help them tailor the rule to improve its efficiency and distributional outcomes. However, this rulemaking is focused on best practices for BCA. Best practices pertaining to EIA and other types of analyses are addressed in existing guidance documents (e.g., OMB's Circular A-4 and EPA's Guidelines).

**Comment:** A commenter supported that the EPA use both VSL and VSLY, instead of only VSL, in monetizing health benefits as is recommended in OMB's Circular A-4 because the value of statistical life is not likely to be a single number relevant for all situations. The commenter added that use of VSLY can better reflect significant differences between the effect on life expectancy for the population affected by a particular health risk and the populations studied. The commenter cited other government agencies that use VSLY in assessing potential benefits. The commenter also supported the claim that it is fully appropriate to focus on life-years, not merely lives, and that both academic and public criticisms of the life years approach are misconceived because no program literally "saves" lives; life-extension is always what is at issue.

**Response:** The commenter refers to topics that are addressed in existing guidance documents but are not addressed in the final rule. We refer the commenter to Appendix B of the Guidelines for Preparing Economic Analyses for further discussion.

**Comment:** A commenter recommended that the final rule require the EPA to assess the direct, indirect, explicit, and implicit costs as defined in EPA's Guidelines for Preparing

Economic Analyses[10] of proposed significant regulatory actions and their alternatives when feasible to ensure social costs are fully examined. The commenter argued that the final rule should require the EPA to examine in detail the unique costs that existing sources incur in adding new control equipment to existing sources that were not built to accommodate the many required changes, and lack the flexibility to start-over in designing a facility; key costs that should be required to be examined include:

- Design and scoping costs required for installing the required technology, including capital repayment;
- Associated engineering costs, project management and revamping costs;
- Equipment/production outages needed to install new technology and handle or dispose of byproducts;
- Direct installation costs, including the cost of piping, electrical and foundation work, rough-in costs, and the cost of not-yet-identified equipment needed for installation; and
- Added costs imposed by site constraints, including land and space, which may affect total costs.

A commenter argued the final rule should require the EPA to undertake efforts to develop a reasonable range of cost estimates for engineering, design, and installation costs associated with required technologies, as well as transitional costs associated with training workers to operate equipment and systems, and costs associated with production outages during the transitional period. The commenter said EOs and various statutes support the inclusion of these costs estimates in EPA's BCA, and pointed out that EO 12866 specifies that an assessment of the costs of a regulation should include "any adverse effects on the efficient functioning of the economy and private sector (including productivity, employment, and competitiveness)" in addition to compliance costs. The commenter said the Unfunded Mandates Reform Act of 1995 requires that cost estimates take into account both indirect and implicit costs on state and local governments. The commenter said the Congressional Review Act places an emphasis on agency analysis to determine whether there is "a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions….". The commenter argued that there may be implicit costs imposed on regulated entities due to output lost when shifting limited resources; and this shift in resources means that it could cost more money to produce the same unit of output and may reduce the value of product variety as a result of restrictions on the production of certain goods. The commenter also said this shift may also increase product research and development costs while regulated entities search for and develop substitute products.

**Response:** The EPA is codifying into regulation general best practices for BCA consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed

[10] The commenter provided the following link: https://nepis.epa.gov/Exe/ZyPDF.cgi/P100PJVS.PDF?Dockey=P100PJVS.PDF (Dec. 17, 2010, revised May 2014).

guidance documents implementing EO 12866). The final rule does not replace any detailed recommendations for Agency analysis included in these existing guidances. The EPA believes that that the definitions of both compliance cost and social costs provided in the proposed rule were broad enough to cover all costs discussed above that are relevant to the BCA. However, both definitions are revised for clarity in the final rule. Additional detailed discussion of cost estimation is provided in existing guidance documents. We also note that EPA already conducts analyses on the effect of each rulemaking on state and local governments under the Unfunded Mandates Reform ACT.

**Comment:** A commenter said that the final rule should include a requirement for the EPA to update capital and labor cost inputs based on recent sales, contracts and vendor guarantees; at a minimum, the EPA should assure that cost inputs are indexed to reflect current pricing.

**Response:** We appreciate the commenters suggestion. However, we consider the level of detail requested out of scope for this rulemaking. Commenters are referred to OMB's Circular A-4 and the guidance documents for directions and procedures for updating cost inputs.

**Comment:** A commenter supported a separate presentation of impact on small entities that the Administrator must consider in making a regulatory decision. The commenter recommended a detailed disaggregation of impacts of regulating small entities, both the costs imposed by and the social benefits from regulating small entities. The commenter argued that by disaggregating benefits and costs of the rule, the EPA can clearly demonstrate how it has considered small business flexibilities in the same framework as other regulatory alternatives, including whether the regulation of small entities can be justified separately from regulation of the industry as a whole. The commenter said this will provide consistency between consideration of aggregate economic impacts and consideration of small entity impacts and increase transparency in EPA's weighing of small entity impacts against other impacts described in the BCA.

**Response:** The EPA disagrees that an additional separate presentation of impacts on small entities is needed to enhance transparency. CAA rules will continue to comply with the requirements of the Regulatory Flexibility Act already which requires EPA to determine whether rulemakings will have a significant impact on a substantial number of small entities. Given this statutory requirement, it is unclear why an additional requirement to discuss or present impacts to small entities is needed in this final rule.

**Comment:** A commenter argued that private benefits should not be included in the BCA by using an example where the EPA proposes a fuel-saving mandate. The commenter contended that the EPA should not include the fuel-savings benefits to the private entity that result from the mandate because in most cases, these entities already recognized the option of undertaking the fuel-saving measures prior to the regulation but did not implement for any number reasons (such as range from a higher opportunity cost for the investment capital, a higher internal discount rate, and vastly different perspectives on the durability and operational requirements of the proposed fuel-saving mandates). The commenter said that counting these so-called "private benefits" in the BCA as a broader societal benefit assumes the firm or individual was irrational in failing to adopt the fuel-saving measure.

**Response:** We appreciate the commenters suggestion. However, we consider the level of detail requested out of scope for this rulemaking. Commenters are referred to OMB's Circular A-4 and the guidance documents for discussion of cost savings or other forms of benefits accruing to parties affected by a rule who also bear its costs.

**Comment:** A commenter contended that the EPA should not count potential savings to the consumer or firm as public benefits if the government is mandating outcomes that are contrary to the firms' or individuals' preferences. The commenter explained that by including these 'private" consumer or firm savings as a public or societal benefit, the BCA may end up counting as a public benefit what may actually be a loss to the firm or the individual. The commenter supported the view that a BCA that mistakenly assumes consumers (or producers) are systematically making irrational decisions will sacrifice welfare gains, too, as it will ignore valid, informed preferences of consumers (or producers); the resulting regulations could restrict and homogenize market choices and therefore harm the people involved. The commenter concluded that the EPA should adopt a policy that omits the calculation of private benefits that are premised on the irrationality of firms or consumer behavior. At a minimum, the EPA should report any such private "benefits" separately and note when reporting such benefits that the actions could result in losses to the consumer or firm.

**Response:** We appreciate the commenters suggestion. However, we consider the level of detail requested out of scope for this rulemaking. Commenters are referred to OMB's Circular A-4 and the guidance documents for discussion of cost savings or other forms of benefits accruing to parties affected by a rule who also bear its costs.

## 6.7 Compliance Costs

**Comment:** Commenters said the proposed rule fails to address the likelihood that compliance costs will be overestimated and benefits will be underestimated. A commenter argued that compliance costs are naturally overcounted in *ex ante* estimates because they overlook economies of scale, the cost-reducing effects of growing expertise, and the innovation-encouraging effects of regulation; the commenter said all of these overlooks are difficult to model. The commenter suggested the EPA focus on improved analytics that are not considered in the proposal. The commenters cited the following references supporting their claim:

- One study[11] concluded that "Regulatory analysis is notorious for failing to take into adequate account the technological innovations that ultimately make many regulations cheaper to implement than regulators anticipate."
- One study[12] showed that the EPA's ex ante estimates of environmental compliance costs were more than double the actual compliance costs in eleven out of twelve cases.

[11] Heinzerling, supra note 92, at 2314, 2314 n.15 (citing Winston Harrington, et al., On the Accuracy of Regulatory Cost Estimates, 19 J. Pol'y Analysis & Mgmt. 297 (Spring 2000); Eban Goodstein & Hart Hodges, Polluted Data, Am. Prospect, Nov-Dec. 1997, at 64; Claudia H. Deutsch, Together at Last: Cutting Pollution and Making Money, N.Y. Times, Sept. 9, 2001, at A1).

[12] Hart Hodges, "Falling prices: Cost of Complying With Environmental Regulations Almost Always Less Than Advertised," EPI Briefing Paper #69, Nov. 1997, available at https://www.epi.org/publication/bp69/.

- An analysis[13] found that automakers would have to invest $886 on average per vehicle in new technology to meet 2025 light duty vehicle standards, compared to EPA's estimate of $1,378.
- A 2011 comparison of *ex post* and *ex ante* studies[14] of the costs and benefits of compliance with environmental and safety regulations revealed, "Most existing studies have found that regulators are more likely to over- than to underestimate costs."
- A 2004 study's review[15] of more than two dozen environmental and occupational safety regulations indicated that "*ex ante* estimates of total (direct) costs have tended to exceed actuals," with twice as many studies overestimating costs as underestimating them.
- An article stated that industry estimates before the 1990 CAA Amendments famously overvalued the cost of compliance by a factor of ten.[16]

A commenter provided several examples where costs were much lower than estimated during the rulemaking.

A commenter opposed the proposal not incorporating the effect of technology innovation into future cost analyses despite its amply-demonstrated relevance.

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines. 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 EPA's Guidelines (specifically, see Chapter 8. Analyzing Costs).

**Comment:** A commenter contended that the EPA should evaluate the costs of implementation to state and local agencies that are delegated authorities under the CAA because some states may be disproportionately impacted by rulemaking over others because we are more sensitive to additional delegated demands. A commenter said that states' environmental laws and regulations expressly adopt the EPA standards in all or some instances, or require an express justification for any deviation. The commenter stated that a fundamental change in how the EPA

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[13] Efficiency technology and cost assessment for U.S. 2025–2030 light-duty vehicles, an assessment of the Technical Assessment Report of the EPA and the National Highway Traffic Safety Administration for the midterm review of the US passenger vehicle greenhouse-gas emission regulation. ICCT, Mar. 22, 2017, available at https://theicct.org/publications/US-2030-technology-cost-assessment.

[14] "Do Regulators Overestimate the Costs of Regulation?," R. David Simpson, National Center for Environmental Economics /U.S. EPA, Aug. 2011, available at https://www.epa.gov/sites/production/files/2014-12/documents/do_regulators_overestimate_the_costs_of_regulation.pdf

[15] Winston Harrington, Richard D. Morgenstern & Peter Nelson, "On the Accuracy of Regulatory Cost Estimates," Journal of Policy Analysis and Management Vol. 19, No. 2 (Spring, 2000), at 297-322, available at https://www.jstor.org/stable/3325616?seq=1

[16] Frank Ackerman & Lisa Heinzerling, "Priceless: On Knowing the Price of Everything and the Value of Nothing," New Press, New York, NY, 2004, at 38.

considers the relative costs and benefits of regulations would consequently affect standards that states typically implement and enforce to protect public health and the environment. The commenter asserted that the correct balance of cooperative federalism in the implementation of these programs by the states depends on the EPA fulfilling its duties as directed by Congress in the CAA, and in a rational manner

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines. We also note that EPA already conducts analyses on the effect of each rulemaking on state and local governments under the Unfunded Mandates Reform ACT.

## 6.8 Partial and General Equilibrium

**Comment:** Commenters opposed EPA's proposed general equilibrium approach. A commenter said a general equilibrium analysis implies that there are reliable ways to analyze the impacts of a rulemaking on the entire economy. The commenter said 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. The commenter pointed out that the EPA notes that general equilibrium models are only useful for assessing actions that have a significant impact on the economy. The commenter argued that compliance costs of EPA rulemakings have rarely, if ever, been as large as $10 billion per year; i.e., less than 5/100th of a percent of the U.S. Gross Domestic Product; and the uncertainty ranges of general equilibrium models dwarf this level of impact, which means it would be a travesty to use them for this purpose. Another commenter said that although the EPA is correct to highlight the potential value added to be gained by using general equilibrium models (because a partial equilibrium analysis ignores any possible ripple effects of the regulation on other markets, or the economy as a whole), there are a number of reasons why general equilibrium models may not yet be ready to be used as a principal analytic framework for undertaking BCA 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. The commenter also argued that general equilibrium models assume that the economy adjusts in a frictionless way from one equilibrium in which all factors of production are employed to another full employment equilibrium.

Commenters supported EPA's proposed general equilibrium approach. A commenter said that a general equilibrium analysis rectifies an imbalance in defining social cost by compliance cost alone by factoring in general welfare costs. A commenter said a broader analysis that includes a general equilibrium analysis becomes especially important when co-benefits are being generated by significant substitution effects.

Commenters recommended against adoption of any bright lines to determine when a partial-equilibrium analysis would be necessary, and/or when a general equilibrium analysis becomes an essential supplement to a partial-equilibrium analysis. A commenter recommended that the EPA always undertake a partial equilibrium analysis of regulatory benefits and regulatory costs; and when the regulation is significant enough, undertake a qualitative

discussion, drawing on "general equilibrium reasoning" and where possible the results from existing general equilibrium models. The commenter recommended that this type of analysis focus on how general equilibrium effects might increase or attenuate benefits and costs estimated from the partial equilibrium analysis. Similarly, another commenter argued that the final rule should 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. The commenter said that if an engineering-based cost estimate is all that is used, then data should be provided to support EPA's view that the affected sectors' actions will have de minimis impacts on their suppliers and on the sector's product prices. The commenter said that if a partial-equilibrium model is all that is used, then the EPA should evaluate its projected price and output results to make the case that there is de minimis possibility that these effects might filter into the economy at large. The commenter also argued that when a regulation will affect a sector that supplies a wide swath of the economy (i.e., for regulations targeting either electricity, natural gas, or petroleum product production), 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 even small price effects in the affected sector's outputs would not be expected to have economy-wide effects.

A commenter contended that spillover effects due to changes in employment are not adequately captured by EPA's current equilibrium analyses. The commenter contended that the "General-equilibrium analysis is built around the assumption" of a perfectly functioning marketplace with constant returns to scale across all industries, such "that for some discrete period of time, an economy can be characterized by a set of equilibrium conditions in which supply equals demand in all markets." However, the commenter added that "on an empirical level, . . . in any economic activity which involves the processing or transformation of basic materials—in other words, in industry—increasing[, not constant,] returns dominate the picture for . . . reasons that are fundamental to the nature of technological processes." The commenter stated that if at least one industry in the economy experiences increasing returns, an increase in employment "generates external or spillover benefits on all persons in the market nexus . . . due to the exploitation of specialization that is made possible by the market's extension." The commenter stated that for these reasons, "[t]he benefit for the hired individual from added employment," which general-equilibrium analysis captures, "is only a part of the overall efficiency benefits," since each new job exerts positive spillover effects on the whole market due to occupational upgrading and increased specialization. The commenter also stated that spillover benefits and costs can be difficult to model, and because of the intimate connection between increasing-returns phenomena and employment, job gains and losses associated with a regulation can serve as an indicator of potential net societal gains or losses due to increasing-returns phenomena in industries. The commenter concluded that including employment effects in BCAs provides a way for the EPA to capture these spillover effects and thus more accurately evaluate the effect of its proposed regulatory actions.

**Response:** The proposed and final BCA rule does not prescribe specific modeling approaches to take but lists three potential frameworks for estimating social costs. As discussed in section V.E.6 of the preamble to the final BCA rule -- compliance cost, partial equilibrium, and general equilibrium -- with different scopes in terms of the degree to which behavioral response and other market imperfections are included. 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. When broader economy-wide impacts are expected as a result of the regulation, a partial equilibrium approach will miss these effects. 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.

## 6.9 Identifying Benefit Endpoints

**Comment:** A commenter supported the proposal when conducting BCA, the EPA should select those health endpoints for which scientific evidence shows a clear or likely causal relationship between exposure and health effect, and where the regulation is expected to change that effect.

A commenter contended that monetizing all benefits in a BCA is not necessary, realistic, or even desirable in most cases. The commenter added that this commitment may open up EPA rules unnecessarily to challenges. Another commenter requested clarification on whether and how the proposed approach differs from EPA's current practice and how it is consistent with the variety of CAA provisions requiring the EPA to consider scientific data in rulemaking.

Another commenter stated that the proposed rule will require illogical procedural burdens in application. The commenter explained that when the EPA is setting a New Source Performance Standard (NSPS) under section 111, there is no basis to expect that presentation of information on "health endpoints" or "concentration-response relationships" would be needed, relevant or useful to the regulatory task. The commenter stated that the various health effects of criteria pollutants were already studied and established when the EPA set the NAAQS. The commenter added that it is arbitrary for the EPA to fail to engage in these structural considerations, specifically in relation to how setting NAAQS without regard to costs drives the interrelated adoption of federal rules needed to achieve the NAAQS.

A commenter contended that the proposal is attempting to specify a one-size-fits-all regulation to address the multiple evolving scientific and policy issues inherent in assessing the effects of various air pollutants on public health. The commenter added that the proposals minimum standards for using scientific information, including the additional requirements on epidemiology, are more like a selective version of the broader and more nuanced approaches that current assessments in air programs already require. The commenter added that neither the preamble nor the rule suggests why EPA's more rigorous approaches that lead to quantitative risk assessments for criteria pollutants would not be enough for a BCA. Instead the rule over-specifies minutia such as the inclusion of negative studies and a potential requirement to use all relevant epidemiology studies. The commenter stated that in the case of the obviously most relevant pollutant in the history of all of EPA's air BCAs, $PM_{2.5}$, this could require a new meta-analysis of 40 or more studies which would lead to opportunities for frivolous lawsuits regarding how well the EPA followed its own rules. The commenter concluded that it is easier to adapt to

new scientific information in guidance and practice than in a fixed regulation and it is much better to allow EPA's more comprehensive assessments to drive the criteria needed for selecting the most useful studies for benefits assessment supplemented, where needed, by ad hoc external scientific reviews of methodology, as was done by a special SAB subcommittee for CAA sections 812(a) and (b).

A commenter contended that the modeling the EPA uses to assess the impacts on human health includes many endpoints that are determined to be causally or likely causally-related to air pollution, such as premature deaths, hospitalization or days missed at school from childhood asthma attacks. The commenter cautioned that these models do not provide an assessment of other similar endpoints, such as new onset lung cancer or low birthweight babies, because cost-relevant studies are not available or have not been incorporated into these models. The commenter concluded that as a result, the value of the benefits to the health of millions of Americans is significantly undercounted. Another commenter stated that the EPA's proposed restriction of endpoint assessment to studies with "causal" or "likely causal" outcomes, for which no explanation is provided, would dramatically and irrationally restrict assessment of the health benefits of regulation. This provision would particularly and inexplicably exclude epidemiological studies, which do not individually determine causality, and would severely limit understanding of a regulation's impact on vulnerable and impacted communities and children. The commenter added that the EPA provides no explanation or justification for such arbitrary and bias-inducing provisions.

Another commenter contended that the EPA should account for all benefits and costs, if feasible, and not just those that are "most influential" or those that limit benefits to endpoints where some scientific evidence questions the extent of a "clear" "causal relationship. The commenter added that selecting endpoints where scientific evidence indicates there is causal link is common under periodic reviews of the National Ambient Air Quality Standards (NAAQS), but the statute does not justify imposing a heightened standard that such causality be "clear" and BCAs for significant CAA regulations should not be constrained by those specific endpoints. The commenter stated that the proposals requirement that BCAs should identify uncertainties underlying the estimation of both benefits and costs and, to the extent feasible, quantitatively analyze those [costs, changes in air quality, and changes in benefit endpoints] that are most influential could allow the EPA to set thresholds that exclude the consideration of benefits from emissions reductions below set levels, where there is uncertainty as to the precise rate at which those benefits accrue at various levels. The commenter concluded that effectively, the EPA could declare benefits below its selected threshold as too insufficiently established to be "influential" to its decision and impose an unsupported assumption that those benefits fall to zero.

The commenter asserted that EPA's proposal to consider only benefit endpoints with "clear" causal connections from scientific studies to estimate benefits, as well as EPA's focus on quantifying benefits and costs that are "most influential," is inappropriately restrictive, and could lead the EPA to reject scientific studies (e.g., epidemiological studies) that are informative for BCAs because they show a correlation but do not establish a causal relationship. The commenter supported considering best practices that allow for the use of the best available science (e.g., from the National Academy of Science) that might not meet the strict criteria for causality, but that can provide important evidence for BCAs on the relationship between pollutant exposure and human health. The commenter concluded that in this respect, the BCA Proposal effectively

imposes a causation standard for proving tort liability for known harms ex post that is inappropriate in rulemakings aimed at reducing risks of potential harms ex ante. Another commenter stated that the proposed requirements for selecting benefit endpoints and quantifying health benefits are arbitrary and would impose significant unanalyzed costs. The commenter stated that the proposed requirement in 40 CFR 83.3(a)(7) could entail significant costs and needed to be clarified, with key terms (e.g., "robust enough to support . . . quantification") undefined. The commenter asserted that the EPA must assess the costs to the EPA and the public under this provision of failing to regulate pollution that it is statutorily charged with addressing, or conducting superfluous analysis

A commenter contended that the proposal inappropriately winnows the health endpoints to be considered, and eschews long-standing, scientifically accepted principles for considering and evaluating the evidence of risk from environmental contaminants by limiting the endpoints and by introducing outcome-driven bases for selecting among and considering concentration-response functions. The commenter added that the proposal directive of including those "studies that do not find a significant concentration-response relationship" when there are multiple studies that satisfy its criteria for consideration are at odds with established scientific practice.

A commenter contended that with its proposed requirements for quantifying health endpoints to be included in a BCA, including the treatment and use of concentration-response studies, the EPA would arbitrarily and irreparably damage the quality of the analysis and misrepresent the evidence on which it relies. The commenter stated that such manipulation of input data would undermine and invalidate the integrity of any ensuing analysis and undermine a core endpoint considered in CAA rulemakings: human health.

A commenter contended that the EPA has a long history of applying a weight of evidence approach to causality determinations, recognizing, and valuing the strength of the approach's incorporation of multiple disciplines and lines of evidence. The commenter noted that in its 2008 *Integrated Science Assessment for Oxides of Nitrogen and Sulfur – Ecological Criteria*, the EPA lays out a causality framework to support assessing causality, providing a five-step weight of evidence framework for assessing causal determination, including causal relationship, likely to be a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and suggestive of no causal relationship. The commenter contended that with these new proposed requirements, the EPA is contradicting its own established methods for assessing causality, which have been endorsed by the scientific community and EPA science advisors. The commenter stated that the changes would rule out consideration of endpoints "suggestive of a causal relationship," an action that would arbitrarily and inappropriately undermine the judgment of scientists and other contributing experts in applying a full weight of evidence approach.

**Response:** This rule does not categorically exclude any specific types of scientific studies (e.g., epidemiological studies) from consideration in the process of selecting and quantifying health endpoints in benefits analysis. It also does not specifically require that EPA turn to particular documents (e.g., those prepared for the NAAQS process) for causality determinations. Rather, the final rule requires that the process of selecting and quantifying health endpoints for benefits analysis must be based upon an evaluation of scientific evidence that follows a systematic review process. The systematic review process is further discussed in Section V.E.7 of the preamble to the final rule.

**Comment:** Several commenters opposed an alternative requirement of solely including benefit endpoints for which there is a positive willingness-to-pay (WTP) conditional on the available scientific literature. A commenter stated that multiple critical endpoints cannot be translated into willingness to pay estimates, including as detailed in the *Guidelines for Preparing Economic Analyses.* The commenter concluded that this screening requirement would do nothing to aid in better-informing BCAs, but rather arbitrarily and inappropriately constrain efforts to conduct a full and detailed analysis. Another commenter stated that EPA's mission is to protect human health and the environment, not to improve utility in a more general sense. The commenter added that requiring scientific evidence of a link between pollutant and health effect, and reason to believe the regulation will change that effect, will ensure that EPA's rulemakings are transparent, grounded in sound science, and focused on the EPA's core mission.

A commenter recommended deleting the alternative approach that would select all endpoints for which there is a positive WTP condition on the available science literature or clarify that the same minimum quality/confidence standards for existence of an underlying causal physical relationship would apply before including any benefits estimate for an endpoint based on such a WTP finding.

**Response:** The final BCA rule does not contain an alternative requirement of solely including benefit endpoints for which there is a positive WTP conditional on the available scientific literature. The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. As discussed in Section V.B of the preamble to the final BCA rule, the EPA agrees with the SAB's recommendation, following 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's Circular A-4.

**Comment1**: A commenter urged the EPA to exercise caution in considering consumer behavior as a result of a rule, as an element of the cost analysis. The commenter contended that in most cases, such considerations are speculative and subjective, and potentially subject to manipulation. The commenter added that such an analysis should not be required but only used where there is sound science behind it.

**Response:** The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines. The final rule is clear that 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. The preamble goes on to discuss the tradeoffs involved. For example, 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.

**Comment**: A commenter questioned how the proposal requirements for concentration-response factors improve on what the EPA currently does without a rule. The commenter

questioned if there are differences, why the EPA was proposing to include or exclude them and if there are not, why it is necessary to codify them.

**Response:** The rule codifies best practices, ensuring EPA is consistent in its approach across CAA rulemakings and transparent in documenting its methods. In particular, the rule is in accordance with guidance from the National Academies of Science specifying the procedure EPA should follow for when selecting relevant health endpoints to quantify and epidemiologic studies from which to parametrize concentration-response relationships.

**Comment**: A commenter contended that the causal framework developed by the Clean Air Science Advisory Committee for reviewing National Ambient Air Quality Standards was not designed to inform cost benefit procedures. The commenter added that expert advisors initially developed the causal framework used by the EPA and the Clean Air Science Advisory Committee (CASAC) in the review of National Ambient Air Quality Standards (NAAQS). The commenter stated that no part of the framework was developed with an eye towards informing decisions in BCA. The commenter opposes the proposal to only select endpoints for inclusion in BCA based on a framework that was not developed for this purpose.

**Response:** This rule doesn't specifically require that EPA turn to documents prepared for the NAAQS process for causal determinations. Rather, the final rule requires that the process of selecting and quantifying health endpoints for benefits analysis must be based upon and evaluation of scientific evidence that follows a systematic review process. The preamble acknowledges that in cases where existing Agency documents (e.g., ISA for criteria pollutants) can provide the review and synthesis consistent with the systematic review process, the final rule allows a BCA to reference this synthesis.

**Comment:** A commenter stated that failing to include concentration-response functions derived from numerous studies collectively showing a positive association between ozone exposure and increased mortality risk is contrary to the stated objective of assessing all the costs and benefits of proposed Agency actions. The commenter added that despite near universal expert science and medical opinion, the most recent Integrated Science Assessment for ozone concluded that the impacts of ozone on mortality and cardiovascular morbidity was "suggestive" of a causal relationship as opposed to "likely" to have a causal relationship. The commenter contended that this downgraded causal determination from the assessment in the previous ISA science review was included in the final version of the document. The commenter added that in the current proposal, the EPA is attempting to draw a sharp line between what is "suggestive of" rather than a "likely" causal relationship when no such bright line exists. The commenter concluded that the evidence is more than sufficient to include ozone impacts on mortality in any BCAs.

**Response:** The rule is in accordance with National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments. As discussed in Section V.E.7 of the

preamble to the final BCA rule, the final rule requires the EPA to identify concentration-response relationships from the scientific literature that best characterize risk among the populations affected by the regulation, using clearly-defined criteria, making use of the breadth of the available evidence.

**Comment:** A commenter stated that because weight of evidence frameworks and the standard for causality are closely related, it is difficult to provide meaningful comments on the latter without knowing what the comments on the former, and EPA's response to such comments, will be.

**Response:** The rule is in accordance with National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments.

**Comment:** Several commenters requested additional clarification on requirements and definitions. A commenter stated subsection (a)(9)(vi) would require the EPA to select and identify concentration-response relationships "with the strongest scientific evidence, as well as evidence necessary to demonstrate the sensitivity of the choice of the concentration-response function on the magnitude and the uncertainty associated with air pollution-attributable effects." The commenter contended that the EPA does not define or provide any guidance as to how to determine the "strongest scientific evidence" in this context. The added that the language in the provision after "as well as" is not clear, including, in particular what "magnitude" is at issue and what the "sensitivity ... on" means. The commenter concluded that it is not possible to understand the meaning or import of this subsection or how it would operate resulting in the provisions being arbitrary and capricious and potentially unlawful, and the EPA should not adopt it.

A commenter stated that subsection (a)(7)(i) would require that any linkage between regulatory requirements and benefits be based on "a clear causal or likely causal relationship." The commenter contended that these terms are not adequately explained, and the restriction the provision would impose would artificially limit consideration of benefits of proposed CAA regulations. The commenter contended that this provision is arbitrary and capricious and potentially unlawful, and the EPA should not adopt it.

A commenter stated that subsection (a)(7) would require that regulatory requirements be linked to "the value that individuals place on the change in benefit endpoints that can be meaningfully attributed to those requirements". The commenter contended that the EPA provides no rationale for the limitation of benefit figures to "the value that individuals place on the change" and does not provide a definition or other indication of what "meaningfully attributed" means. Accordingly, this provision is arbitrary and capricious and potentially unlawful, and the EPA should not adopt it.

A commenter supported the proposal but contended that without further amendment, the provisions could be interpreted as free-standing criteria that could conflict with causal

framework criteria for determining which health endpoints should be quantified. The commenter suggested the following definitions to clarify the requirements:

> Causal – the evidence is sufficient to conclude that there is a causal relationship between the relevant pollutant exposure and the outcome. Causality is supported when an association has been observed between the pollutant and the outcome in studies in which chance, bias, and confounding could be ruled out with reasonable confidence, and when the animal and mechanistic evidence from studies in exposed humans is consistent with (i.e., not contradicted by) the epidemiologic evidence.
>
> Likely Causal – the weight of evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists, and the association cannot readily be explained by plausible noncausal alternatives (e.g., chance, bias, or confounding).

The commenter noted that the definition of "likely causal" recommended is based on the Institute of Medicine's (IOM) thorough, evidenced-based analysis of causality. The commenter added that the IOM recommended a systematic review of the evidence to determine the strength of the evidence using the following four categories:

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

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

**Response:** The rule is in accordance with National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments. As discussed in Section V.E.7 of the preamble to the final BCA rule, the final rule requires the EPA to identify concentration-response relationships from the scientific literature

that best characterize risk among the populations affected by the regulation, using clearly-defined criteria, making use of the breadth of the available evidence.

**Comment:** A commenter stated that subsection (a)(9)(v) would expressly restrict the EPA to consideration of one factor technical feasibility-when determining the number of alternative concentration-response functions quantified for each endpoint. The commenter contended that the EPA does not explain why this should be the sole factor, to the exclusion of other factors, perhaps including the cost of developing alternative functions. The commenter also stated that this restriction to consideration of only one factor is internally inconsistent, since in the preamble to the proposed rule, the EPA indicates that at least one other factor could be considered, namely, the "sensitivity of net benefits to the choice of concentration-response relationships." The commenter concluded that the provision is arbitrary and capricious and potentially unlawful, and the EPA should not adopt it.

**Response:** The rule is in accordance with National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments. As discussed in Section V.E.7 of the preamble to the final BCA rule, the final rule requires the EPA to identify concentration-response relationships from the scientific literature that best characterize risk among the populations affected by the regulation, using clearly-defined criteria, making use of the breadth of the available evidence.

**Comment:** A commenter stated that Subsection (a)(9)(ii) would require a description of the "sources, extent and magnitude of significant uncertainties associated with the assessment." The commenter added that the EPA does not define what "significant" means in this context, and the EPA could therefore interpret this requirement in an ad-hoc, biased way to inappropriately exclude appropriate information and practices from its preparation of BCAs. The commenter concluded that the provision is arbitrary and capricious and potentially unlawful, and the EPA should not adopt it.

**Response:** The rule is in accordance with National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments.

**Comment:** A commenter contended that the guidelines for which scientific studies can be used for the estimation of benefits is vague and potentially limiting. The commenter added that proving a true causal relationship in science described in this proposal as a requirement for selecting benefit endpoints is oftentimes impossible and causal language is commonly avoided by scientists as good practice.

**Response:** The rule is in accordance with National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air

pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments. As discussed in Section V.E.7 of the preamble to the final BCA rule, the final rule requires the EPA to identify concentration-response relationships from the scientific literature that best characterize risk among the populations affected by the regulation, using clearly-defined criteria, making use of the breadth of the available evidence. In the process for identifying studies the following aspects are preferred: (1) peer-reviewed and of higher quality based on criteria defined in the review protocol; (2) use of human data when available; (3) specification of the exposure route, duration, and levels, with preference given to those studies assessing exposure similar to those experienced by the general population; (4) employment of a design or analysis that adequately addresses relevant sources of potential critical confounding; (5) consideration of how exposure is measured, particularly those that provide measurements at the level of the individual and that provide actual measurements of exposure; and (6) the ability 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 concentration-response relationships and associated risk estimates. Consistent with the general principles of systematic review, the evaluation should emphasize transparency and replicability the evaluation process.

**Comment:** A commenter contended that the proposed rule would raise the bar and exclude any health or environmental endpoints that are slightly uncertain even if, despite the uncertainty, they might prove highly significant to the BCA. The commenter noted that this proposal is especially problematic given the controversial nature of some recent assessments of causality such as EPA's recent Integrated Science Assessment of Ozone downgraded the relationship between short-term ozone exposure and total mortality from "likely to be causal" (as determined in 2013) to just "suggestive of . . . a causal relationship." The commenter recommended that rather than excluding any benefit that falls slightly short of any particular determination of conclusive causality, EPA should continue—as instructed by OMB's Circular A-4 and its own Guidelines—to consider all important categories of costs and benefits, characterizing their likelihood when some uncertainty exists, and testing the sensitivity of the BCA to the inclusion, exclusion, or alteration of key assumptions around such estimates. A commenter said that the proposed rule intended to rely on a flawed integrated science assessment document to selectively remove mortality impacts attributable to ozone and future benefit calculations. The commenter contended that this flawed approach would not only fail to reflect the collective body of evidence regarding the adverse impacts of ozone, but would also compound the institutional shortcomings that were on display during the last review of the NAAQS for ozone in which there was no meaningful revision to the ISA based on contributions from qualified experts that participated in the public comment process.

The commenter added that at the same time that the proposed rule seeks to raise the bar on evidence of causality, the proposed rule also seeks to alter the standard for studies that suggest alternate concentration-response functions. The commenter opposed the proposed rule's specific references to "studies that do not find a significant concentration-response relationship" and to the use of "alternative" and "multiple" concentration response functions because it raises the prospect of sanctioning the use of studies that break from the consensus scientific understanding that many key pollutants have no clear threshold for safe exposure. The

commenter noted that EPA's Guidelines warns that focusing too much on outlier and tail-end risk estimates can lead to biased benefits estimates. The commenter added that the proposed rule incongruently seems willing to give weight to individual studies that break from consensus to find a lack of a concentration-response relationship, even as the proposed rule simultaneously raises the bar to demand scientific consensus on causality before considering benefit endpoints. The commenter concluded that the proposed rule departs from the best practices for economic analysis, which instead direct analysts to consider all important categories of effects while using sensitivity analysis and other tools to properly disclose and weigh uncertainty.

A commenter stated that the proposal (85 FR 35626, 40 CFR 83.3(a)(9)) would impose numerous new and amorphous criteria on EPA's use of concentration-response functions in selecting the health endpoints to quantify in its benefits analyses without any demonstration that these criteria will improve the EPA's ability to fulfill its statutory mandates. The commenter noted that 40 CFR 83.3(a)(9)(iii)(D) of the proposed rule applies specific criteria to concentration-response functions in epidemiological studies "that the study must assess the influence of confounders, that the study location must be appropriately matched to the analysis, and that the study population characteristics must be sufficiently similar to those of the analysis", but the proposal did not define any of these terms, leaving agency staff to guess at which studies would be "appropriately matched" in location or "sufficiently similar" in population characteristics (85 FR 35621). The commenter said that determining whether it is "technically feasible" to quantify alternative concentration-response relationships as required in proposed 40 CFR 83.3(a)(9)(v)) would add a step to EPA's assessment of the scientific evidence, and staff would have to ascertain which concentration-response function would have the greatest effect on benefits. The commenter contended that the EPA cannot finalize the rule without considering the costs to the EPA of running this gauntlet of analytical requirements, as well as the likely effect of the new requirements on public-health protections.

**Response:** The proposed rule would not raise or lower the bar on the inclusion of health or environmental endpoints in the BCA. Rather, the rule codifies current best practices, which themselves are based upon best practices encouraged by the National Research Council and Institute of Medicine, for identifying, synthesizing, and quantifying evidence for use in air pollution risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments.

**Comment**: A commenter noted that for many health effects linked to historically high levels of climate warming carbon dioxide, there is no EPA work to assess causality because EPA's leaders do not even acknowledge that the climate crisis is real and a threat to our health and the economy.

**Response:** This rulemaking's requirements pertaining to the assessment of causality are codifying what is already EPA current practice for health benefits analyses. The value of CO2 emissions changes resulting from a regulation has been included in EPA regulatory analyses since Advance Notice of Proposed Rulemaking: Regulating Greenhouse Gas Emissions under the Clean Air Act (73 FR 44353) published in July 2008. There is nothing in the final rule that would preclude the quantification or monetization of benefits (costs) arising from reductions (increases) in carbon dioxide and other greenhouse gas emissions in BCAs.

**Comment**: A commenter expressed concern that the proposals limitation on health endpoints will allow the EPA to exclude endpoints that do not meet the EPA's causality criteria. The commenter noted the EPA Administrator's recent use of an interpretation of causality widely condemned by the scientific community to justify his decision to retain the current National Ambient Air Quality Standard (NAAQS) for fine particulate matter ($PM_{2.5}$). The commenter stated that this decision was made despite overwhelming scientific evidence of increased mortality and morbidity at levels below that standard and EPA staff recommendations to the contrary, and codifying this provision would allow for a similar disregard or devaluation of benefits associated with reductions in exposure to $PM_{2.5}$ and other pollutants.

**Response:** The rule is in accordance with National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments. As discussed in section V.E.7 of the preamble to the final BCA rule, the final rule incorporates recommendations made by the SAB on the importance of using systematic review principles 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. Commenters are referred to the preamble for a detailed discussion of the benefit endpoints.

## 6.10 Uncertainty Analysis

**Comment:** Some commenters opposed EPA's proposal to include requirements at 40 CFR 83.3(a)(10) for an uncertainty analysis in the BCA as well as the requirements at 40 CFR 83.3(a)(11)(iv) for a detailed assessment and presentation of "sources of uncertainty that are likely to have a substantial effect on the results of the [benefit-cost analysis]". These commenters said these proposed provisions are arbitrary and at least one of these commenters also said these proposed revisions are capricious and not appropriate. A commenter argued that EPA's repeated emphasis on uncertainty seems designed to, and may result in, inappropriate disregard of, or inappropriate reduction in the weight or consideration given to, certain benefits due to an excessive concern with uncertainty and an unrealizable desire for certainty in scientific, medical, or other analysis or evaluation, with the result of biasing BCA in favor of costs and against approval of proposed actions. Another commenter said the EPA unjustifiably weights the burden of uncertainty assessment on benefits rather than costs, placing more prescriptive requirements on the analysis of the uncertainty of benefits which will likely skew the assessment of uncertainty towards benefits more than costs, depicting benefits as more uncertain than costs.

A commenter said that the EPA has not provided any basis to conclude that EPA's identification and analysis of uncertainties in the past has been inadequate, so there is no demonstrated need for the provision at 40 CFR 83.3(a)(10). The commenter said the EPA has not defined or provided any other guidance as to what it means by "feasible" when it requires that the EPA use quantitative methods to analyze uncertainty " to the extent feasible" or uses that term elsewhere in this subsection. The commenter said it may be "feasible" to use quantitative methods for this purpose but unreasonable because of cost or other factors.

With regard to the proposed requirements at 40 CFR 83.3(a)(10)(iii), a commenter said that where cost or benefits are known to be jointly distributed, the proposal would require the EPA to complete an uncertainty analysis assuming they are independently distributed; however, the commenter argued that this is not technically correct analysis and could potentially lead to a significant overestimation of the uncertainty of the BCA results.

With regard to the proposed requirements at 40 CFR 83.3(a)(10)(v), a commenter argued the EPA has provided no basis to conclude that the EPA's past work has been inadequate on the EPA characterizing how probability distributions for input assumptions impact distribution of benefits and costs. The commenter said the EPA has not provided any discussion of the benefits and costs of this requirement or otherwise justified this requirement, and the EPA has not even discussed the extent to which this evaluation of the relationship between input and output distributions could even be done.

A commenter argued that the EPA has not defined or provided any other guidance on how to determine a "substantial" effect as used in context with the requirements in 40 CFR 83.3(a)(11)(iv). The commenter said the EPA has presented no basis for concluding that in the past the EPA has not given due consideration to uncertainty, or has not adequately discussed it in its BCAs, consistent with EPA's guidelines for preparing economic analyses.

Finally, a commenter said uncertainty should be recognized as an accepted element of scientific research, as long as research has been conducted according to accepted scientific methods and has undergone peer review. The commenter argued that because researchers cannot measure every individual's exposure or every confounding factor in a population-based epidemiological study, the key factor is to address the known uncertainties and limitations, and make sure those are transparent and scientifically valid and the studies are evaluated in the context of the current status of scientific evidence. The commenter said that the proposal would vastly exceed these well-accepted principles by requiring regulators to estimate the influence of uncertainties on results for specific studies.

A commenter opposed EPA's proposal to include requirements at 40 CFR 83.3(a)(10) for an uncertainty analysis in the BCA because it is an attempt to dictate rigid, judicially enforceable analytical requirements. A commenter said the proposal requires seemingly endless layers of analyses, directing that multiple facets of uncertainty be quantitatively characterized and mandating that sources of uncertainty be considered "independently as well as jointly" as much as possible; and also imposes numerous explanatory burdens, stipulating that the EPA "must include a reasoned explanation for the scope of the uncertainty analysis" and must justify departures from the proposed preference for quantitative analyses.

A commenter also argued that the proposal to include an uncertainty analysis in the BCA potentially imports substantive constraints and judgements under the guise of characterizing uncertainty. The commenter provided an example where in directing that "BCAs characterize how the probability distributions of the relevant input assumption uncertainty would impact the resulting distribution of benefit and cost estimates," the proposal dictates that the EPA enlist "probability distributions for relevant input assumptions" where these "are available, characterize significant sources of uncertainty in the assessment, and can be feasibly and credibly combined." The commenter said that in a related vein, in its request for additional comments, the

EPA asks whether it should impose additional requirements to assess "uncertainty in risk analyses (e.g., . . . requirements relating to the use of probabilistic risk analysis for reducing uncertainty in risk analysis)?" The commenter said that such requirements are reductionist and often inaccurately reflect actual risks experienced by sensitive populations, including those with increased susceptibility and/or exposure to air pollutants.

A commenter also said including requirements for an uncertainty analysis in the BCA are excessively burdensome and wasteful, with the proverbial tail of uncertainty analysis wagging the dog of EPA rulemaking. The commenter argued that EPA will have to expend considerable time and resources attempting to satisfy the proposal requirements or justify departures from them – lest it leave itself vulnerable to litigation by those seeking any opportunity to challenge the agency's work; and the unsurprising result will be fruitless delays in rulemakings under the CAA, undermining its efficient implementation.

Finally, a commenter argued that an uncertainty analysis in the BCA would result in defeating the CAA's goals. The commenter said the proposed analytical requirements will influence substantive outcomes, as the EPA either enlists its prescribed methods (e.g., probabilistic risk analysis and combined probability distributions) or engages in strategic self-censorship to avoid the legal risks of more protective rules.

Commenters supported EPA's proposal to include requirements at 40 CFR 83.3(a)(10) for an uncertainty analysis in the BCA. Some of these commenters said that EPA should include relevant ranges and ancillary benefits as part of the results of cost benefit analyses. Some of these commenters provided more context for this support and others provided additional suggestions for including an uncertainty analysis in the BCA:

- A commenter encouraged EPA to use probability distributions of risk when calculating benefits; and the commenter said assumptions embedded in the EPA's Benefits Mapping (BenMAP) tool about how benefits are estimated should not be neglected by the EPA in its uncertainty assessment. The commenter suggested EPA refer to the Clean Air Scientific Advisory Committee's comments on the risk assessment section of the Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft, September 2019 for examples of concerns about applying benefits estimates to regulatory assessments.
- A commenter said numerous EPA Science Advisory Board and NAS reports have recommended EPA consider this uncertainty in addition to traditional analysis around data variability and uncertainty. The commenter pointed to Science and Decisions, Chapter 4. NEDA/CAP on "Increasing Consistency and Transparency in Considering Benefits & Costs in the CAA Rulemaking Process" Docket No. EPA-HQ-OAR-2020-00044 Aug. 3, 2020.
- A commenter said inconsistency in EPA's conduct of uncertainty analysis in the BCA for previous CAA regulatory actions undermines public understanding and confidence in the regulatory process. The commenter recommended that the BCA should catalogue the major sources of uncertainty and variability in the BCA and any underlying risk assessment, consistent with the NRC's recommendations; and the EPA should also quantify the effect of the major sources of uncertainty and variability on the risk estimates, benefit estimates, and cost estimates. The commenter argued that by providing this information, EPA can better

demonstrate how the CAA regulatory action is expected to provide more benefits than costs and under what conditions net benefits will occur.

- A commenter said that EPA can improve its position as an authority on regulations by being clear about key assumptions that drive these analyses, as well as a frank disclosure of uncertainty or risk in the models used and how that may influence decision making. The commenter argued that there should be standard protocol for EPA to publish clear and understandable discussion of the uncertainties inherent in all "benefit" calculations and what that means to the public; and in order to avoid the false appearance of certainty, the Agency should clearly discuss statistical error and variance in predicted economic impacts.
- A commenter said that BCAs, while not prescribed in the CAA, should include endpoints for which the "scientific evidence indicates there is a clear causal or likely causal relationship between pollutant exposure and effect" as this is typical practice in review of National Ambient Air Quality Standards;[17] however, BCAs should not be limited to only such endpoints. The commenter argued that uncertainties for the effects of endpoints for which evidence of causality is suggestive would be expected to be more uncertain than those that are causal or likely to be causal, but such uncertainties can be accounted for, in principle, as part of quantitative or qualitative uncertainty analysis.

A commenter said they support advancement of provisions that require: (1) characterization of the potential model uncertainty in concentration-response functions (CRFs) across studies and models; and (2) identification and analysis of uncertainties underlying BCA projections, and use of benefit/cost probability distributions and associated communication of input sensitivities.

**Response:** As discussed in Section V.E.8 of the preamble to the final BCA rule, the SAB made several recommendations related to the proposed requirements for uncertainty analysis. First, the SAB recommended the preamble of the final rule discuss the broader purposes of uncertainty analysis beyond simple transparency. Second, the SAB explained that since 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 and EPA's Guidelines, which are the existing peer reviewed guidance

[17] The commenter provided the following link: https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf

documents implementing EO 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 possible 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 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 independently as well as jointly. The BCA should also discuss the extent to which qualitatively assessed costs or benefits are characterized by uncertainty.

### 6.11 Hurdle Rate

**Comment:** Commenters supported the use of OMB's current standard discount rates of 3 percent and 7 percent in OMB's Circular A-4. Another commenter said a base-case rate of 7 percent is reasonable, based on the marginal rate of return to private capital in the economy.

A commenter argued that it is not correct to treat OMB's two discount rates (i.e., 3% and 7%) as a range because the rates represent empirically derived estimates of two different "prices," that apply to two different goods.

A commenter argued that the true NPV is not somewhere in between the NPVs calculated at a discount rate of 3% and 7%. The commenter said the EPA mistakenly embraces this view in its Guidelines for Economic Analysis (p. 6-19) because the guidelines say that in most cases the results of applying the more detailed "shadow price of capital" approach will lie somewhere between the NPV estimates ignoring the opportunity costs of capital displacements and discounting all costs and benefits using these two alternative discount rates. The commenter contended that with a complex temporal pattern of benefits and costs, including capital costs, there is no reason to think that the math will work out as viewed in the Guidelines for Economic Analysis. The commenter argued that although "ignoring" the opportunity costs of capital will result in an underestimate of total costs, using the 7% RRC to discount all costs and benefits could result in either an overstatement or an understatement of the correctly calculated NPV.

Another commenter stated that the EPA should recognize that the private return on equities is the best measure of opportunity cost of capital for typical CAA regulatory actions.

The commenter contended that EPA's best practices for discounting must recognize that rates below return on private equity will drive business investment outside of the U.S., with corresponding environmental and social impacts, reduce the market incentive to innovate, etc. The commenter added that since most environmental regulation redirects private parties' spending, the private return on equity is a more valid measure the opportunity costs than broad-based, intergenerational measures of spending preferences.

**Response:** The EPA is codifying into regulation general best practices consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866). The final rule does not replace any detailed recommendations for Agency analysis included in these existing guidances. Detailed recommendations regarding the appropriate discount rate to use in the analysis is one example of a topic that is discussed in the existing guidance documents and not addressed in the final rule.

**Comment:** A commenter argued that consumption costs should not be discounted at 3%, and capital costs at 7% because capital costs have a higher opportunity cost than pure consumption; therefore, discounting them at 7 percent would make them appear smaller relative to other costs.

A commenter said that although discounting benefits that flow from a capital investment at 7% is a common practice and is consistent with OMB guidance, it is analytically incorrect. The commenter argued that if there are two options to eliminate a particular workplace hazard: one is a costly change in operating procedures, the other is a piece of capital equipment, then the analysis should not pretend that the benefits are different. The commenter said in this scenario, there will be extra costs associated with capital investments, but those should appear on the cost side of the ledger; and the NPV of benefits alone should not be affected by how we choose to purchase them.

A commenter argued that it is not always true that there is a partial displacement if a dollar-for-dollar displacement of private capital is not assumed because the capital displacement may be well above 100%. The commenter suggested that the EPA be careful to maintain the distinction between prices (the discount rate) and quantities (amount of displaced capital), rather than try to adjust one to compensate for assumed misestimates in the other.

**Response:** The EPA is codifying into regulation general best practices consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866). The final rule does not replace any detailed recommendations for Agency analysis included in these existing guidances. Detailed recommendations regarding the appropriate time horizon to use in the analysis is one example of a topic that is discussed in the existing guidance documents and not addressed in the final rule.

**Comment:** A commenter argued that the Lind-82 SPC approach (i.e., the "simple SPC method" that OMB adopted) should not apply to an open economy like the U.S., which can easily borrow overseas. The commenter said that it is true that the Lind-82 treatment is based on a closed-economy model, in which the supply of capital is constrained and therefore carries a

shadow price. The commenter said we can think of this shadow price as capturing the "positive externalities" of scarce private investment, which mostly take the form of extra tax revenues to domestic governments. The commenter argued however that when U.S. companies borrow overseas, some of those positive tax externalities are exported, rather than displaced; therefore, from the point of view of a domestic BCA, those exported externalities still represent a loss and the shadow price (when our supply of capital is constrained) has simply been replaced by a real price (when we go out and buy more capital abroad). The commenter said that the full treatment of these effects would require a complex analysis of tax structures across the world and their interactions, as well as the varying rates of saving in different economies and cultures; this may be a good project for OMB, CEA, and Treasury to pursue, but it is not a project to undertake within the confines of an RIA. The commenter said that for RIA purposes, agencies should assume that the empirically derived OMB guidance on discount rates accurately captures the underlying costs to the U.S. economy.

A commenter argued that although the Lind-82 SPC approach (i.e., the "simple SPC method" that OMB adopted) requires a general equilibrium analysis,[18] agencies should use the Mazur-87 method[19] because it does not need a General Equilibrium model to apply those prices in the microeconomic analysis of a particular rule.

The commenter argued that the SRTP and the RRC is a complex undertaking, but using them correctly in a regulatory analysis is relatively simple if you use the Mazur-87 method. The commenter said that the Mazur-87 method makes the Lind-82 SPC approach more practical as well as more accurate. The commenter said that for short term capital commitments, the NPV using the Mazur-87 method becomes indistinguishable from consumption; and as the duration of the capital commitment gets longer, the additional opportunity costs grow larger. The commenter said that for very long-term capital investments the Mazur-87 approach is identical to the Lind-82 SPC approach. The commenter said Mazur's methodology makes it clear that the major weakness of the Lind-82 SPC approach was not that it assumed 100 percent displacement of private capital, but that it implicitly assumed permanent displacement. The commenter said that the Lind-82 SPC approach errs by ignoring the time dimension of capital commitments, which is the essential feature that distinguishes them from consumption.

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation general best practices consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866). The final rule does not replace any detailed recommendations for Agency analysis included in these existing guidances. Detailed

[18] The commenter cited Lind, R.C., ed. Discounting for Time and Risk in Energy Policy. Washington, DC: Resources for the Future, 1982.

[19] The commenter cited the first footnote in OMB's original Regulatory Impact Analysis Guidance in Appendix V in the Regulatory Program of the U.S. Government (April 1, 1988 – March 31, 1989). The commenter said this 1988 guidance introduced OMB's two discount rates, but it omitted critical instructions that Mike Mazur had drafted, shortly before his death in 1987, about how to use them properly. The commenter provides detailed methodology for using Mike Mazur's 1987 drafted instructions.

recommendations regarding discounting is one example of a topic that is discussed in the existing guidance documents and not addressed in the final rule.

## 6.12 Scientific Peer Review

**Comment:** Several commenters recommended the EPA require a peer review of the BCA. Some commenters said BCAs and risk assessments should undergo peer review in accordance with EPA's Peer Review Handbook which has stipulations[20] regarding technical expertise; and adherence to the Handbook will further ensure adherence to best practices. A commenter said solid, unbiased scientific information and peer review is key to developing honest risk-assessments, cost estimates and smarter regulations. A commenter said employing balanced peer review and scientific advisory panels when evaluating rules will ensure outdated, partial or flawed studies do not influence our public policies; and an open and honest regulatory process allows public stakeholders to understand the cost-benefit and engage in a clear dialogue about methods and data. A commenter said neutrality is important in determining whether or not there is sufficient justification for proposed regulations; and verification of economic data from a party which neither supports nor opposes the regulation in question will provide an increased level of certainty to the rulemaking process and also help bolster the record for regulations in the event of litigation.

**Response:** The rule is in accordance with the National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments.

**Comment:** A commenter said a journal "peer review" is not adequate. The commenter said the Information Quality Act Peer Review Guidelines require that any Highly Influential Scientific Assessment (HISA) used by the EPA be independently reviewed and also require that any model be available to the public without fee. The commenter said the ICF IPM model does not meet this requirement and cannot be used by the EPA is any policy related analysis.

**Response:** This comment is out of scope of the BCA rulemaking.

**Comment:** A commenter said that although using thoroughly peer-reviewed science is a best practice in setting regulatory requirements, actions to control emerging pollutants may be required prior to a lengthy peer-review process. The commenter said the EPA should not hinder its ability to control dangerous, toxic, and deadly pollutants while waiting for the full quantification of exposure and health impacts, and the extensive epidemiological understanding that would be required under the proposed rule. The commenter said pollutants may have numerous variants, only some of which have been studied and quantified; and requiring studies

[20] The commenter cited US EPA Peer Review Handbook, 4th Edition. Science and Technology Policy Council. October 2015. EPA/100/B-15/001. Page 20. "It is conducted by qualified individuals (or organizations) who are independent of those who performed the work and who are collectively equivalent in technical expertise to those who performed the original work (i.e., peers)."

to precisely match the pollutant(s) in question, limits or eliminates the ability to quantify or monetize impacts that may be substantially similar.

**Response:** The rule is in accordance with the National Research Council and Institute of Medicine developed best practices for identifying and synthesizing evidence for use in air pollution risk assessments. The rule also specifies minimum criteria that such evidence must meet for EPA to use this information to support risk assessments. Taken together, following these guidelines will ensure the EPA follows best practices for performing air pollution risk assessments.

**Comment:** A commenter argued that the EPA should demonstrate that it provided the SAB with the proposed rule no later than when it was sent to any other federal agency for review and comment and that the SAB has had an opportunity to review and comment on the proposed rule. The commenter said that under ERDA, the administrator is required to notify the SAB of Planned Actions at the time it sends those actions for formal review by other agencies.

**Response:** In response to commenters' statements that the proposed rule must be provided to the Science Advisory Board (SAB) for review, the proposed rule was presented to the SAB on August 11, 2020. The SAB submitted a report with comments on the proposed rule to the EPA on September 30, 2020. The preamble to the final rule contains a discussion of several of these SAB comments and responses, in particular in Section V.C.

## 6.13 Overarching Best Practices

**Comment**: Commenters supported the provisions that require preservation of the Administrators ultimate judgement in making regulatory decisions, irrespective of whether central estimates of net benefits exceed a proposed rule's costs.

**Response:** The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The BCA merely identifies procedures to be used when conducting a BCA, and does not institute specific criteria to make decisions.

**Comment:** A commenter supported requiring a BCA for regulations to maximize transparency even when it is not required. The commenter explained that the CAA prohibits the consideration of costs in establishing National Ambient Air Quality Standards, but for transparency, the costs of meeting the NAAQS should still be shown. The commenter also added that if a BCA is not explicitly prohibited, or called for in major rule makings, one should be done for consistency.

**Response:** The EPA agrees with the comment. The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The BCA merely identifies procedures to be used when conducting a BCA, and does not institute specific criteria to make decisions and is not required when expressly prohibited.

**Comment:** A commenter contended that it is important that the EPA does not impose costs that are disproportionally cumbersome and expensive on smaller businesses compared to

larger companies. Another commenter added that aggregate analyses can mask significant economic impacts on small entities. Several commenters supported incorporating elements of the Regulatory Flexibility Act (RFA) into this rule, to directly address the disproportionate impacts that regulatory decisions can have on small entities. A commenter explained that the RFA requires the EPA to "solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration," suggesting that impacts on small entities should be given substantial weight. The commenter concluded that the EPA should present the impacts of small entities alongside the impacts directly addressed in this proposed rule so that the public can transparently understand the way that the EPA has weighed impacts on small entities in its regulatory decisions. The commenter noted that an accurate description of small entities in a regulated industry is also crucial to credible cost assessment. The commenter stated that a cost assessment based only on the behavior of large entities in response to new regulatory mandates risks mischaracterizing the economic impacts of a regulatory proposal on small entities, raising questions about the aggregate economic impacts as well. The commenter recommended that a BCA always have a description of regulated industries, including where feasible the number of small entities regulated and how they differ from large businesses in the same industry. Another commenter added that the RFA's screening analysis would complement the proposed rule such as the required screening analysis. The commenter recommended that section 83.3(a)-(b) should include identification of (1) the reasons why the EPA is considering the action, (2) the objectives and legal basis for the proposed rule, (3) the kind and the number of small entities to which the proposed rule will apply; (4) the projected reporting, recordkeeping and other compliance requirements of the proposed rule, and (5) all federal rules that may duplicate, overlap or conflict with the proposed rule. The commenter added that the EPA should include robust information and data collection efforts upfront targeting input from small entities. The commenter noted that small entities often experience difficulties understanding the true impact of regulations, especially when multiple linked rules are issued affecting the power sector. The commenter recommended the BCA should analyze the benefits and costs of linked rules in the EPA's analysis because analyzing multiple rules as if they were one rule simplifies the baseline specification, comparing them to the world in which none of the linked rules are in place.

**Response:** The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. Each of these include discussion on the consideration of alternatives that may, for example, assess different size of businesses. Section II.A of the preamble of the final rule provides further information on this topic. Also, CAA rules will continue to comply with the requirements of the Regulatory Flexibility Act so it is unclear why an additional requirements specific to small entities is needed in this final rule.

**Comment:** A commenter contended that because regulation is not cost free, faulty cost-benefit assessments can result in a serious misallocation of resources with perverse policy consequences and the commenter fully supported the application of cost-benefit analysis based on sound economic assumption in regulatory rulemaking.

**Response:** We thank the commenters for their observations. The EPA is codifying into regulation best practices for the development of BCAs consistent with the existing guidances that

EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866).

**Comment:** A commenter conceded that it may be appropriate for the EPA to provide for deviations from strict observation of the requirements of this rule in particular rulemakings. However, the commenter expressed concern that this proposal (in both the preamble and the proposed regulatory text) at times provides for deviations without establishing a sufficient threshold for deviating or parameters to guide the degree of deviation. The commenter stated that if the EPA in the future relies on these exceptions too frequently, they may swallow the rule and frustrate its purpose of bringing consistency and transparency to the consideration of benefits and costs in CAA rulemaking. The commenter noted the following:

- 85 Fed. Reg. at 35,617/3 & Proposed 40 CFR 83.3(b) - which proposes to require only a "reasoned explanation" for a particular BCA to depart from best practices.
- 85 Fed. Reg. at 35,618/2 - "It will not always be possible to express in monetary units all of the important benefits and costs. When it is not . . . ."
- 85 Fed. Reg. at 35,618/3 - where the EPA does not analyze at least three regulatory options, the analysis "must explain why it is not appropriate to consider more alternatives."
- 85 Fed. Reg. at 35,620/3 & Proposed 40 CFR 83.3(a)(8) - BCA will follow the prescribed methodology "as well as practicable in a given rulemaking." 85 Fed. Reg. at 35,622/1 & Proposed 40 CFR 83.3(a)(12) (EPA will protect "other privileged, non-exempt information," with no further definition or constraint on the scope of information to be withheld from public disclosure).
- 85 Fed. Reg. at Proposed 40 CFR 83.3(a)(1)(iii) - BCA must include an assessment of regulatory options' benefits and costs relative to the baseline "[t]o the extent feasible."

The commenter concluded that the EPA should establish some threshold of legitimacy and limited frequency for deviations from full compliance with this rule—for instance, by enumerating in more detail the set of legitimate reasons for deviating, and/or explicitly stating the "fallback" methodology that will be employed in the case of a deviation from the rule's full requirements.

**Response:** None of the public 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 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The BCA merely identifies procedures to be used when conducting a BCA, and does not institute specific criteria to make decisions. OMB's Circular A-4 acknowledges that professional judgement will sometimes be necessary in conducting a BCA. "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." (p.3)

**Comment:** Commenters contended that the inherent inflexibility of EPA's proposed BCA process could ultimately prove detrimental to public health and the environment. The commenter stated that a flexible analytical framework respects that not all sources of air pollution respond to the same control technologies, not all types of air pollution cause the same types of harms, and not all public health impacts are distributed uniformly across all communities.

**Response:** The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The BCA merely identifies procedures to be used when conducting a BCA, and does not institute specific criteria to make decisions. 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., EO 12866), OMB Circulars (e.g., OMB's Circular A-4), and EPA documents (e.g., EPA's Guidelines).

**Comment:** A commenter suggested that the EPA account for lifetime loss of earnings instead of assuming that any worker displaced as a result of regulation will immediately be rehired elsewhere at the same wage.

**Response:** We thank the commenters for their suggestions. We typically analyze employment impacts and other distributional impacts for rules that warrant this type of analysis, particularly in the EIA for a rulemaking. However, this rulemaking is focused on BCA, and does not address EIA or other types of analysis conducted pursuant to executive orders or statutory requirements.

**Comment:** A commenter recommended that regulators should be removed as the sole adjudicators of estimating cost-effectiveness because there is a perception that regulators could bias the analyses to recognize only those costs which will support the rules and regulations that the regulators have already committed to in federal or state implementation plans and/or local air quality management plans. The commenter stated that the responsibility for calculating "cost effectiveness" should at least be a shared responsibility with recognized entities in the business sector that is being most affected by a particular rule or regulation. The commenter added that if peer reviews are believed to be necessary, then the findings, or conclusions by these private entities could be scrutinized by scholarly experts in recognized economic or academic institutions.

**Response:** EPA disagrees with the comment. EPA notes that the business sector and the general public have the opportunity to comment on the draft BCA as part of a proposed rule. EPA must consider the public's comments and address concerns as appropriate and consistent with this final rule. Also, the comment is outside the purview of the rule as it refers to cost-effectiveness, not BCA.

**Comment:** A commenter requested clarification on whether it intends to require that adverse public health or welfare outcomes be considered on the costs or benefits side of the analysis. The commenter stated that while the absolute math does not change, by including them as a cost, it will make the costs of the rule seem larger. The commenter added that cost is generally considered as the cost to comply, so it is more appropriate to include adverse public health and welfare benefits as a negative on the benefits side of the ledger. To the extent there are negative benefits, that will reduce the total amount of benefits, which is a more straightforward approach for the analysis.

**Response:** The final rule notes that 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. This is consistent with best practices for treatment of "Ancillary Benefits and Countervailing Risks" in OMB's Circular A-4. .

**Comment:** Commenters stated that any proposed rule should consider differences among areas of the country where the regulation will be implemented. A commenter contended that this has been a problem with EPA regulations in the past where the EPA sought to apply a single numeric standard to the entire United States. Commenters stated that in order for proposed regulations to be more workable, they need to be flexible enough to recognize unique aspects of the localities charged with their implementation.

**Response:** None of the comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation general best practices consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866). The final rule does not replace any detailed recommendations for EPA's analysis included in these existing guidances. How best to consider differences among areas of the country where a future regulation will be implemented is beyond the scope of this rulemaking.

**Comment:** A commenter contended that the EPA should make explicit, in both the preamble and the text of its final regulations, how it has tailored the requirements to appropriately balance the policy of ensuring significant rules are informed by rigorous and replicable BCA with the policy of ensuring important rulemakings can proceed reasonably expeditiously.

**Response:** The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The BCA merely identifies procedures to be used when conducting a BCA, and does not institute specific criteria to make decisions.

**Comment:** A commenter recommended the EPA annually publish a report in the Federal Register detailing the EPA's progress in conducting BCAs on a specified timetable, and ensure that any changes to the codified requirements must follow formal rulemaking procedures.

**Response:** The EPA disagrees that an annual report in the Federal Register detailing the EPA's progress in conducting BCAs is necessary in this rulemaking. All significant CAA rulemakings will continue to follow formal rulemaking procedures.

**Comment:** A commenter contended that several of the proposal requirements will cause delay and promoting wasteful litigation, including those relating to defining the right "baseline scenario" for the analysis, the procedures for "quantifying health endpoints," and the requirements for "uncertainty analysis." The commenter also objected to the repeated requirement that the EPA provide a "reasoned explanation" for any departures from the procedural analytical requirements when the proposal does not make clear what would constitute a "reasoned explanation."

**Response:** The EPA disagrees with the comment. The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. These guidance documents also provide additional discussion of each topic, such as the considerations regarding baselines and the use of multiple baselines.

**Comment:** A commenter contended that net benefits cannot be meaningfully calculated unless all significant costs and benefits can be expressed in monetary terms. The commenter noted that kind of complete monetization is rare to nonexistent in EPA rulemakings. The commenter concluded that a codified requirement that the EPA present a net-benefits calculation for every significant rule would only serve to further deemphasize and obscure the many important categories of regulatory benefits that the EPA is only able to describe in qualitative terms.

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation BCA procedures that are already prescribed as best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The final rule requires that BCAs provide available evidence on all non-monetized and non-quantified benefits and costs, including why they are not being monetized or quantified and what the potential impact of those benefits and costs might be on the overall results of the BCA.

**Comment:** A commenter contended that the EPA ignored opportunities for improving the EPA's BCA when those improvements would have the effect of supporting stronger rules. The commenter listed such "best practices" might include better accounting tools for qualitatively described benefits or new analytic approaches that would give greater attention to cumulative burdens suffered by historically marginalized groups and other similar distributional concerns.

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation procedures that are consistent

with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines.

**Comment:** A commenter contended that the proposal unrealistically assumes that the EPA has ready access to extensive comprehensive and granular data on the precise impacts to human and ecological health caused by each of the hundreds of pollutants it regulates. The commenter noted that a close review of the EPA's past BCAs indicates the large data gaps under which the EPA must operate. The commenter concluded that despite these clear data gaps, the proposal nonetheless assumes that complete quantification and monetization is the norm and that departures are the rare exception. The commenter added that Congress was well aware of the data gaps the EPA will face in measuring regulatory impacts when it wrote the original CAA, as well as the law's later updates resulting in Congress choosing to build the statute around a distinctly precautionary approach. The commenter contended that by adopting its myopic focus on quantification and monetization, the proposal thus flies in the face of that conscious policy choice by Congress and undermines the precautionary approach embedded in the CAA.

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA disagrees that the proposal assumes quantification and monetization is the norm. The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines. The final rule requires that BCAs must provide available evidence on all non-monetized and non-quantified benefits and costs, including why they are not being monetized or quantified and what the potential impact of those benefits and costs might be on the overall results of the BCA.

**Comment:** A commenter stated that the EPA should provide proper justification in its BCA of why a given course of action responds to direction from Congress, including prerequisites to regulations like an examination of whether regulation would be "appropriate and necessary." The commenter added that these analyses should examine all reasonably feasible alternatives after performing cost-effectiveness analysis of various alternatives discussed. The commenter stated that not thoroughly discussing and disclosing all the costs of a given regulation renders BCA an ineffective tool where almost any regulatory decisions could be justified in light of alleged "net benefits" they provide to society.

**Response:** The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The BCA merely identifies procedures to be used when conducting a BCA, and does not institute specific criteria to make decisions.

**Comment:** A commenter expressed concern that too much discretion will be allowed for governmental agencies undertaking a BCA, resulting in undermining the analytic rigor of the BCA. The commenter explained that the rule does not give parameters as to how the EPA should consider economic behavior or require it to state assumptions and reasoning regarding behavioral changes from policy scenarios. The commenter explained that potential effects on consumer and producer behavior are among the most speculative elements of a BCA and without requirements to state implicit assumptions, methodologies, and analysis, this new rule will certainly result in a lack of transparency as to the assumptions included in a BCA's overall calculus and surely lead

to inconsistencies in how this consideration is conducted between BCAs. The commenter contended that the proposed rule engages in virtually no analysis of its likely impacts on the net outcome of the BCAs of future rules. The commenter added that without an explicit textual understanding of what outcomes the rule might necessitate, commenters are left to rely on public statements to decipher the proposed rule's intent. The commenter noted that the EPA stated that the rule would focus on weighing only the economic impact of a proposed action, without taking into account some possible benefits such as public health, despite the CAA's purpose to protect and enhance the quality of our air and promote public health.

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines.

**Comment:** A commenter contended that the proposal pays very little attention to distributional analysis, yet such analysis is required by the guidance documents it discusses. The commenter noted that distributional analysis is an important supplement to BCA: BCA focuses on total net benefits and does not indicate who gains and who losses. The commenter added that EO 12866, which establishes the requirements for regulatory analysis, notes that "...agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)". The commenter also cited OMB's implementing guidance in OMB's Circular A-4 which notes that "...regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency."

**Response:** None of the public comments received have led the EPA to materially change its views from the proposal. The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines.

**Comment:** A commenter contended that the EPA must make decisions according to criteria provided in the CAA and CAA provisions do not call for making decisions according to BCAs, and often limit how or whether costs may be considered. The commenter added that where consideration of BCA is appropriate, it should be one of multiple inputs to decision-making, not the sole criterion. The commenter added that the EPA should not elevate economic efficiency considerations over all others, and should give substantial weight to equity considerations – including who benefits and who loses from pollution -- both in its economic analyses and in its decision-making, whenever permissible under the law. The commenter recommended that whenever permissible, the EPA should give strong weight to unquantified health and environmental risks and to unquantified benefits of regulatory action.

**Response:** The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866. The BCA merely identifies procedures to be used when conducting a BCA, and does not institute specific criteria to make decisions.

**Comment:** A commenter supported some kind of a regular annual or biannual review of the BCA and public hearings to revise that and update it, stating that it should be an integral part of the rule.

A commenter stated that the EPA should design a process by which its economic analysis are independently verified. The commenter contended that neutrality is important in determining whether or not there is a significant justification for proposed regulations.

A commenter urged the EPA to commit to using BCA to inform its development of regulatory options at the early stage of a rulemaking, rather than only creating a BCA at the conclusion to justify the EPA's choice of preferred option.

**Response:** The EPA disagrees with the comment. The EPA is codifying into regulation a procedure that is already prescribed as a best practice in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866, and to be required of significant rulemaking actions as defined in section III.B of the preamble.

# 7.0 Best Practices – Risk Assessment

## 7.1 Incorporating Risk Assessments

**Comment:** Several commenters supported the EPA adopting the best practices to characterize risk. A commenter added that risk assessments should use the best available science, be transparent, and capable of being reproduced.

The commenter added that the best available science includes a weight of the scientific evidence approach as an integral component of effective BCAs including the use of probabilistic risk analysis for reducing uncertainty in risk analysis. The commenter continued that codifying the selection criteria for selecting among studies characterizing concentration-response relationships and a more standardized approach for synthesizing evidence across the literature will also further increase transparency and credibility of risk assessments used in rulemaking.

A commenter encouraged the EPA to include detail concerning the best practices in the preamble of the final rulemaking and in the regulatory text. The commenter specifically requested promulgate language that guarantees all underlying risk assessments supporting significant CAA regulation, especially those that provide key inputs to the development of the EPA's health benefit estimates in the BCAs, are consistent with best practices.

**Response:** We thank the commenters for their support. Regarding the comment that EPA promulgate language that guarantees all underlying risk assessments supporting significant CAA regulation are consistent with best practices, we note that the BCA final rule is solely concerned with codifying the best practices for conducting a BCA and does not provide direction on conducting a risk assessment or cover the underlying risk assessments. Therefore, the commenters request is out of the scope of this rulemaking.

**Comment:** A commenter stated that there are fundamental and recurring flaws with current risk assessment practices at the EPA and other agencies.

- Selection of poor quality studies as the basis for estimating health impacts of pollutant exposures can lead to under- or over-estimation of the health impacts and significantly distort the estimates of the benefits that result from the intended regulation.
- All studies have some degree of uncertainty, and the failure to account for uncertainty in the quantitation of health benefits that might be achieved by the intended regulation would lead to less precise, less informed, and less objective estimates of health benefits.
- After decades of reports on risk assessment by the National Academies of Sciences ("NAS"), as well as numerous publications by many other leading authorities, including the EPA – the use of deterministic risk assessment approaches at the EPA and other agencies still commonly inflates estimated health benefits due to the compounding of conservatism that is inherent in deterministic approaches.

Commenters supported that the EPA incorporate three approaches that would enhance the scientific rigor of a BCA in the NAAQS review and rulemaking process.

1. the use of modern systematic review practices to ensure that selected studies reporting associations between criteria pollutants and health effects are of sufficient quality to be used for the quantitation of health benefits;
2. the use of integrated uncertainty analysis (IUA) that incorporates measured error and model uncertainty of selected studies to adjust benefits estimation; and
3. the use of probabilistic risk assessment in criteria development to connect the estimated net benefits more accurately and transparently to realized net benefits by reducing the compounded conservatism introduced by the deterministic method.

A commenter noted that all of these approaches are consistent with existing statutory requirements to establish federal drinking water standards. Another commenter added that these reforms can and should be used for many CAA rulemakings (and for many other programs of the EPA and other agencies), but they are particularly urgent for EPA's NAAQS program, given its great importance and impact. The commenter reference NCASI's comments on the proposed rule.

A commenter stated that the final rule should retain and strengthen information quality standards to require reforms including modern, credible approaches to systematic review, integrated uncertainty analysis, and probabilistic risk assessment. The commenter added that while proposed 40 CFR 83.3(a)(9)(iii)(A-D)39 refers to study features that should be evaluated under a systematic review framework, it is not exhaustive or complete, and does not provide a systematic approach for the integration of this evidence to prioritize studies that provide the most accurate characterization of health impacts from a pollutant of concern. The commenter added that in the absence of systematic review, study selection becomes highly subjective, and the potential for lower quality studies or those with poor relevance to be used in a BCA increases.

One commenter indicated that while the current NAAQS review process does compile a large amount of scientific literature related to the potential health effects from exposure to criteria pollutants, many, if not most of the critical features of systematic review are absent from the current process. The commenter stated that studies presented in Integrated Science Assessments (ISA) have not been appropriately ranked based on study quality and method veracity. The commenter contended that this leads to the reliance on studies that either have disqualifying amounts of uncertainty inherent to their design or are not designed to address the policy relevant question at hand and, in some cases, exclusion of studies from consideration that may be extremely informative for evaluating cause-and-effect relationships between criteria pollutants and health outcomes.

The commenter indicated that it and other organizations have developed a proposed systematic review protocol to evaluate the evidence base in order to more specifically characterize the uncertainties and study quality issues that exist within currently available studies. The commenter referenced their comments submitted as part of the Review of the National Ambient Air Quality Standards for Particulate Matter Proposed Action [EPA–HQ–OAR–2015–0072; FRL–10008–31–OAR]. The commenter explained that the risk of bias

analysis, performed using their proposed systematic review protocol, ranks studies as Tier 1, 2, or 3 through an in-depth analysis of study features and methods. The commenter added that Tier 1 studies are those that directly contribute to the evidence base to support an exposure/disease relationship, Tier 2 studies are not sufficient on their own to evidence an exposure/disease relationship but may support Tier 1 studies in evidence integration, and Tier 3 studies are considered to have a degree of risk of bias that disqualify them from contributing to the evidence base. The commenter added that in their analysis of six studies featured in the ISA and the policy assessment (PA) for the NAAQS PM rule, one study ranked Tier 2 and five studies ranked Tier 3. The commenter concluded that the results of this analysis indicate that the majority of the studies reviewed are not of sufficient quality to contribute to the evidence base, and that none are of sufficient quality to directly contribute as primary sources of evidence. The commenter stated that based on their analysis, the use of these studies as a basis for quantitating the potential health benefits of altering the PM standard is expected to produce an inaccurate estimate. The commenter contended that the use of systematic review allows for studies not fit for the purpose of quantitating health benefits to be disqualified and restricts selection of studies to those that possess minimum standards of quality and study features needed for this purpose. The commenter stated that the need for and value of such a systematic review process is magnified by the rapid, ongoing declines in ambient concentrations of all criteria air pollutants. The commenter explained that the implication of these observed trends, as well as further dramatic declines that will result from existing regulations and technological advances, is that historical evidence to support an exposure/morbidity relationship may become increasingly uncertain over time and may warrant disqualification of studies that are not representative of current or future exposures.

**Response:** As discussed in Section V.E.7 of the preamble to the final BCA rule, we agree with the recommendations from the SAB and commenters on the importance of using systematic review principles 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. Commenters are referred to section V.E.7 of the preamble to the final BCA rule for a detailed discussion of systemic review in the BCA process.

**Comment:** Several commenters supported probabilistic risk assessment instead of deterministic risk assessment. Commenters stated that deterministic risk assessment approaches cause three fundamental and recurring problems:

1. Assuming that the entire population experiences upper bound estimates of multiple exposure parameters inflates the estimated benefits of the intended regulation because much of the population does not actually experience those conditions. Exposure assessment is air dispersion modeling, which takes stack emissions and distributes them across a region. Assumptions on the quantify of emissions from the stack over time, changes in wind directions, and atmospheric transformation of air pollutants can be major factors influencing true exposures for the surrounding population. And when models that are used to estimate “background” concentrations of air emissions from other sources are conservatively derived and added to the specific sources contributions that might also be overly conservative, the result can be further compounded conservatism. Those who currently experience a real exposure scenario

that is not relevant to adverse health outcomes would receive no benefit from the regulation.

2. Since it is unknown what proportion of the population actually experiences multiple, compounded upper bound estimates of exposure parameters, it is not possible to transparently link the intended regulatory standard to the population it actually applies to. The number of people who actually experience all of the upper bound exposure estimates designed into the regulatory standard may be far lower than the population the regulation was designed to protect, and the real number of these individuals may be as low as zero (e.g., it is possible that no receptors experience all upper bound estimates of the exposure scenario).
3. Even if unbiased deterministic methods are used, they do not capture the full distribution of consequences and treat everyone as if they are located at the mean.

A commenter stated that as an exposure scenario developed under the deterministic method of risk assessment (which is the current USEPA default method) typically selects a single, upper bound (highly conservative) estimate for each parameter that describes exposure. The commenter provided an example where the concentrations of air pollutants often vary daily, seasonally, and regionally, and differ indoors and outdoors, but under the deterministic method, a single upper bound estimate of exposure is applied equally to the entire population. The commenter added that the duration of exposure is typically parameterized as a 70-year lifetime period, ignoring the mobility of the majority of the population, which move in and out of areas where the exposure estimate is relevant.

The commenter contended that when deterministic risk assessments use additional exposure parameters with single, upper bound or upper percentile values (e.g. oral ingestion from air particles, dermal absorption, air pollutant deposition on food and soil, etc.) the resulting phenomena of compounded conservatism can lead not only to excessive conservatism in criteria but also a lack of transparency in understanding any linkage between the criteria and the degree of health protection provided.

By compounded conservatism, the commenter referred to the unintended conservatism that is introduced into risk assessment by using multiple upper bound estimates of exposure throughout an exposure scenario. The commenter expanded on their example where an exposure is assumed to always be present at the maximum concentration allowed by the proposed criterion AND persists for 70 years. The commenter added that some individuals may be exposed to the maximum concentration of the pollutant, some individuals may be exposed for 70 years, but the number of individuals that experience both of those conditions is less than either one or the other, and may be as low as zero. The commenter stated that if the goal was to develop an exposure scenario that applied to 90% of individuals, using a 90th percentile estimate for two different parameters in the exposure scenario will lead to a higher overall coverage than the intended 90%.

Commenters contended that probabilistic risk assessment is capable of reducing some of the compounded conservatism that exists in the in the deterministic approach and provides a more transparent link to the proportion of the population that experience the stated exposure conditions in the risk assessment. A commenter added that the probabilistic approach does not

alter the risk equation or the toxicity value used in the risk equation, and in fact, the only difference between the probabilistic approach and the deterministic approach is the use of distributions of exposure values in lieu of single, upper bound estimates to populate parameter values. The commenter stated that this approach directly address the issue noted in the proposal where the EPA states "Upperbound risk estimates must not be used unless they are presented in conjunction with lower bound and central tendency estimates."

The commenter explained that instead of using single, upper bound estimates for exposure concentration and exposure duration, real world data can be used to create a distribution of exposure concentrations and durations that apply to the target population. The commenter added that these distributions can then be integrated to yield potential criteria values that link risk thresholds to the portion of the population who actually experience the range of exposure conditions. The commenter stated that this approach would allow a risk assessor to determine what exposure concentration AND exposure duration is relevant to 50%, 90% or 100% of the population. The commenter concluded that by using more data, in the form of an entire distribution, the probabilistic approach is inherently more informative than the deterministic approach that relies on single, upper bound point estimates.

The commenter noted that probabilistic risk assessment has broad applicability for various criteria developed under the CAA. The commenter stated that the evaluation of benefits from NAAQS criteria have been discussed to the extent that receptor exposures may be parameterized as distributions rather than single, upper-bound estimates in order to produce a more realistic estimation of benefits. The commenter added, likewise, in residual risk assessment for source categories, where exposure is often modeled using upper bound (sometimes referred to as 'worst case') estimates of parameters that impact exposure (e.g. meteorology) probabilistic risk assessment provides the opportunity to parameterize these variables as distributions, thereby producing a more realistic estimate of the benefits achieved by use of Maximum Achievable Control Technology (MACT) and the selection of emissions limits in permitting. The commenter concluded that by developing criteria through the use of probabilistic risk assessment, a clear and transparent link can be drawn between the criterion and the population that will benefit from the proposed criterion, substantially increasing the robustness of a health benefits analysis.

Some commenters urged the EPA to adopt for CAA proposed regulatory risk characterizations, the same risk characterization direction that Congress added to the Safe Drinking Water Act (SDWA). The commenters supported the requirement in Section 1412(b)(3)13 of SDWA requiring the EPA Administrator to show the lowerbound, upper-bound, and central estimates of risk to any population, and to show each significant uncertainty identified, as well as studies that support or fail to support any estimate of health effects. The commenters supported, for any BCAs under the CAA, the EPA also should require that each risk assessment provide a central tendency estimate of risk to the population and the risk estimate for meaningful subpopulations of the U.S. population. The commenters stated that adoption of the SDWA "risk characterization" best practice also would be consistent with the recommendations the EPA has received from several independent peer review panels. The commenters added that the term "central tendency" recognizes that the true mean, median, most likelihood estimator and other statistical standard descriptors may be uncertain.

A commenter concluded that by adopting the central tendency estimate, the EPA will adopt the best estimate of the estimated incremental risk to the individual at the 50th percentile of the affected population. Another commenter added that characterizing the risk to other subpopulations also would fulfill the EPA's mission to consider and to protect underserved populations, by providing important information to policy officials and to the public. The commenter cautioned that, in seeking this objective, it is important to avoid constructing a hypothetically, highly exposed individual that is unlikely to exist or ever to exist. The commenter stated that basing decisions primarily on this hypothetical individual leads to standards with additional levels of stringency and diverts limited resources away from other public health priorities. The commenter urged the EPA to adopt Congress' language in the SDWA amendments as its risk policy, based on the law's legislative intent that the EPA should characterize the estimated risk to subpopulations that are identifiable, exist, and comprise a meaningful proportion of the general population in risk assessments supporting BCAs for CAA regulatory actions.

**Response:** As discussed in Section V.E.8 of the preamble to the final BCA rule, we are 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. 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 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 independently as well as 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, characterize significant sources of uncertainty in the assessment, 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 practicable due to data or other limitations, the EPA will strive to present a range of benefits and costs. 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 unless they are presented in conjunction with lower bound and central tendency estimates.

Additional discussion of these best practices related to uncertainty analysis is provided in OMB's Circular A-4 (specifically, see Treatment of Uncertainty), and throughout EPA's Guidelines and in Section V.E.8 of the preamble to the final BCA rule.

**Comment:** A commenter contended that the proposal goes against the specific recommendations of the National Academies of Sciences, Engineering and Medicine (NAS) with respect to best practices for risk assessment. The commenter noted that while the proposal includes elements recommended by the NAS, it also includes several elements that were flatly denounced by the NAS in its review of the precursor to the 2007 Updated Principles. The commenter stated that the NAS ultimately recommended that this precursor document, OMB's 2006 Proposed Risk Assessment Bulletin, be rejected because of flawed provisions like these. The commenter provided an example where the proposed rule revives a requirement that expected benefits be determined based on "the central tendency of risk," a requirement that the NAS had explicitly cited as among the problems with the OMB's 2006 OMB Proposed Risk Assessment Bulletin.

**Response:** 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 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. This rule is also consistent with the 2007 OMB and Office of Science and Technology Policy's Updated Principles for Risk Analysis, which also builds off of the National Academies and SAB recommendations as well as the EPA's Risk Characterization Handbook.

In their review of the proposed rule, the SAB also provided recommendations related to the selection and quantification of health endpoints. 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 EPA's Consolidated Human Toxicity Assessment Guidelines will be evaluated and incorporated. Commenters are referred to Section V.E.7 of the preamble to the final BCAC for further discussion of SAB recommendations that were incorporated into the final BCA rule.

**Comment:** A commenter expressed concern that the proposed rule threatens the quality and scientific integrity of EPA's risk assessment practices. The commenter stated that BCA should instead seek to present a fulsome analysis of adverse human health impacts (mortality and morbidity) to all individuals, accounting for their varying susceptibilities and exposures, instead of aggregating individual impacts.

**Response:** The BCA rulemaking codifies the best practices for conducting a BCA that are already included in OMB's Circular A-4 guidelines and other economic guidelines, and also requires that risk assessments used to support BCAs should follow best methodological practices for risk characterization and risk assessment. The BCA final rule is solely concerned with codifying the best practices for conducting a BCA and does not provide direction on conducting a risk assessment or cover the underlying risk assessments.

**Comment:** A commenter opposed the rulemaking specifying best practices related to assumptions about technological change and/or learning effects in BCA unless such trends are

reasonably foreseeable and relevant market-driven trends (instead of government mandates). The commenter contended if such changes should be considered because they might affect the outcome, there should be a requirement for the EPA to write down what other technological changes or learning effects have occurred and how that might or should change the proposed agency action, such as limiting the proposal only to cost-effective actions that can be taken within the following several years. The commenter stated that codifying something as abstract as either of these theoretical presumptions is not necessary, and in the alternative, setting them forth explicitly in this regulation to "freeze" their usage, until the next revision of the regulation, also seems unreasonable. The commenter concluded that the EPA to set forth the particulars of assumptions that they are using for purposes of the particular action being evaluated.

**Response:** EPA thanks the commenters for their suggestion. EPA considers all relevant activities and situations that change technologies, including market trends, technology improvements, government action in order to get a complete picture of the cost of a rulemaking.

**Comment:** A commenter contended that BCAs conducted by the EPA will not be consistent unless the rule is clear that it applies to all underlying risk assessments as key inputs to the BCA, including components such as the hazard assessment and hazard values. The commenter noted that EPA's 2010 Guidelines for Preparing Economic Analyses make this clear, stating that "[b]ecause economists rely on risk assessment outcomes as key inputs into benefits analysis, it is important that risk assessments and economic valuation studies be undertaken together." The commenter stated that, although the 2010 Economic Analysis Guidelines do cite some EPA risk assessment guidelines, many more exist. The commenter added that there are inconsistencies within the EPA regarding how these guidelines are interpreted that could result in inconsistencies in BCAs (e.g., using linear extrapolation versus a threshold approach for health effects relevant to certain endpoints). The commenter added that inconsistency in methodologies among the risk assessments used to support benefit estimates and the risk/hazard assessments used to support regulatory decisions would create inefficiencies and be confusing for decision makers and the public. The commenter added that ensuring that the final rule is clear that it includes all underlying risk assessments (inclusive of both hazard and exposure) and best practices will promote consistency and transparency and improve scientific rigor.

One commenter stated that risk assessments for exogenous chemicals with endogenous exposures should systematically account and consider endogenous or background levels of chemicals. The commenter encourage the development of data and models to put exogenous exposures to endogenous or background chemicals in context as an integral part of risk assessment, and to review endogenous or background chemicals with exogenous exposures in a systematic manner.

**Response:** The BCA rulemaking codifies the best practices for conducting a BCA that are already included in OMB's Circular A-4 guidelines and other economic guidelines and does not provide direction on conducting a risk assessment or cover the underlying risk assessments. Therefore, the commenters request is out of the scope of this rulemaking.

**Comment:** A commenter supported the final rule incorporating a transparent and structured process to identify, evaluate and integrate scientific evidence for both the hazard and exposure assessments. The commenter added that this should also include an evaluation of the

criteria used to determine if data are acceptable or unacceptable for use in the exposure assessment. The commenter stated that the final rule should require exposure assessments to provide objective and realistic estimates of likely exposure based on the best available knowledge regarding toxicity and anticipated exposure.

**Response:** We thank the commenter for these recommendations. The rule references the National Research Council recommended approach to performing systematic review, including problem formulation, evidence identification, evidence evaluation and evidence integration. This approach ensures EPA will follow a transparent and systematic approach to synthesizing evidence.

**Comment:** A commenter contended that in assessing risk and when extrapolating risk from high exposures to relevant public exposure, the EPA should establish a clear preference for relying on representative, measured data in lieu of modeled results or default assumptions. The commenter added that if gaps exist in the measured data, then modeled results can be used to draw inferences for those gaps. The commenter noted that this is a widely accepted principle in risk assessment and has been generally adopted by the EPA, and cited that EPA's staff paper Risk Assessment Principles and Practices embraces the preference for data and recognizes that the default values should only be used as a last resort. The commenter stated that under this practice the EPA invokes defaults only after the data are determined to be not usable at that point in the risk assessment, which is a different approach from choosing defaults first and then using data to depart from them. The commenter noted that a data-first preference is also apparent in EPA's posted procedures for conducting a human health risk assessment. The commenter explained that when data from human studies are unavailable, the EPA then turns to animal data and models based on the data to draw inferences about risks to human health. In each case, the EPA begins by thoroughly reviewing existing data. The commenter concluded that establishing a preference for measured data in the final rule would achieve greater clarity and encourage the production of measured data to address data gaps that would otherwise trigger the use of defaults. The commenter stated that while consideration of data quality and reliability is a critical step in the evaluation process, the use of data, including the use of data from well-designed laboratory studies, is preferred over explicit and implicit assumptions that can significantly alter the results of the risk assessment in ways that may not always be apparent.

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

**Response:** The BCA rulemaking codifies the best practices for conducting a BCA that are already included in OMB's Circular A-4 guidelines and other economic guidelines. With regard to selecting and quantifying human health endpoints for BCA, the final rule specifies that a systematic review process be used to determine concentration-response functions used to

quantify changes in those endpoints. The EPA believes this is the best approach to ensure that BCA is based upon the best available data.

## 7.2 Estimating Value of Incremental Risk

**Comment:** A commenter stated that the EPA has in the past assigned the same public health value to every avoided or controlled ton of emissions of criteria pollutants, even if the reduction occurs in a county or region that is in attainment with National Ambient Air Quality Standards, which are established at a level sufficient to protect the public health plus a sufficient margin of safety. The commenter added that this assumes there is no threshold level of exposure to the atmospheric concentrations of the emissions regulated by the NAAQS. The commenter contended that this assumption is inherently in conflict with how the NAAQS are established. The commenter stated that it was contradictory for the EPA to on one hand establish NAAQS requirements that stake out goals at which the public health is presumed to be protected, plus a margin of safety, and then on the other hand assume public health is further improved once reductions occur beyond those goals. The commenter added that the EPA should emphasize that it is no longer assuming all reductions of criteria pollutants achieve the same level of public health on either side of attainment thresholds, by establishing benefit endpoints based on peer-reviewed scientific evidence showing a causal link between exposure and effect. The commenter concluded that the EPA must refine and improve its process regarding causality, as the Clean Air Scientific Advisory Committee has recommended.

**Response:** The final rule does not alter the Agency's approach for setting the NAAQS or for quantifying the benefits attributable to air quality changes occuring above or below the NAAQS. The final rule requires that the process of selecting and quantifying health endpoints in benefits analysis must be based upon an evaluation of scientific evidence that follows a systematic review process. The systematic review process is further discussed in Section V.E.7 of the preamble to the final rule.

## 7.3 Methods of Quantify Endpoints

**Comment:** A commenter supported the proposed rules requirements of requiring the EPA to select and quantify health endpoints in a BCA by: (1) explaining the basis for significant judgments, assumptions, data, models, and inferences used or relied upon in the assessment or decision; and (2) describing the sources, extent and magnitude of significant uncertainties associated with the assessment. The commenter contended that the proposed rule's requirements, to explain the basis for significant judgments, assumptions, data, models, and inferences used and to describe the sources, extent and magnitude of significant uncertainties, are consistent with EPA's current procedures and should be required in risk assessments supporting significant regulatory actions under the CAA. The commenter added that to provide further information on the role of key assumptions in risk assessment, the EPA should list the major assumptions used to characterize/estimate exposure and to derive toxicity values and their potential impact on the final risk estimates using quantitative ranges.

**Response:** The BCA rulemaking codifies the best practices for conducting a BCA that are already included in OMB's Circular A-4 guidelines and other economic guidelines. The BCA final rule is solely concerned with codifying the best practices for conducting a BCA and does not provide direction on conducting a risk assessment or cover the underlying risk assessments.

## 7.4 Risk Analysis

**Comment:** A commenter supported applying the proposed risk assessment requirements more broadly to all risk assessments used in CAA significant rulemakings. The commenter contended that objective and transparent risk assessments are the foundations to good regulatory decisions and to objective and transparent BCA. The commenter added that it would be confusing and misleading for the EPA to apply different standards and procedures for evaluating risks for purposes of benefit analysis compared to EPA's assessment of risk and endangerment required by the CAA. The commenter concluded that such inconsistencies could lead to risk estimates supporting regulatory decisions that are inconsistent with the risk estimates used as a basis for BCA. The commenter stated that the EPA should identify the procedures that will ensure objective and transparent analysis of potential risks, including the assumptions and uncertainties that are inherent in the risk assessment process. The commenter stated that this rulemaking, and revisions to the rule over time, provide an appropriate process with opportunity for public comment for the EPA to develop and refine its risk assessment procedures.

Another commenter opposed extending the proposed risk assessment requirements to all significant CAA rulemakings. The commenter contended that the proposed requirements would hinder EPA's missions to protect human health and the environment and be contrary to the CAA's requirement to use the best available science.

**Response:** The BCA rulemaking codifies the best practices for conducting a BCA that are already included in OMB's Circular A-4 guidelines and other economic guidelines and does not provide direction on conducting a risk assessment or cover the underlying risk assessments. Therefore, the commenters request is out of the scope of this rulemaking.

**Comment:** A commenter supported applying the final to any related risk assessment to estimate both baseline risk and the risk-reduction benefits estimated in the BCA. The commenter also supported applying the information quality requirements to any other risk assessments, or analyses related to each step integral to the risk assessment process -- including a hazard assessment, dose-response assessment, exposure assessment, and risk characterization -- or other risk analyses prepared by the EPA or its contractors that: (1) may eventually be used in CAA programs, and (2) may reasonably be anticipated to directly or indirectly lead to an effect on the economy of $100 million or more or that the EPA Administrator or the Administrator of the Office of Information and Regulatory Affairs at the Office of Management and Budget determines may raise novel or precedential scientific, technical or policy issues. The commenter stated that the final rule should apply to assessments prepared by EPA's Integrated Risk Information System ("IRIS") program and its contractors that play an important role in the CAA program. The commenter added that the EPA should expand the scope of the rule to clarify that its information quality standards apply to BCA, risk assessments, and related risk analyses.

**Response:** The BCA rulemaking codifies the best practices for conducting a BCA that are already included in OMB's Circular A-4 guidelines and other economic guidelines and does not provide direction on conducting a risk assessment or cover the underlying risk assessments. Therefore, the commenters request is out of the scope of this rulemaking.

## 7.5 Epidemiologic Study Criteria

**Comment:** Several commenters opposed the proposed "minimum standards" for studies, particularly epidemiological. Commenters contended that the proposal disqualifies valid studies in estimating benefits. A commenter contended that the language regarding epidemiologic studies appears aimed at setting the stage to exclude epidemiology altogether by creating vague ambiguous criteria that could be narrowly interpreted to exclude almost any study. Other commenters added that if epidemiological studies are intentionally being limited, the full benefits of regulation will not be realized.

A commenter stated that the scientific community already uses the peer review process to ensure sound science is published. The commenter added that the EPA has independent advisory boards that regularly review the science used for policy-related purposes. The commenter added that The Clean Air Science Advisory Committee and the Science Advisory Board (among others) were established to explicitly provide a diverse, independent, scientific peer review of all the science considered in rule-makings so that the Administrator would have a process to receive regular reports on emerging and cutting edge scientific studies and corresponding policy options to consider in parallel to those recommended by staff. The commenter concluded that limiting epidemiology studies is unnecessary and could cause serious adverse impacts on future policy-making and public health. A commenter opposed codifying into regulation "the proposed selection criteria for selecting among studies characterizing concentration-response relationships," because these selection criteria do not advance the already robust risk analysis decision making framework and associated literature. The commenter also opposed incorporating additional requirements on the subject. The commenter added that they opposed codifying into regulation the proposed requirement for "synthesizing evidence across the literature," because proposed practice threatens to distort risk analyses and weaken protections, with no upside for scientific understanding or protection of public health. The commenter concluded that the EPA would be forcing an arbitrary practice without technical or logical merit.

A commenter stated that the restrictions would place far fewer limits on the types of laboratory studies that tend to be sponsored by and favor industry, thereby placing a thumb on the analytical scale.

The commenter added that it would also give costs an unreasonable advantage in the EPA's BCAs, making it more likely that the EPA would weaken or eliminate existing air-quality protections, adopt inadequate new protections, or refuse to regulate in the first place, all on account of costs.

A commenter stated that the proposal requirements the studies are insufficiently described and also unduly stringent. The commenter stated that based on costs and ethical considerations, many epidemiological studies are natural experiments and may not perfectly meet these criteria, reducing the amount of critical evidence that might have been used to calculate benefits.

A commenter noted that epidemiological studies based on "natural experiments" could be excluded if the populations that were affected do not correspond exactly to the population under evaluation in the analysis. The commenter added that epidemiological studies are essential to

environmental regulations, and any restrictions on the use of those studies should be established in conjunction with the scientific community

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

**Comment:** Commenters requested the EPA further explain what a “scientifically robust study” means. A commenter contended that stating that the EPA "must quantify effects for endpoints which scientific evidence is robust enough to support such quantification" appropriately requires quantification of effects but introduces ambiguity in its linkage of this requirement to the vague requirement that the science be "robust enough," potentially leading to a less comprehensive quantification of effects in the analysis.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA..

**Comment:** A commenter requested clarification on what is actually meant by the phrase in the proposal “it must assess the influence of confounders.” The commenter questioned whether this mean that all confounders must be quantified, and also requested direction if there are potential confounders argued by some stakeholders that are actually unimportant or not really confounders and that were not quantified in a given study. The commenter questioned who would decide that some confounders are not applicable. The commenter concluded that this is an example in which BCAs should be subject to peer review, rather than subject to regulations that have the underlying intent of excluding salient scientific evidence.

Another commenter stated that uncertainties regarding exposure assessment and the role of potential confounders in epidemiology studies can fundamentally alter the perception of risk. The commenter explained that the general difficulty of observational epidemiologic studies, regardless of design, is that exposure is not randomized but rather is determined by where people live or work, what they eat, what social group they belong to, or a host of other factors that can affect disease risk. The commenter stated that as a result, associations between exposure and disease risk can occur even if the exposure does not cause the disease.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

**Comment:** Several commenters opposed the proposal to require “the study population characteristics must be sufficiently similar to those of the analysis.” Several commenters contended that the proposal is highly vague language on what it means, how it is determined, by who it is determined, and by what process is used to determine it. A commenter contended that the language seems guaranteed to be used as a weapon to exclude the use of epidemiologic

studies. Other commenters opposed the proposal to require "the study location must be appropriately matched to the analysis." A commenter contended that the EPA failed to adequately define “appropriately matched” and “sufficiently similar” and such vague language risks rejection of scientifically valid studies due to a narrow interpretation of alignment between the study and the EPA proposal being analyzed.

Commenters contended that the new geography and population-based constraints on epidemiological studies could severely limit the use of epidemiological data in CAA BCAs, which would prevent the EPA from considering the best available science and obscure the true environmental and health benefits of clean air regulations for vulnerable communities. A commenter stated that the proposed rule does not explain or justify why these criteria are necessary, which only serves to highlight their arbitrary nature. Another commenter contended that the EPA did not provide examples where such an approach would be appropriate (e.g., examples where the geographic location of a study would impact epidemiological endpoints) nor indicate in any meaningful, objective way how the EPA would conclude studies are appropriately matched or that populations are sufficiently similar. Another commenter stated that the proposal fails to consider that, for certain pollutants and in certain regulatory contexts, the best available science may consist of studies conducted in different locations and focused on different populations. The commenter added that such studies may still provide strong evidence as to the health impacts of pollution, and should not be discarded based on the arbitrary criteria in the proposal.

A commenter stated that the EPA appears to arbitrarily narrow the number of alternative concentration-response functions that must be developed without providing clear criteria and only "available data and resources" are mentioned as a means for determining if development of these functions is "technically feasible." The commenter contended that an alternative, appropriate approach would be to evaluate the number of alternative concentration-response functions considered, not just through available data and resources, but also by their potential to improve estimation and uncertainty related to critical benefit endpoints.

Another commenter opposed invalidating epidemiological studies because the underlying personal data of the individuals involved in the study is anonymized. The commenter provided an example of studies with anonymized epidemiological data could be thrown out of consideration for future BCA as their population characteristics might not be, “sufficiently similar,” to those of the analysis. The commenter stated that in estimating benefits, economists look to the best available scientific data, and if no study of a similar enough location exists at the time of regulation, this requirement could hamper monetization of major benefit categories, reducing the ability to systematically compare benefits and costs of proposed rules.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

**Comment:** A commenter expressed concern that less current studies may be discounted relative to more current studies. A commenter stated that scientific studies should not be discounted simply due to being performed further in history than recent studies because high-

quality science depends more on the data and methods employed, rather than a study's published date.

Another commenter stated that the proposed requirement to consider the "age of the air quality data," as opposed to the *quality* of the air quality data, threatens to rule out scientifically valid studies for arbitrary, ambiguous, and unscientific reasons. The commenter stated that such an outcome runs counter to the longstanding, science-backed the EPA process of assessing all relevant reliable scientific studies, inclusive of studies conducted in different locations and on different populations. The commenter stated that existing EPA scientific literature review processes already account for excluding studies when they fail to meet quality standards; these added restrictions, therefore, would not serve to address any identified gaps in processes, but rather arbitrarily hinder the EPA's ability to develop science-based standards.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

**Comment:** Several commenters opposed eliminating studies with sensitive and private patient information from inclusion and claimed such decisions would reduce the quality and rigor of the science underlying the CAA and other statues foundational to EPA's activities and mission.

A commenter opposed the requirement that all information the EPA use be publicly available, and that, if the EPA uses any proprietary information, the EPA must make available, to the extent permitted by law, underlying inputs, assumptions and other information, while continuing to provide appropriate protection for confidential business information, personally identifiable information and other protected information. The commenter contended that the EPA provides no reasons for imposing this requirement. The commenter added that the rule language contains undefined and unexplained exceptions, such as "to the extent permitted by law," and "continuing to provide appropriate protection" for various, not completely defined, types of information, resulting in confusion on what this provision would or would not require that the EPA disclose. The commenter contended that to the extent that ambiguity provides an opportunity for the EPA to selectively make ad-hoc, unprincipled decisions as to what information to use, what information not to use, and what information to disclose, that would be arbitrary and capricious and contrary to EPA's purported goal in this proposed rulemaking of increasing consistency and transparency.

A commenter expressed concern that making data publicly available always presents the possibility that the privacy of individuals will be compromised. The commenter added that even if privacy were not compromised, the choice of data and models to be used to support a standard could be biased by whether or not the data could be made freely available, thus eliminating from the evidence well conducted epidemiologic studies, resulting in compromising the validity of the analysis of risks, benefits, and costs.

**Response:** The BCA rulemaking codifies the best practices for conducting a BCA that are already included in OMB's Circular A-4 guidelines and other economic guidelines.

**Comment:** A commenter contended that the Proposal's extensive restrictions and limitations on the selection and use of concentration-response relationships are unlawfully vague and seem arbitrarily designed to exclude or restrict evidence of such relationships. The commenter contended that the rule proposes restriction of the universe of concentration-response relationships to pollutants that "match" the pollutant of interest without explaining how specific the "match" must be. The commenter added that this restriction is inappropriate because related pollutants may operate in similar ways, and strict requirements for matching may result in the EPA excluding concentration-response data that would elucidate potential benefits from reductions of a pollutant.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

**Comment:** A commenter contended that the EPA has provided no valid reason to deviate from the Draft 2020 EPA Guidelines for Preparing Economic Analyses, particularly related to benefit endpoints, including relative importance of the endpoint, importance of the endpoint to disadvantaged and minority populations, and the potential for the endpoint to vary across policy options under consideration.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

**Comment:** A commenter stated that the proposal's discussion of endpoints raises concerns in suggesting a need for "robust" scientific evidence that supports quantification before an effect on an endpoint should be quantified. The commenter stated that EO 13563 already provides useful guidance in its discussion of the use of "best available science." The commenter stated that "best available science" comports with EPA's numerous statutory obligations to evaluate the "best available science," provides a more expansive consideration of the types of endpoints that may be considered, and acknowledges that emerging, "best available" science related to impacts of air pollution may limit the number of studies available for quantification of effects. The commenter added that 2020 EPA Draft Guidelines for Preparing Economic Analyses provides an extensive discussion of benefits estimation, highlighting the need for a comprehensive list of potential endpoints that can be updated as more scientific information becomes available. The commenter stated that if there are uncertainties in the quantification of an endpoint because of more limited scientific information, this can be addressed in a discussion of the uncertainties related to the benefits.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA..

**Comment:** A commenter contended that it is unclear whether the EPA has considered the use of multi-pollutant concentration-response functions and the proposal fails to account for how such functions would be treated under this rule.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

**Comment:** Another commenter suggested the requirements for epidemiology studies could be enhanced by requiring the EPA to give preference to studies that have conducted a quantitative bias assessment and that have evaluated the potential for exposure misclassification and ways to reduce it.

Another commenter supported including additional criteria for selecting epidemiology studies for purposes of identifying concentration-response functions. The commenter noted that the EPA proposed three criteria for using epidemiological studies: (1) the study must assess the influence of confounders; (2)the study location must be appropriately matched to the analysis; and (3) the study population characteristics must be sufficiently similar to those of the analysis. The commenter supported the three criteria, with the following modifications:

- The first criterion above should be clarified to include covariates as well as confounders, and
- The second and third criteria should be retained, with clarification that preference be given to studies of United States populations.

The commenter also supported additional criteria that the EPA give preference to epidemiology studies that:

- Explored which of its model specifications may have predictive validity;
- Conducted a quantitative bias assessment;
- Evaluated the potential for exposure misclassification and its impact; and

Have taken steps to reduce this potential.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

**Comment:** A commenter supported considering all credible epidemiological studies, including "negative" findings. The commenter provided an example for the NAAQS PM of studies showing no correlation between $PM_{2.5}$ exposures and health effects. The commenter stated that by not considering the "negative" studies, the EPA erroneously gives the impression that all credible studies find significant associations when they do not.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA..

## 7.6 Weight of Evidence

**Comment**: Several commenters opposed requiring best practices related to any weight-of-evidence (WOE) frameworks in the final rule. A commenter contended that these frameworks should evolve as science evolves. The commenter added that such frameworks should be developed by agency scientists and reviewed by external scientific experts, including the EPA advisory committees such as the SAB and CASAC. A commenter contended that existing guidance, including OMB's Circular A-4 and EPA's Guidelines (and any updates or supplements to those documents that have gone through an appropriate review process), provide sufficient instruction for analysts on these matters.

Other commenters supported including requirements for best practices related to weight of evidence frameworks that the EPA uses in the development of CAA significant rulemakings. Some commenters supported updating the weight-of-evidence framework to include a more complete toolbox, including requirements for causal discovery techniques (especially manipulative causation). A commenter added that event tree analysis and fault tree analysis techniques should be among the options available to the EPA's risk assessors. A commenter added that since WOE relies on evaluation and integration of evidence and to formulate conclusions based on inferences, selection of hazard and mechanistic data, analysis of the data for quality, relevance, and reliability, and integration of the data using clearly delineated objective criteria are critical to a WOE assessment. The commenter added that risk assessments must be based on a framework that takes into account and integrates all relevant studies, while giving the greatest weight to information from the most relevant and highest quality studies.

A commenter noted that multiple frameworks have been published in the scientific literature representing best practices. The commenter cited one study that reviewed approximately 50 WOE frameworks and identified four minimum elements of WOE assessments, including: 1) defining the causal question and developing criteria for study selection, 2) developing and applying criteria for review of individual studies, 3) evaluating and integrating evidence and 4) drawing conclusions based on inferences. The commenter concluded that the final rule should adopt a WOE framework that includes these minimum elements, taking into account all relevant studies.

A commenter stated that the final rule should ensure that the WOE framework used in the underlying risk assessment incorporates modern knowledge of mode of action (MOA) to determine potential risks to humans at environmentally relevant exposures. The commenter explained that determination of the likely operative MOA is central to the assessment of human relevance and selection of dose-response extrapolation methods for quantifying risks at environmentally relevant levels of exposure. The commenter concluded that the BCA should ensure that a consistent WOE framework was applied, based on specific hypothesized MOAs to permit data from laboratory experiments, epidemiological investigations, and mechanistic

research to be integrated in a manner that provides a robust understanding of the MOA and the potential hazards and risks that exposures to a substance could pose to humans.

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

The commenter also noted that adverse outcome pathways (AOPs) can also be used to organize potential mechanisms into models that describe how exposure might cause cancer (e.g., using the approach of the OECD Adverse Outcome Pathway (AOP) methodology).

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

**Response** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

### 7.7 Risk Bias and Uncertainty

**Comment:** Commenters opposed the proposed additional requirements to ensure consistency and transparency in the assessment of bias and uncertainty in risk analyses. A commenter stated that quantification of uncertainty does not reduce uncertainty. The commenter added that the EPA would benefit from flexible guidance on analyses aimed at characterizing uncertainties, but does not require a regulation for such practices. The commenter concluded that the development of such guidance should be done by the EPA scientific staff and be subject to external review via cognizant advisory panels, such as the SAB or CASAC, when they are returned to proper function in terms of membership and procedures. Another commenter stated the emphasis on the uncertainties is of particular concern in light of EPA’s invocation of uncertainty in its determination that a residual risk in excess of the range that is generally considered acceptable was instead acceptable. The commenter also added that historically, cancer risk estimates have been based on upper bound potency estimates due to the severity of the effects (e.g., death) associated with that endpoint. The commenter stated that a central tendency estimate would underestimate that risk.

Other commenters supported requiring best practices for uncertainty analysis. A commenter added that if a numerical estimate of risk is provided, the information quality requirements should mandate that the EPA shall provide: (1) the “most likely estimate” for specific populations or natural resources which are the subject of the risk characterization; and (2) a statement of the reasonable range of scientific uncertainties. A commenter added that for

each BCA, the EPA should prepare a quantitative uncertainty analysis for each economically significant regulatory action. The commenter explained that an uncertainty analysis would document the major sources of uncertainty and, because uncertainty compounds how any assumptions, any model parameters, or any mathematical relationship within the models, it affects the range and likelihood of risk assessment results. The commenter stated that numerous EPA Science Advisory Board and NAS reports have recommended the EPA consider this uncertainty in addition to traditional analysis around data variability and uncertainty. Another commenter stated that providing a sense of the magnitude and uncertainty of potential risks estimates will allow the information to be utilized more appropriately. The commenter added that Chemical-Specific Adjustment Factors (CSAFs) or Data-Derived Uncertainty Factors (DDEFs) should be considered instead of default uncertainty factors whenever possible.

A commenter contended that EPA's past uncertainty analyses in CAA BCA vary in their quality, scope, and rigor. The commenter added that the EPA does not routinely conduct assessments of the uncertainty in the mathematical relationships and the assumptions in internal or external quantitative models. The commenter stated that, as a result, past uncertainty analyses can convey a false impression of the sources of uncertainty and their relative magnitude. The commenter added that modeling results can appear more certain if major sources of uncertainty and variability are excluded from analysis. The commenter stated that this inconsistency in EPA's conduct of uncertainty analysis in the BCA for CAA regulatory actions undermines public understanding and confidence in the regulatory process. The commenter supported promulgating a final rule that will trigger a quantitative uncertainty analysis and greatly improve the quality and transparency of agency risk assessments. The commenter concluded that, at a minimum, BCA should catalogue the major sources of uncertainty and variability in the BCA and any underlying risk assessment, consistent with the NRC's recommendations, and quantify the effect of the major sources of uncertainty and variability on the risk estimates, benefit estimates, and cost estimates.

One commenter stated that while there are multiple sources of uncertainty in human health risk analyses based on epidemiologically derived concentration response curves, two broad categories of uncertainty include 1) statistical (or "aleatory") uncertainty, which is due to the random variability inherent in the statistical estimate of the concentration-response (C-R) function used to calculate risk, and; 2) model (or "epistemic") uncertainty, which is due to imperfect knowledge about the true shape of the health–risk relationship that lies beneath the observed statistical associations in epidemiological studies, leading to more than one plausible C-R function estimate. The commenter added that models are chosen by researchers because they address one or more features of the dataset better than alternative models. The commenter continued that no model addresses all data distribution issues with equal robustness and choosing to address one feature of a dataset often comes at the price of a tradeoff for another feature, potentially introducing epistemic error.

The commenter contended that when models are associated with this type of epistemic uncertainty, the results from them can be treated with integrated uncertainty analysis (IUA) to more realistically characterize C-R values that inform on the health impact of pollutants at policy relevant concentrations and, consequently, the potential benefits from an alternative standard. The commenter added that by defining a probability distribution over each uncertain assumption, and then assessing the probabilities of the combined effects of all those assumptions, IUA

produces a single probability distribution over the risk estimate that is more comprehensive and useful for decision-making purposes. The commenter provided an example using the ozone NAAQS. The commenter stated that using the traditional approach to estimate benefits of altering the current ozone NAAQS suggested that there would be a 100% chance of receiving some health benefit even if the ozone standard was incrementally lowered to zero. The commenter added that applying the IUA approach, which incorporates multiple aspects of model uncertainty, demonstrates that as the NAAQS ozone standard theoretically decreases, the health benefits also progressively decrease with further lowering, thus providing a more realistic estimate of the actual health benefit that could be realized by lowering the ozone standard. The commenter concluded that given that the lower bound of the C-R curve is typically of greatest interest for risk assessment and policy making, and also where the impact of model uncertainty can have its greatest effect, health benefits analysis that do not apply IUA in estimating health impact are expected to produce unreliable results.

One commenter expressed concern about combining concentration-response functions and recommended Section 83.3(a)(9)(iv) of the proposed rule should be amended to require EPA to address uncertainties that may not be adequately represented in the selected functions. The commenter explained that the full range of concentration-response functions in the selected studies is unlikely to represent all of the uncertainties present. The commenter added that even when including the full range of concentration-response functions from the selected studies, risk assessors must recognize that the selected studies may not include all relevant study designs or models, thereby limiting EPA's ability to assess concentration-response functions that have not been evaluated or included. The commenter noted that the selected concentration response functions may also be based on similar models giving a false impression of greater robustness even though they may fail to include the model/study design with the greatest predictive power. These, and other limitations of CRFs, should be described when EPA characterizes their strengths and limitations. The commenter cited several studies that showed that ignored estimation errors can obscure the shapes of the true concentration-response curves and lead to unrealistic predictions of changes in risk, and measurement errors resulted in reduced statistical significance for risk ratio estimates, with the average attenuation ranging from 18 to 92 percent. The commenter concluded that the final rule should require that the risk analysis address these significant sources of scientific uncertainty that may not be fully reflected in the range of the selected concentration response functions.

One commenter stated that EPA should carefully assess the full distribution of exposure values to determine the role of outliers on the results. The commenter added that concentration-response function that gets more weight within this range is a subjective judgment that may only be made by the Administrator in the final analysis. The commenter recommended to address the uncertainties, EPA should include a discussion of the relative strengths and weaknesses of each concentration response function included, recognizing that all studies taken together as a whole reflect model uncertainty that should be accounted for in the risk assessment.

**Response:** As discussed in Section V.E.8 of the preamble to the final BCA rule, the SAB made several recommendations related to the proposed requirements for uncertainty analysis. First, the SAB recommended the preamble of the final rule discuss the broader purposes of uncertainty analysis beyond simple transparency. Second, the SAB explained that since 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 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 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 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 independently as well as jointly. The BCA should also discuss the extent to which qualitatively assessed costs or benefits are characterized by uncertainty.

**Comment:** A commenter supported Section 83.3(a)(9)(viii) of the proposed rule requiring the use of probability distributions to reflect the significant uncertainties present in risk estimates. The commenter noted that probability distributions for risk estimates can only be developed through subjective informed judgment about the alternative risk assessment input assumptions.

The commenter contended that the proposed rule is incorrect in requiring the EPA to rely on central tendency measures of risk when it is infeasible to estimate a probability distribution. The commenter stated that central tendency estimates, such as the mean and median are, by

definition, based on a probability distribution, and it is impossible to arrive at a mean or median estimate without first estimating a distribution. The commenter recommended the final rule omit the requirement for central tendency estimates if a distribution is infeasible, and instead should require that the full range of estimates be provided with explicit acknowledgment that a "central" or "best" estimate is infeasible to estimate.

The commenter stated that probability distributions can be used to: (1) characterize the variation in the estimated slopes of the concentration-response functions reported in the selected studies -- a majority of which are likely to be linear-no-threshold models that differ only in terms of their slope; or (2) characterize scientific uncertainties that remain with the available set of statistically-estimated concentration response functions. The commenter added that of the two potential approaches for characterizing uncertainty in risks, applying the first alone would omit major sources of uncertainty and would likely misinform decision makers and the public more than simply presenting the minimum and maximum risk estimates from the set of selected studies.

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

The commenter contended that exposure measurement error and limited data at very low exposures also contribute to scientific uncertainty regarding the shape or continued existence of a concentration-response relationship at lower exposures levels in the study and at levels below the lowest measured levels in the study, and if so, what the mode of action may be. The commenter added that these important forms of scientific uncertainty may not be represented by the range of concentration-response functions from the selected studies but can significantly alter the risk and benefit estimates. The commenter contended that judgments need to be made about the relative likelihood of each of these uncertainties if a proper probability distribution on risk is to be calculated. The commenter concluded that if the EPA is not prepared to make the requisite subjective judgments, substantial insight about the role of these uncertainties for decision making can be obtained by thorough quantitative sensitivity analyses, including joint sensitivity analyses in which two or more uncertain input assumptions to the risk estimation formula are considered in various combinations across their individual possible ranges. The commenter provided an example on sensitivity analysis providing information on the impact of uncertainty on the shape of the concentration-response curve.

The commenter suggested using different concentration response functions that reflect the full range of studies selected as a starting point for the risk analysis. The commenter added that by plotting the sensitivity curves for each alternative CRF, a range of potential risk estimates at each potential threshold level could replace the single curve shown in the figure. The commenter contended that this type of analysis would provide the EPA and the public with valuable information of how the potential risks vary across the full range of concentration-response functions from the selected studies and the full range of uncertainties regarding different threshold values.

The commenter also suggested the EPA consider a second approach, used in a 1997 $PM_{2.5}$ risk assessment, to addressing key uncertainties by applying three alternative probability distributions ("cases") over potential threshold levels when conducting its risk analysis. The commenter added that in each of the three cases, the risk assessors assigned specific probabilities to the existence of a threshold at various levels, using four discrete levels as a condensed summary of the full range of potential levels. The commenter stated that each probability distribution "case" could be viewed as an alternative possible subjective view on this uncertainty, although not attributed to any specific individuals. The commenter concluded that this allowed a probabilistic analysis of uncertainties to proceed as a form of sensitivity analysis -- in this case the sensitivity being explored was sensitivity to different possible points of view about the likelihood and level of an effects threshold.

The commenter recommended the following revisions to the regulatory text for Section 83.3(a)(9)(viii):

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

**Response**: As discussed in Section V.E.8 of the preamble to the final BCA rule, we are 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. 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 independently as well as 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, characterize significant sources of uncertainty in the assessment, 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 practicable due to data or other limitations, the EPA will strive to present a range of benefits and costs. 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 unless they are presented in conjunction with lower bound and central tendency estimates.

Additional discussion of these best practices related to uncertainty analysis is provided in OMB's Circular A-4 (specifically, see Treatment of Uncertainty), and throughout EPA's Guidelines and in Section V.E.8 of the preamble to the final BCA rule.

## 7.8 Air Quality and Risk Study Selection Criteria

**Comment:** Commenters opposed adding additional requirements to the study selection criteria in the proposed rule. A commenter stated that additional requirements are often advocated by stakeholders with a conflict of interest for the purpose of excluding scientific information and to raise the burden of proof beyond that required by statute.

A commenter stated that 40 CFR 83.3(a)(8)(iv) could result in the dilution and devaluation of risk estimates derived from well-run studies and appropriate concentration-response models. The commenter added that 40 CFR 83.3(a)(8)(v) is contrary to scientific principles regarding modeling. The commenter stated that the number of available "technically feasible" models is irrelevant; models are appropriately selected based on their applicability to the study methodology and endpoints, not on whether running them is technically feasible. The commenter stated that the criteria in 40 CFR 83.3(a)(8)(vii)(A) is a mechanism for devaluing risks calculated using the most scientifically defensible models.

A commenter expressed concern with how the proposal would interact with other rules, and specifically noted the Transparency Rule, resulting in eliminating many of the studies that the EPA should be relying on to do accurate cost-benefits. The commenter provided an example using the ozone Integrated Science Assessment because it changed ozone causality for short-term term exposure to ozone and its link to mortality from likely causal to suggestive of insufficient to infer a causal relationship. The commenter added that a similar change was made in downgrading causality of cardiovascular effects for short-term ozone exposure. The commenter concluded the end result was that the ozone impacts would not be included in the future BCA.

Another commenter stated that the proposal is deficient in providing and applying transparent study-selection criteria for NAAQS under review. The commenter recommended applying a more explicit, systematic, and transparent process for selecting, evaluating, summarizing, and interpreting studies. The commenter added that the EPA should show the results of this process for individual studies. The commenter suggested the EPA accurately summarize final results from a systematic review and critical evaluation and synthesis of relevant studies relied on to reach conclusions, including negative studies and studies of nonlinear C-R functions for ozone omitted in the draft (integrated science assessment) ISA that should inform the policy assessment (PA). The commenter added that this review should be done in the ISA and summarized and referenced in the PA. The commenter recommended additional criteria to help identify and give preference to studies that have fully evaluated the data in a transparent way. The commenter specifically noted that the EPA should give preference to studies that explore a broad range of alternative models, including threshold models, and that investigate spatial heterogeneity. The commenter concluded that it is also important that selected studies evaluate the potential influence of covariates and make available all results referenced in the study.

A commenter stated that the rule should also include specific requirements that force the EPA to identify and examine fundamental epistemic uncertainties with regard to model selection, model shape and form, and other unknowns using sensitivity analyses. The commenter recommended the EPA include a full range of studies that meet the study-selection criteria, and should also recognize that the existing pool of studies may not sufficiently address core scientific uncertainties with regard to the model and the shape of the dose-response curve, particularly at low exposure levels, and whether the observed association is causal. The commenter stated that these epistemic uncertainties have much larger impacts than the narrower statistical uncertainties that surround selected concentration-response curves and are often disproportionately discussed. The commenter contended that for these reasons, the EPA should identify and clearly explore the uncertainties that are not fully addressed in existing studies. The commenter supported the EPA requiring, at a minimum, sensitivity analyses of the range of concentration response functions from selected studies. The commenter cautioned that this range may not fully reflect all of the core scientific assumptions and uncertainties affecting the risk estimates, including whether the selected concentration-response functions reflect a true causal relationship. The commenter added that sensitivity analyses should be conducted of all major uncertainties, not just those that flow from the selected studies.

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

A commenter stated that risk assessments should employ uniform evaluation methods to determine the quality, relevance, and reliability of the various types of studies and information used in the assessment, which can include epidemiologic, toxicologic, and mechanistic information. The commenter added that results of individual study evaluations, based on the application of consistent criteria, should be made available to the public for review. The

commenter suggested that the criteria should consist of clear and transparent principles for evaluating the quality and relevance of studies used to address the whether the identified studies are of sufficient quality and are applicable to the risk assessment. The commenter added that criteria for evaluation of study quality and relevance should be provided in enough detail to allow for replication. The commenter concluded that all relevant information of sufficient quality should be used in the risk assessments, including both positive and negative results.

A commenter recommended amendments to the proposed criteria and the insertion of additional criteria to ensure that the EPA relies on studies that reflect the best available evidence while encompassing the range of potential scientific uncertainties.

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

The commenter recommended deletion of the criterion in Section 83.3(a)(9)(iii)(C) that states "concentration-response functions must be parameterized from scientifically robust studies." The commenter contended that, as currently drafted, this criterion conveys no specific meaning and would not effectively help the EPA discriminate among studies. The commenter suggested that alternatively, the EPA should include criteria that assure the EPA is capturing the full range of model and shape uncertainties reflected in well-conducted epidemiology studies. The commenter contended that at this point in the risk assessment process, the objective should not be the elimination of uncertainties but rather the full investigation of the many potential scientific uncertainties affecting model selection and the shape of the concentration response function.

The commenter recommended the EPA include the following criteria to guide the EPA in selecting studies and give preference to studies that:

- Make available the results of all models referenced in the study, and the models and data necessary for replicating the study in a manner that protects confidential business and personal information in accordance with current law.
- Have published protocols a priori on sites accessible to the public.
- Have adequate statistical power considering Type I and Type II errors.
- Assess the influence of covariates.
- Present the results of all statistical analyses along with a discussion of the reason a method was used, any assumptions made in the analysis, identification of any outliers and their disposition, and the validity of the conclusions.
- Explore a broad range of alternative models, including models with alternative shapes, exposure windows and lag times, nonparametric models that incorporate fewer assumptions, and various threshold models across the dose or exposure range.

- Investigate factors that might account for spatial heterogeneity.

**Response:** Based on best practices described by the National Research Council and the Institute of medicine, the rule specifies that the EPA follow a systematic review process for identifying and quantifying health endpoints for BCA. The BCA rule does not control or make changes to risk assessments used outside of a BCA.

## 8.0 Transparency

**Comment:** Several commenters supported the general concept of transparency in conducting BCA, because transparency improves the quality of regulatory decision-making. Some commenters 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. A commenter stated that BCA's with improved transparency will better inform the EPA decision makers. A commenter supported the EPA presenting disaggregated benefits and costs within a table that summarizes conclusions of the BCA.

Another commenter strongly supported the requirement for analysis of key sources of uncertainty as provided in proposed 40 CFR 83.3(a)(10)(i) - (iv), and stressed the need for the EPA to explain the scope and methods used to evaluate uncertainty. The commenter recommended if causal or likely causal benefits cannot be quantified, the final rule should require qualitative assessments of these uncertainties as proposed in (iv). The commenter suggested the EPA consider applying contingency tables (where sensitivities are evaluated one-by-one) or qualitative ranking tools or tables that assign percent ranges of the magnitude of the likely uncertainty level present in a non-quantifiable benefit. The commenter also recommended, for any non-quantifiable benefits considered, that the EPA create descriptors using words or symbols to indicate the direction and magnitude of uncertainty for each factor. The commenter suggested that 40 CFR 83.3(a)(10) be amended to state: The EPA must identify uncertainties underlying the estimation of both benefits and costs and, to the extent feasible, quantitatively analyze using sensitivity analyses those that are most influential; and must present benefit and cost estimates in ways that convey their uncertainty. The EPA must provide a reasoned explanation for the scope and specific quantitative or qualitative methods chosen to identify and analyze significant uncertainties.

The commenter supported the requirement of proposed 40 CFR 83.3(a)(10) to require the EPA to characterize uncertainty by presenting benefits and costs as a probability distribution or a range of values and to determine the combined uncertainty of all relevant factors affecting costs and benefits to determine "switch points" (as discussed in EPA's 2020 Draft Economic Guidelines), which characterize the conditions under which the balance of benefits and costs would switch direction to indicate a different policy decision. The commenter added that to be more helpful in situations involving more than one important uncertainty, the concept of switch points can be extended to "breakeven frontier" graphs that depict the sensitivity of the net benefits switch point to various combinations of two major uncertain BCA input assumptions.

The Commenter advocated against using reduced-form tools, such as a benefits-per-ton metric, because such tools prevent sensitivity or uncertainty analysis to be conducted on the scientific uncertainties associated with the dose-response relationship of regulated pollutants.

The commenter agreed with the concept of qualitatively characterizing benefits that cannot be monetized, but stated that the EPA should differentiate casual classification (e.g., suggestive, likely causal, causal) to help the public understand the significance of non-quantifiable benefits.

Several commenters objected to the transparency provisions of the rule. A commenter objected to proposed 40 CFR 83.2(a)(11)(i) stating that it is unclear what is meant that EPA's presentation of BCA results should be "reproducible to the extent reasonable possible." The commenter 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. The commenter stated that because the paragraph is incomprehensible and serves no purpose, it should not be adopted.

Some commenters contended that the proposed cost-benefit requirements would obscure the basis for the EPA's decisions. A commenter contended it is inappropriate to require consistency, quote-unquote, "consistency across the Clean Air Act." given the differences in statutory obligation for different pollutants. Commenters claimed that EPA's regulatory assessments already are transparent and the proposed rule, if adopted, would just muddy up the regulatory analysis and not increase transparency. The commenter claimed that the general public will be confused by terms like statistical lives and market decisions and implications that benefits that can be quantified are more important than those that cannot. The commenter stated that further confusion and lack of transparency will be generated by requiring a BCA even when the EPA is statutorily prohibited from considering cost and by barring consideration of scientific research that is relevant to the regulation in question. A commenter 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. The commenter recommended that instead of BCA the EPA should pursue a regulatory analysis concept described in an article by legal scholars Shapiro and Schroeder, "Beyond Cost-Benefit Analysis: A Pragmatic Approach" (article attached to their comments).

One commenter did not support the proposed "Additional Presentation Requirements" (40 FR 35623) to increase transparency, stating that risk assessment requirements and other procedures relating to BCA should be specified in guidance specific to the action being taken and not in a regulation.

**Response:** As discussed in section V. A of the preamble to the final rule, we are finalizing the BCA requirements because transparency improves the quality of regulatory decision-making. We have determined that the Final Rule is necessary to ensure that BCA practices are implemented in a transparent and consistent fashion prospectively. We believe 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. We also agree with commenters that providing information on the data, models, assumptions, and uncertainties will increase public participation by improving the dialog between EPA and stakeholders and creating a better-informed public. We disagree with commenters stating 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. We also note that the procedures that are being codified are consistent with the principle of transparency discussed at length in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866.

For example, the practice of ensuring that results are reproducible is taken directly from OMB's Circular A-4. OMB's Circular A-4 encourages transparency in practices, including the expression of costs and benefits in monetary units that allow for the evaluation of "incremental benefits and costs of successively more stringent regulatory alternatives" such that an agency can "maximize net benefits. Therefore, after reviewing public comments, the EPA is finalizing the transparency requirements as proposed.

# 9.0 Rulemaking

## 9.1 Codifying Best Practices for Development of BCA

**Comment:** Commenters supported the codification of best practices for conducting and presenting BCA, because codification would standardize procedures to would achieve consistency over time and provide for better transparency. A commenter argued for codification of best practices because the EPA guidance documents are too hard to locate. A commenter pointed out 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.

A commenter stated that the EPA should codify institutional mechanisms for continuous improvement of best practices for BCA, such as establishing expert panels like the External Environmental Economics Advisory Committee that was established after dissolution of the EPA Science Advisory Board.

Some commenters objected to codification of best practices for BCA, advocating instead for guidance on best practices for BCA. Some commenters objected because a regulation establishes rigid practices that make it difficult for the EPA to readily adopt future improvements in risk assessment procedures, economics, and the underlying sciences. A commenter pointed out that codification, by ignoring future developments, intentionally limits the EPA from aspiring to use "best practices." Commenters stated that the EPA has not shown that the use of guidelines has resulted in inadequate, inconsistent, or nontransparent practices or has compromised the EPA's abilities. Another commenter argued that making the use of specific best practices a legal requirement provides unlimited opportunity for regulated industries to challenge future rulemakings, leading to wasteful litigation and delays in environmental protection. A commenter argued that because the methodology for BCA is sophisticated and nuanced, good analysis requires flexibility and professional judgement. Therefore, the commenter argued that existing guidelines with future updating are the appropriate repositories for best practices, and it is not wise to ossify the requirements in federal regulations.

Another commenter recommended that the EPA should make certain elements of this regulation less likely to be a source of significant litigation by making certain requirements explicitly subject to feasibility, as the NOPR does with respect to the requirements in Section 83.3(a)(10)(iv), so that the EPA would explain why complying with the regulatory requirement is not feasible in a particular case and the EPA would not have to comply with the specific requirement. The commenter added that the EPA should carefully consider and explain which requirements should be subject to such a "feasibility" or "appropriateness in the discretion of the Administrator" test, and which provisions of the rule should be clearly and in all cases mandatory.

**Response:** As discussed in the preamble to the proposed and final rules, we maintain that codifying best practices into regulation provides additional certainty of 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 Agency, has not consistently estimated, presented, and considered benefits and costs in line with best practices and principles set forth in long standing executive orders governing regulatory analysis. EPA has not had procedural 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. 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 the BCA of significant CAA regulations follow best practices and complement more detailed existing guidance's 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. Thus, we maintain codifying the best practices 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. 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. We refer commenters to Section V.A of the final rule and Chapter 3.0 of this document for our more detailed discussion of the need for this rulemaking.

## 9.2 Definitions

**Comment:** Several commenters supported changes to the definitions in the proposed rules. A commenter supported consistent terminology and definitions, and disclosing which factors are and are not considered in a BCA, can ensure uniformity and clarity in rule making for affected industries. A commenter stated that the EPA consistently used vague terminology throughout the proposal.

A commenter stated that the proposed definition of "social cost," while accurate, does not assure that EPA's benefit-cost analysis includes all the necessary cost elements. The commenter stated that to ensure a comprehensive and clear analysis of costs, EPA should include definitions which are based on EPA's 2010 Economic Guidelines. Another commenter stated that consistency and transparency would be significantly improved by working towards standardized definitions for the risk assessment portion of the Agency's benefit-cost analyses and advised EPA to consider the article, Goodman et al., 2016. "What Does Research Reproducibility Mean?" Science Translational Medicine, 8: 341.

Commenters requested redefining or adding the following terms:

*Benefit Cost Analysis*

- Means an evaluation of the positive and negative changes associated with the action. The normative foundation of BCA is the potential compensation test of Kaldor and Hicks. BCA answers the question of whether the benefits for those who gain from the action are sufficient to, in principle, compensate those burdened, such that everyone would be at least as well off as before the policy. The calculation of net benefits (benefits minus costs) measures the economic efficiency of a regulation, where economic efficiency refers to Kaldor-Hicks

efficiency, a situation whereby the dollar value of aggregate wealth in society is maximized.

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

*Compliance cost*

- Means the private costs that a regulated entity incurs to comply with a regulation and for interrelated services, equipment, or regulatory requirements, including professional services (e.g. installation and operation of pollution abatement equipment and the legal and engineering services associated therewith). A commenter claimed that as written, "compliance cost" does not include all of the costs that a source incurs for rule compliance.

*Direct Costs*

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

*Explicit Costs*

- Are those costs for which an explicit monetary payment is made, or for which it is straightforward to infer a value.

*Favorable effects of a policy action*

- Means positive benefits to human health and the environment, which are defined, discrete, and demonstrable by numeric data. Finding of a favorable effect of policy action shall not be based in part or in whole on: (1) modeling; (2) potential adverse health or environmental effects; or (3) suspected adverse health or environmental effects.

*Implicit Costs*

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

*Indirect Costs*

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

*Most likely estimate*

- Means a scientifically appropriate estimate which is based, to the extent feasible, on one of the following: (1) central estimates of risk using the best available data and most likely assumptions; (2) an approach which combines multiple estimates based on different scenarios and weighs the probability of each scenario; or (3) any other methodology designed to provide the most unbiased representation of risk, given the current status of scientific information available to the Agency. Each of these approaches should characterize uncertainty and variability quantitatively to the extent feasible. EPA should document the major sources of uncertainty in models and assumptions used and conduct sensitivity analyses using alternative plausible models and assumptions to determine and disclose the impact of uncertainties on the resulting risk estimates. This will help demonstrate how the CAA regulatory action is expected to provide incremental benefits that justify the incremental costs.

*Most likely estimate or central estimate of risk*

- Is the mean or average of the distribution; or a number which contains multiple estimates of risk based on different assumptions, weighted by their relative likelihood; or any estimate judged to be most representative of the distribution. See, e.g., Charles A. Holloway, Decision Making Under Uncertainty: Models and Choices (1979), at 76, 214, 91–127; Theodore Colton, Statistics in Medicine (1974), at 28–31. The central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk. See Science and Judgment in Risk Assessment, at 170– 75.

*Objective*

- Includes the presentation of information in an accurate, clear, complete, and unbiased manner, including the presentation of information in the proper context, identifying the sources of the information, and disclosing and providing access to the supporting data and models, so the public can determine for itself whether there may be some reason to question the objectivity of the sources. The term also means, as a matter of substance, ensuring accurate, reliable, and unbiased information. In a scientific, economic, statistical, or financial context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods, including the identification and evaluation of error terms and model uncertainties. Third, the data and regulatory impact analysis, including the benefit-cost analysis and any risk assessment, shall be "capable of being reproduced." Consistent with the OMB government-wide information quality guidelines, EPA shall ensure "a high degree of transparency about data and methods to facilitate reproducibility of such information by

qualified third parties," while ensuring appropriate safeguards, including for privacy, intellectual property, and trade secrets, etc.

*Opportunity cost*

- Means the value of the next best alternative to a particular activity or resource. Willingness to pay captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit.

*Opportunity cost of capital*

- Means the returns to invested capital that are not reflected in a capital asset's price. It can be expressed as the marginal before-tax rate of return to private capital in the US economy. A base-case rate of 7 percent shall be used to account for the opportunity cost of capital in the EPA's regulatory analysis.

*Social costs or costs*

- Means the negative incremental changes incurred as a result of the regulation or policy action. Costs are measured in terms of their social opportunity cost, which in practice usually refers to the minimum amount society is willing to accept as compensation for a loss.
- A commenter stated that the definition of "social costs," includes the "sum" of all costs, but the definition of social benefits does not. This apparent direction to include all costs but not all benefits is inconsistent with the general principles of benefit-cost analysis and would bias the analyses.

*Social opportunity cost*

- The value society is willing to forego to enjoy a particular benefit. It refers to what the market price of a resource would be in a perfectly competitive market, free of distortions such as externalities. If the market for a resource does not exist or substantial market failures are present in a market for a good, then the social opportunity cost of the resource is the price that would emerge if the market did exist and if affected third parties (including those in the future) could trade in the market at zero transaction costs.

*Society*

- Refers to all individuals with standing in the analysis, now and in the future. By default, those with standing are typically citizens and residents within the United States. Standing can be granted to other individuals when impacts on other individuals are of concern.

*Social benefits or benefits*

- Means the positive incremental changes accrued as a result of the regulation or policy action. Benefits are measured in terms of their social opportunity cost,

which in practice usually refers to the maximum amount society is willing to pay for the benefit.

*Positive changes*

- Means a demonstrable increase in quality of life taking into account economic and financial factors, such that clear numeric data demonstrate the society wellbeing is documented to be improved exclusively due to the proposed EPA policy or rulemaking.

*Social well-being*

- Means improved quality of human health and environment demonstrable by numeric data.

*Unbiased*

- Means neither under-estimating nor over-estimating risk.

*Weight of the evidence*

- Means the consideration and integration of all relevant studies while giving greatest weight to information from the highest quality and most relevant studies, taking into account factors such as the quality of the studies, the appropriateness of the study methods, the potential for systematic error, overt or hidden sources of bias, consistency of results across studies, whether the exposure-response data is reflective of current or projected real-world conditions for affected populations, the biological plausibility of statistical associations, and the similarity of results to responses and effects in humans.

Other commenters requested EPA define the following terms and phrases in the proposal:

- "material way" to be used for interpreting EO 12866 to help clarify when a BCA is required for a rulemaking.
- "to the extent permitted by law" in the definition of publicly available. A commenter pointed out that it is ambiguous whether EPA is referring to the Clean Air Act, other laws that EPA implements, or entirely unrelated federal laws. The commenter also stated that the definition must clarify if state laws governing the release of information will be respected, pointing out that in some situations a researcher and EPA both have access to a model, and the researcher is prohibited from releasing it under state law.
- "privileged, non-exempt information." The commenter stated it is unclear which privileges EPA is contemplating, and what the information may or may not be exempt from. The commenter concluded that EPA's failure to explain the meaning of terms that are central to the function of the Proposal is arbitrary and deprives the public of an opportunity to comment on what the Proposal would actually do.

**Response:** We have reviewed the definitions and incorporated input from SAB. Except for the following definitions, we are maintaining the definitions we proposed. In the final rule we are modifying definitions for the following terms: benefit-cost analysis, compliance costs, regulatory options, social benefits or benefits, and social costs or costs. Section V.C of the final rule's preamble provides further information on definitions.

## 9.3 Other Rulemaking

**Comment:** Commenters asserted that the proposal is so vague that it is not possible to comment on exactly how the EPA will use the results of BCA to make decisions in future rulemakings. As an example, a commenter stated although the Administrator has publicly stated that co-benefits would not be used to justify a rule, the statement is contradicted in the preamble, which states that "The EPA…is not proposing to mandate that a significant CAA regulation be promulgated only when the benefits of the intended action justify its costs." The commenter added that because the preamble provides no indication of a change to EPA's longstanding policy to consider all benefits to justify regulations, the final BCA rule cannot adopt provisions to back away from that approach without a supplemental notice to obtain public comment on the basis and purpose of the change. Another commenter stated that the use of BCA in rulemaking is a complex topic, and the proposal does not contain sufficient detail for commenters to be able to foresee and comment on all the positions that the EPA could take.

A commenter advocated that all BCAs for significant rules should evaluate the cost effectiveness (incremental cost per ton of pollutant reduced) of regulatory alternatives, even for rules where factors other than cost govern the outcome.

**Response:** We disagree with the commenters. In the proposed and final rule EPA has laid out clear procedures for rulemakings to be more transparent and consistent and to incorporate the best practices. Commenters cite statements that are not part of the administrative record in support of their contention that the rule is vague, however they identify no portion of the rule to support their contention. The rule specifies the details of how the BCA should be conducted and requires a summary presentation of the overall BCA results for the rule, including total costs, benefits, and net benefits with the goal of increasing consistency and transparency.

**Comment:** A commenter recommended that section 40 CFR 83.3(b) should be supplemented with clarification of how the BCA is subject to administrative procedures and judicial review. The commenter added that interested persons should have the opportunity to contest a BCA, which violates established regulatory principles pursuant to the Administrative Procedures Act. The commenter also recommended that 40 CFR 83.3 should be revised to include subpart: (c) The final BCA published by the EPA is final agency action subject to review under the Administrative Procedures Act.

**Response:** As discussed in the section V.B of the preamble, EPA has determined that the final rule is enforceable against the Agency. A BCA conducted in a future rulemaking pursuant to the final rule would be part of that administrative record of that rulemaking.

## 10.0 BCA Results in Decision Making

**Comment:** Commenters supported a requirement that the EPA take into account the results of the BCA in rulemaking decisions. However, many of these commenters said this approach is only appropriate where the statute does not preclude it, and noted that the Supreme Court has ruled that the EPA cannot do so when setting NAAQS, and that other parts of the CAA prohibit the EPA from considering costs in setting certain standards. The commenters added that even in the few instances where the EPA cannot set a standard based on costs, a BCA will help to inform the public of the effects of the standard and provide valuable information on how to minimize costs.

Other commenters argued that almost all CAA substantive provisions authorize or require the EPA to consider cost in setting regulatory standards, and the authority or obligation to consider cost provides the EPA with the legal authority to promulgate regulations specifying how it will consider cost. The commenters stated that this regulatory approach also is consistent with Supreme Court decisions on BCA, particularly *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208 (2009) (EPA has substantial discretion in interpreting even a statute that is silent on cost-benefit balancing as authorizing it) and *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (EPA's statutory interpretation that cost is not a relevant factor in determining whether to regulate under the capacious phrase, "appropriate and necessary" was arbitrary and capricious). According to one of these commenters, these decisions apply the fundamental principle, established in *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), that it is arbitrary for an agency to neglect an important aspect of a regulatory problem and, unless Congress clearly requires otherwise, costs and benefits inevitably are important aspects of a regulatory problem. The commenter argued that *Entergy* and *Michigan* set forth a default rule that "agencies must weigh costs and benefits, at least in some fashion," absent a clear statutory instruction to the contrary[21] and these cases provide a firm legal foundation for the EPA to require the use of BCA in CAA regulatory decision making.

The commenter argued that the EPA also has authority to establish a legislative rule on how the EPA interprets provisions of its regulatory statute to require BCA under *Chevron;*[22] i.e., unless a statutory provision unambiguously precludes BCA (which is highly unlikely after *Entergy* and *Michigan*), there should be little doubt that such a rule would be lawful.[23]

The commenter cited several examples of CAA authorities that may be used to require BCA and benefit-cost balancing:[24]

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[21] Jonathan S. Masur and Eric A. Posner, Cost-Benefit Analysis and the Judicial Role, 85 U. Chi. L. Rev. at 975-81 (discussing an emerging default rule under federal common law that agencies must weigh costs and benefits absent contrary statutory instructions); see Cass R. Sunstein, Cost-Benefit Analysis and Arbitrariness Review, 41 Harv. L. Rev. 1, 40-42 (2017) (concluding that "[u]nder the APA, agencies must avoid arbitrariness, and a regulation that imposes costs without conferring benefits is arbitrary"); see also, Noe and Graham, at 144.

[22] Chevron USA Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837 (1984).

[23] Noe and Graham, at 139.

[24] See Regulatory Improvement Council Coalition Comments on EPA's Proposed Rule: Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process.

- NSPS: The commenter argued that the EPA must consider cost in setting NSPS emissions standards, but the EPA in the past has used a cost-effectiveness analysis in setting NSPS and incorrectly reasoned that because CAA section 111 "omits any reference to air quality benefits," the EPA should not balance costs and benefits.[25] The commenter stated that EPA's approach to assessing cost has varied under this program; sometimes analyzing industry-wide impacts, while at other times looking at the cost-effectiveness of control measures (e.g., in dollars per ton removed).[26] The commenter argued that the EPA should correct its statutory interpretation and require BCA for establishing NSPS in light of *Entergy* and *Michigan*, as well as *State Farm*.

- NESHAP: The commenter argued that CAA section 112 allows the EPA to mandate BCA for making "above the floor" determinations, and CAA section 112(f)(2) also requires the EPA to conduct a risk assessment within 8 years after promulgating a MACT standard to determine whether it should be adjusted to address significant remaining risks, and cost is a factor that the EPA must consider in making the ample margin of safety determination as part of the risk assessment.[27] The commenter also noted that CAA section 112(d)(6) requires the EPA to conduct a technology review at least every 8 years for each MACT standard, and argued that Courts have made clear that the EPA has the discretion to consider cost in deciding whether advances in technology warrant a change to an existing standard,[28] and this would be consistent with *Michigan v. EPA*.

- BACT (CAA section 169(3)): The commenter stated that as defined in CAA section 169(3), the EPA must determine BACT, taking into account "economic impacts and other costs," and noted that the EPA has commonly used the cost-effectiveness of emissions controls (usually measured in dollars per ton removed). The commenter argued that the EPA should require the use of BCA in its own PSD permits and encourage the use of BCA in state-issued PSD permits.

- Regional Haze (CAA sections 169A and B): The commenter noted that CAA section 169A(g)(1) provides that the "costs of compliance" must be taken into consideration in determining reasonable progress, and argued that the EPA should encourage states to use BCA in assessing cost in making reasonable progress demonstrations, including whether the 1999 regulatory goal of eliminating man-made visibility impacts by 2064 is justified.[29]

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[25] See U.S. Environmental Protection Agency, EPA's Use of Benefit-Cost Analysis 1981-1986, EPA-230-05-87-028 (Aug. 1987), at p. 3-3.

[26] Because feasibility analysis can be an easily manipulatable, "standard-less" standard and produce quite disparate industry-by-industry outcomes, consideration of costs using such a feasibility approach could be arbitrary and capricious. See, e.g., Jonathan Masur and Eric A. Posner, Against Feasibility Analysis, 77 Univ. Chi. L. Rev. 657 (2010) (concluding that feasibility analysis lacks a normative justification, can just as easily lead to under-regulation as to over-regulation, and should have no place in government regulation).

[27] NRDC v. EPA, 529 F.3d 1077, 1083 (D.C. Cir. 2008).

[28] Ass'n. of Battery Recyclers, Inc. v. EPA, 716 F.3d 667, 673-4 (D.C. Cir. 2013); Nat'l Ass'n for Surface Finishing v. EPA, 795 F.3d 1, 5 (D.C. Cir. 2015).

[29] See 40 C.F.R. § 51.308.

- RACM and RACT (CAA section 172(c)(1)): The commenter noted that cost is a relevant factor in determining both RACM[30] and RACT.[31] The commenter argued that the EPA should encourage states to employ BCA in making their cost-effectiveness assessments in preparing their implementation plans.

The commenter also noted that the Administrative Procedure Act (APA) prohibits arbitrary agency action, 5 U.S.C. 706(2)(A), and grants every agency "all authority necessary to comply with the requirements of [the Act] through the issuance of rules or otherwise." 5 U.S.C. § 559. The commenter argued that *Entergy* and *Michigan* make clear that the failure to balance benefits and costs is arbitrary, absent contrary statutory language.[32]

The commenter argued that while the Supreme Court has held that the EPA may not consider costs in setting NAAQS, the EPA can and should require BCA to be performed for NAAQS rulemakings. The commenter noted that while in the *American Trucking* decision, the Supreme Court held that cost may not be considered in setting NAAQS,[33] CAA section 109(d)(2)(A) requires the Administrator to establish the Clean Air Science Advisory Committee (CASAC) to provide advice on NAAQS standard setting, and CAA section 109(d)(2)(C) specifies that CASAC's advice must include "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of [NAAQS]."[34] The commenter concluded that because CASAC largely relies on information generated by the EPA to fulfill its responsibilities, CAA section 109 provides the legal basis for requiring BCA to be performed for each NAAQS rulemaking, even if benefit-cost balancing cannot determine the NAAQS standard.

Commenters added that a requirement where benefits must justify costs is a common-sense requirement. Commenters argued that EO 12866 has expressed the principle that agencies should regulate only when they can reasonably determine that benefits justify costs.[35] A commenter added that the EPA could also consider ancillary benefits, and costs, to help evaluate regulatory outcomes as described in OMB's Circular A-4, and not require that only direct benefits exceed costs. A commenter stated that this approach would codify a legal obligation consistent with the longstanding directive of every president since 1981 that executive agencies "shall . . . propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."[36]

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30 Sierra Club v. EPA, 294 F.3d 155, 162-3 (D.C. Cir. 2002).

31 40 C.F.R. § 51.100(o).

32 Noe and Graham, at 140 & n. 225.

33 Whitman v. American Trucking Ass'ns. Inc., 531 U.S. 457 (2001).

34 CAA § 109(d)(2)(C) (emphasis added).

35 See EO 12866, § 1(b)(6)

36 EO No. 12866 § 1(b)(6), 58 Fed. Reg. 51565 (Oct. 4, 1993) (Clinton, G.W. Bush, Obama, and Trump) ("Each agency shall . . . propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs"); EO No. 13563, § 1(b)(1), 76 Fed. Reg. 3821 (Jan. 21, 2011) (Obama and Trump) ("each agency must . . . propose or adopt a regulation only upon a reasoned determination that its

Commenters opposed a requirement that the EPA take into account the results of the BCA in rulemaking decisions for at least one of the following reasons (presented in no particular order):

- It is contrary to the directives of the CAA. In instances where the CAA does not authorize the EPA to consider costs, the EPA would not be authorized by Congress to take the results of a BCA into account in informing the rulemaking. Alternatively, according to the commenter, in instances where the EPA can or must consider costs in the rulemaking process, how the EPA weighs those costs and benefits must still be dictated by the statutory directives of the CAA.
- It is already guided by caselaw,[37] EO 12866,[38] and under the Administrative Procedure Act, rulemakings must be supported by non-arbitrary justifications, including the assessment of all important aspects of the problem under consideration.
- Results of the BCA should only be used to provide information regarding a rule's predicted impacts, and they should play no role in informing the EPA's decision-making under the CAA because it is either antithetical to or explicitly prohibited by the statute.
- A single cost-benefit approach for all CAA programs would ignore important distinctions (for example, different regulatory approaches, different categories of sources, and different health impacts from different pollutants) of various CAA programs, conflict with statutory directives, and eliminate important flexibilities that can be used to account for these distinctions.
- BCA is an imperfect tool that can frequently overstate costs, and can only incompletely articulate the scope and diversity of environmental, health, and safety benefits that cannot be monetized. The EPA has estimated that the CAA has delivered benefits in its first twenty years that exceeded costs by a factor of forty, and by thirty-to-one since 1990.[39]

benefits justify its costs"); see also EO No. 12291, § 2(b), 46 Fed. Reg. 13193 (Feb. 17, 1981) (Reagan and G.H.W. Bush) ("Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society"). See also OMB's Circular A-4, at 10 (on measuring incremental benefits and incremental costs of successively more stringent regulatory alternatives).

37 See, e.g., Policy Integrity Comments on MATS, supra note 36, at 2-3; Policy Integrity Amicus Brief, supra note 36, at 12-15 (summarizing regulatory history and literature).

38 EO 12,866 § 1(b)(6).

39 U.S. EPA, "Benefits and Costs of the Clean Air Act," available at https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act.

- BCA flattens the variety of human experience into a monetary metric;[40] undercounts the preferences of the poor vis-à-vis the rich;[41] devalues the lives of our children and grandchildren;[42] ignores distributional inequities;[43] fails to account for low-probability catastrophic outcomes;[44] and rests on a vision of human nature and behavior that has been shown to have many empirical flaws.[45]

Commenters argued that the EPA should follow all applicable federal law, such as the relevant provisions of the CAA, for future CAA regulations, and continue its current practice of assessing and weighing costs and benefits consistent with statutory requirements, EOs, and applicable OMB and EPA guidance. A commenter contended there was no reason or legal basis for the EPA to create constraints on its future actions even those arising under a specific provision of the Act. The commenter added that the EPA should not impose a requirement that the EPA take action under the Act only if the action's benefits justify its costs, which would be both unnecessary, where relevant statutory provisions already establish a strict benefit-cost test for action, and unlawful, where Congress chose not to establish such a test. The commenter added that the EPA has no authority to ignore or modify statutory directives and there also may be situations where distributional impacts or other equitable or policy factors counsel in favor of regulation or other agency action, even when an unweighted BCA might not. The EPA has provided no reason to promulgate a mandate that the EPA slavishly follow the outcome of BCAs and thus rule out the possibility of making decisions based on such broader considerations.

A commenter said that the EPA should provide a thorough legal analysis for how taking into account the results of the BCA in rulemaking decisions would be consistent with EPA's obligations under CAA and allow an opportunity for public comment on that analysis before moving forward with such an addition.

Commenters argued that the final rule should require the EPA to fully consider the results of the BCA in making regulatory decisions under the CAA unless the specific statutory provision clearly prohibits such consideration, but that a hard, absolute test is not needed and that the

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[40] Elizabeth Anderson, Value In Ethics And Economics 55-59 (1993); Mark Sagoff, The Economy Of The earth: Philosophy, Law, And The Environment 1-7 (1988); Cass R. Sunstein, *Incommensurability and Valuation in Law*, Mich. L. Rev. 779, 841-42 (1994).

[41] Richard A. Posner, Economic Analysis of Law 13 (5th ed. 1998); C. Edwin Baker, *The Ideology of the Economic Analysis of Law,* 5 Phil. & Pub. Aff. 3, 6 (1975); Duncan Kennedy, *Cost-Benefit Analysis of Entitlement Problems: A Critique*, 33 Stan. L. Rev. 387, 422-44 (1981); Arthur A. Leff, *Economic Analysis of Law: Some Realism About Nominalism*, 60 Va. L. Rev. 451, 478-79 (1974).

[42] Lisa Heinzerling, *Discounting Our Future*, 34 Land &Water L. Rev. 39, 40-41 (1999); Douglas A. Kysar, *Discounting . . . on Stilts*, 74 U. CHI. L. REV. 119, 119-20 (2007); Richard L. Revesz, *Environmental Regulation,*
*Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941, 955-86 (1999).

[43] Amy Sinden, *Cost-Benefit Analysis*, in EDWARD ELGAR ENCYCLOPEDIA OF ENVIRONMENTAL LAW, VOL II, ENVIRONMENTAL DECISION MAKING (Glicksman & Paddock eds.).

[44] Daniel A. Farber, *Uncertainty*, 99 GEO. L.J. 901 (2011); Martin L. Weitzman, *On Modeling and Interpreting the Economics of Catastrophic Climate Change*, 91 REV. ECON. & STAT. 1 (2009).

[45] DANIEL KAHNEMAN & AMOS TVERSKY, CHOICES, VALUES, AND FRAMES (2000); Amartya Sen, *The Possibility of Social Choice*, 89 AM. ECON. ASS'N 349 (1999); Tuba Tuncel & James K. Hammitt, *A New Meta-Analysis on the WTP/WTA Disparity*, 68 J. ENVTL. ECON. &MGMT. 175 (2014).

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

A commenter noted that in the 1996 primer, *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation: A Statement of Principles*, the authors write that while benefit cost analysis should be required in developing all regulations, "agency heads should not be bound by a strict benefit-cost test. Instead, they should be required to consider available BCA and to justify the reasons for their decision in the event that the expected costs of a regulation far exceed the expected benefits." The commenter argued that this statement seems to contradict the EPA's current proposal that the benefit-cost analysis procedures be codified with specific and consistent methodology. The commenter also noted that, Principle 5 in this primer explains, "There may be factors other than economic benefits and costs that agencies will want to weigh in decisions, such as equity within and across generations. In addition, a decision maker may want to place greater weight on particular characteristics of a decision, such as potential irreversible consequences." The commenter argued that this is particularly true when it comes to environmental justice initiatives that seek to build healthier communities in areas that have faced systemic disinvestment, and that the EPA's proposed change to its benefit cost rule would make it difficult for decision makers to include these considerations in a final regulation.

A commenter also recommended that in presenting summary information of the results of the benefits and costs analysis, EPA should also include in the preamble and in the BCA the results of its determination of whether the statutory-objective benefits justify the costs of the recommended option. The commenter stated that if the Agency selects an option where those benefits fail to justify the costs, the EPA should include in the preamble and the BCA summary the reasons why EPA selected an option with higher costs than benefits.

Other commenters noted that in most RIAs, the BCA often includes benefit and cost categories that cannot be quantified or, if quantified, cannot be monetized. The commenters said they were concerned that these categories would not be fully considered in a hard benefit-cost calculation. A commenter also said they believed that there are other important considerations that need to be factored into the decision including distributional, ethical, and legal issues. The commenter argued that employment or economic growth effects are separate factors that might be considered in making a decision, and these factors should be considered separately from benefits and costs because they are not commensurable, additive, or directly related in any mathematical way to costs.

A commenter acknowledged that in many instances, Congress has left no room for EPA to further weigh costs in setting standards. The commenter cited CAA Section 112(d)(3), which specifies that standards for emissions of hazardous air pollutants from new stationary sources must be not less stringent than, "the emission control that is achieved in practice by the best controlled similar source…," and the standards for existing stationary sources must not be less

stringent than, "the average emission limitation achieved by the best-performing 12 percent of the existing sources…." In the realm of hazardous emissions standards, therefore, EPA may consider costs only when adopting standards that are more stringent than those that Congress has required.

A commenter (SCAQMD) expressed concern that by seeking comments on what the rule should prescribe how BCA should inform regulatory options, EPA seems to be indicating a preference that BCA should be the controlling factor in shaping regulations. The commenter noted that the same paper that EPA cites as support for requiring BCAs broad rulemaking also states that BCA should not be the sole basis for decision-making and should not be used as necessarily even sufficient for decision-making. The commenter argued that BCA is a more appropriately one input out of many in developing regulations aimed at protecting public health, and there are many areas where the Clean Air Act prohibits or limits consideration of cost in establishing standards. The commenter requested that EPA reconsider this proposed rule and instead focus on implementing and improving existing economic guidelines and practices to ensure the development of robust transparent BCAs.

**Response:** Responses to comments regarding legal issues, including EPA's legal authority to promulgate the BCA rulemaking are found in Chapter 3 of this document and in Section V.B of the preamble to the final rulemaking.

The EPA disagrees with the comment that BCA frequently overstate costs, and can only incompletely articulate the scope and diversity of environmental, health, and safety benefits that cannot be monetized. The rule codifies into regulation BCA procedures consistent with the existing guidances that EPA relies upon to develop high quality regulations (e.g., OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866). The final rule requires that BCAs must provide available evidence on all non-monetized and non-quantified benefits and costs, including why they are not being monetized or quantified and what the potential impact of those benefits and costs might be on the overall results of the BCA

As discussed in section V.D of the preamble to the final rule, the EPA is finalizing the requirement that all future significant proposed and final regulations promulgated under the CAA be accompanied by a BCA. We have determined, based on the comments received, executive orders, and judicial decisions, that when permitted for consideration under the specific provision of the CAA under which a future regulation is promulgated, the EPA 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. 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 EPA decides to regulate. Consideration of the results of BCA in regulatory decision-making is also consistent with the requirements of EO 12866.

We disagree with the comment that the statement quoted from the 1996 primer is inconsistent with this rule. The final rule declines to formulate a specific benefit-cost 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. Additionally, there is nothing in this final rule that would prohibit EPA from considering other information as appropriate under the specific CAA provision under which a future regulation subject to this rule is promulgated. Consideration of one metric does not bar consideration of another; commenters will retain the ability to provide the EPA with information, and the EPA will be required to consider such information and respond to comment as is dictated by the process governing the future CAA rulemaking. Thus, commenters concerns that the final rule is contrary to directives in the CAA that the EPA weighs costs and benefits as dictated by the statutory directives of the specific CAA provisions or that a single cost-benefit approach for all CAA programs is inappropriate are unfounded. 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. 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.

**Comment:** A commenter stated that while the proposal asked for comment on how BCA results should inform future regulatory actions, it was unclear how this may translate to CAA statutory provisions, such as the Renewable Fuel Standards (RFS), that require ongoing or annual rulemakings for fuel blending requirements. The commenter noted that the RFS was finalized a decade ago, but each year, the EPA is required to set an annual renewable volume obligation (RVO), and regulations are occasionally promulgated to approve pathways under the RFS. The commenter stated that they we would have significant concerns about the EPA performing a BCA analysis for each RVO each year as doing so would completely undermine the certainty and investment expectation created when this program was first put into force.

**Response:** As discussed in section V.D of the preamble to the final rule, the EPA is finalizing the requirement that all future significant proposed and final regulations promulgated under the CAA be accompanied by a BCA. However, we decline 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.

**Comment:** A commenter argued that the EPA has not issued any proposal on whether and under what circumstances the EPA could determine that a future significant CAA regulation be promulgated only when monetized benefits exceed the costs of the action; therefore, any final

rule requiring rules to pass a cost-benefit test would fail the logical outgrowth test and thus be unlawful.[46]

The commenter argued that the EPA cannot satisfy the notice requirement through "general notice that it might make unspecified changes. . . . Agency notice must describe the range of alternatives being considered with reasonable specificity."[47] The commenter added that the EPA notice must take "a concrete and focused form so as to make criticism or formulation of alternatives possible."[48] The commenter stated that EPA's proposal has not served "three distinct purposes": "ensuring that agency regulations will be tested by exposure to diverse public comment"; enabling "fairness to affected parties"; and "giving affected parties an opportunity to develop evidence in the record to support their objections to a rule…enhanc[ing] the quality of judicial review."[49]

The commenter argued that the EPA's solicitation of comment on this topic leaves profound questions as to what the EPA is actually considering, and that the EPA has not even defined what it means by "monetized benefits" or "costs" in this context. The commenter noted that elsewhere in the Proposal, the EPA acknowledges that not all benefits and costs can be monetized but proposes to "exercise its subject matter expertise" in assessing the importance of those benefits and costs.[50] The commenter argued that the proposal has provided no signal of whether imposing a requirement that monetized benefits exceed costs would complement EPA's Proposal, displace it, relegate it to irrelevance, or something else. The commenters argued that they were left to guess whether the EPA means that monetized benefits would need to exceed only monetized costs, or *all* costs that the EPA decided to consider (a possibility raised by the literal wording of the solicitation for comment). The commenter also argued that the Proposal describes "three broad frameworks for estimating social cost—compliance cost, partial equilibrium, and general equilibrium,"[51] and they are left to guess which of those cost frameworks would be used as the benchmark for monetized costs, or whether the EPA would select its preferred framework on a rulemaking-specific basis, leading to an outcome that present commenters could not possibly anticipate.

The commenter argued that the EPA has not specified which monetized benefits it would include in this analysis, and that in several places, the EPA suggests that the presentation of benefits should be sliced and diced into various categories (even though the EPA already has a longstanding practice of clearly delineating the components of its benefits estimates). The commenter notes, that for example, the Proposal would require the EPA to disaggregate co-

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46 *See, e.g.*, *Sierra Club v. Costle*, 657 F.2d 298, 352 (D.C. Cir. 1981) (imposing the "logical outgrowth" in the context of the Clean Air Act). *See also* CAA section 307(d)(3); 5 U.S.C. § 553(b). EPA's statement that this Proposal is "a rule of Agency procedure . . . [and] exempt from the notice and comment requirements," 85 Fed. Reg. at 35613, is factually inadequate and legally flawed. But it is particularly inapt here, where EPA considers explicitly establishing a new substantive factor affecting the stringency of future health and environmental protections.

47 *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983).

48 *Home Box Office, Inc. v. Fed. Commc'ns Comm'n*, 567 F.2d 9, 36 (D.C. Cir. 1977).

49 *Small Refiner*, 705 F.2d at 547.

50 85 Fed. Reg. at 35,618.

51 *Id.* at 35,619.

benefits in the presentation of BCA results,[52] but EPA's solicitation of comment does not specify whether the monetized benefits in this context would include *all* monetized benefits, or only those that the EPA deems not "ancillary." The commenter noted that the Proposal also raises the possibility that "domestic" benefits and costs should be reported separately from those that are "non-domestic,"[53] but the EPA's solicitation of comment does not specify whether the cost-monetized benefit test would be limited to a domestic scope, and warned that there are instances where dividing benefits into "domestic" and "non-domestic" is analytically unsound, which further confuses this issue.[54]

The commenter concluded that considering the various ways that the EPA could attempt to impose a benefit-cost test upon future significant regulations, it is currently infeasible to provide informed comments. The commenter argued that accounting for the different methods of accounting for costs and benefits combined with the multiple sections of the CAA that could be affected, it would be infeasible to meaningfully address all of the possibilities under any circumstances, but especially given the brevity of the comment period,[55] and it is unlikely that *any* single methodology could be rationally applied to the full range of CAA rulemakings.

A commenter argued that the proposed rule improperly assumes economic efficiency is always the goal, but the EPA must recognize that economic efficiency is nowhere defined as the goal of CAA regulation. The commenter noted that EPA cites *Husqvarna v. EPA,* 254 F. 3d 195, 200 (D.C. Cir. 2001) (85 Fed. Reg. 35616 c 2) for the proposition that where the statute lacks a mandate for a particular method of cost analysis, the agency will be granted wide discretion. The commenter argued that the EPA fails to recognize this case actually recognizes specific Congressional intent which EPA had honored, and the court rejected industry's claim that EPA must adopt a rule with the "best balance" of cost and benefit. Instead, the court upheld, according to the commenter, as consistent with statute, EPA's choice to give primary emphasis to achieving the greatest degree of emission reduction, while relegating cost to a secondary consideration. This, the commenter argued, even where the statute allows consideration of costs, it does not necessarily support an approach which would reject a rule merely because monetized benefits may not exceed costs.

The commenter argued that neither Congress nor the courts have endorsed the proposition that EPA must reject any rule where the benefits cannot be shown to exceed the costs. The commenter noted that EPA cites *Lignite Energy Council v. EPA*., 198 F. 3d 930, 933 (D.C. Cir. 1990) as granting the agency a great deal of discretion in balancing the statutory factors. However, according to the commenter, that court also concluded EPA's choice will be

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52 *Id.* at 35,622.

53 *Id.* at 35,623.

54 *See, e.g.*, Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis* 17 (Aug. 2016).

55 *See* Environmental Defense Fund, Clean Air Task Force, Earthjustice, Environmental Law & Policy Center, Environmental Protection Network, National Parks Conservation Association, Sierra Club, *Request to Immediately Halt and Withdraw EPA's Clean Air Act Cost-Benefit Rulemaking Action, and Extend Deadline for Public Comments on EPA's Notice of Proposed Rulemaking*, Docket ID EPA-HQ-OAR-2020-0044-0052 (June 26, 2020); Union of Concerned Scientists, *Request for an Extension on Comment Period for EPA's Notice of Proposed Rulemaking, "Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process,"* Docket ID EPA-HQ-OAR-2020-0044-0053 (June 29, 2020).

sustained unless the environmental or economic costs of using the technology are "exorbitant." Thus, according to the commenter, EPA would not be required to adhere to any formal, strict cost-benefit balance.

The commenter added that, in the leading case regarding consideration of cost, the Supreme Court held that "[n]o regulation is 'appropriate' if it does *significantly* more harm than good." *Michigan v. EPA,* 135 S Ct 2699, 2707 (emphasis added). The commenter argued that the Court gave as a caricatured hypothetical example a rule imposing billions of dollars of economic costs in return for a few dollars in health or environmental benefits. *Id*. Therefore, the commenter stated, EPA need not always demonstrate that monetized benefits outweigh the economy-wide costs of a regulation, particularly when benefits cannot be easily fully monetized. The commenter asserted that there may be cases where the benefits of the rule are more important to Congress's purpose than the costs so that even a rule with net costs would be appropriate, for example, a rule correcting an environmental injustice may be seen as worth the costs even if the costs somewhat outweigh the monetized benefits.

The commenter argued that, even where the statute allows consideration of costs, EPA must be sensitive to any guidance Congress provides in how to consider costs. The commenter noted that CAA 202(a)(1) regarding standards for motor vehicles requires EPA to set the compliance date giving "consideration to the costs of compliance within such periods." The commenter argued that here, Congress has limited consideration to the costs of compliance, which are usually thought of as the direct costs to comply with a rule, not all indirect costs that ripple through the economy. The commenter argued that the term "compliance costs" means all the expenses that a firm incurs to adhere to industry regulations, and this concept would not include indirect costs to consumers, or to those other businesses that the consumers would otherwise patronize. The commenter noted that EPA recognizes "a compliance cost approach typically identifies the private expenditures associated with compliance in the regulated sector(s)"[56] and the proposed rule identifies "compliance cost" as "the private cost that a regulated entity incurs to comply with a regulation (e.g., installation and operation of pollution abatement equipment."[57] The commenter noted that similar language is found in other sections of the CAA, including Section 213(a)(3) regarding emission standards for nonroad engines and Section 231(b) regarding emission standards for aircraft. Thus, the commenter concluded, the mere use of the word "cost" in a statute does not necessarily give EPA unfettered discretion to reject a regulation on the basis of indirect and far-removed costs.

**Response:** As discussed in section V.D of the preamble to the final rule, the EPA is finalizing the requirement that all future significant proposed and final regulations promulgated under the CAA be accompanied by a BCA. In this Final Rule, we decline 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. We disagree with the commenters assertions regarding the BCA prescribing requirements when the costs exceed the benefits of a rulemaking. We do not prescribe requirements for when costs exceed benefits in a rulemaking.

[56] 85 Fed. Reg. 35619

[57] 85 Fed. Reg. 35625

The EPA is codifying into regulation procedures that are consistent with best practices for estimating benefits and costs as discussed at length in OMB's Circular A-4 and EPA's Guidelines, which are the existing peer reviewed guidance documents implementing EO 12866.

# 11.0 Other Requests for Comment

## 11.1 Use of Third Party Models

**Comment:** Commenters supported the proposal that the EPA should only use third-party models where the third party makes its models and assumptions publicly available to the extent permitted by law. Similarly, another commenter stated that the use of third-party models should be restricted to only those cases where it is the only option and the models have and can be peer-reviewed and validated independently. A commenter argued that while it is important for the EPA to protect confidential or privileged material, it is also important for the public to understand not only the conclusions but the methodology and underlying data of the models which the EPA considers in its rulemakings. Another commenter stated that this is needed to allow for independent evaluation and verification.

On the contrary, other commenters opposed the proposal to allow the EPA to use models offered by a third party only where the third party makes its models and assumptions publicly available, to the extent permitted by law. A commenter supported the EPA's stated goal to increase transparency in regulatory BCA, but said that it worried that such an approach may limit the health data that the EPA is permitted to analyze. The commenter suggested that such an approach could be used to justify the use of industry-funded models/data over epidemiological studies, for which the raw individual health data is protected by law, or academic models that may be protected as intellectual property. The commenter also said it was concerned that this approach could limit regulatory action in cases of urgent importance that protect the health of U.S. citizens when such models/data are the only relevant information available. The commenter stated that to facilitate transparency, the EPA should explicitly explain why and how such information was used, and the potential limitations associated with that use.

A commenter urged the EPA to release the data, assumptions, and calculations used in proprietary models so that commenters can adequately analyze and address any issues. The commenter added the EPA must not exclude inputs and assumptions from valid, peer-reviewed science based on the inability to release underlying data.

A commenter stated that there may be circumstances when third parties face legitimate restrictions that prevent public release of their models. The commenter argued that it would be inconsistent with EPA’s obligation to use the best available information for the EPA to knowingly use a less rigorous or robust model—or no model at all—on that basis. The commenter asserted that there are other measures short of public release that can reassure and inform the public about the validity of a model and EPA’s use thereof, and there is no indication that the EPA considered these alternatives. The commenter argued that it would be arbitrary, capricious, and unlawful for the EPA to impose an across-the-board requirement for the release of third-party models used by the EPA without assessing (i) the constraints this requirement could place on the EPA’s use of the best available information, (ii) the various reasons that the release of third-party models may be unauthorized or impracticable, and (iii) the options short of public release that may be available in certain circumstances.

The commenter argued that third parties may have valid concerns about making their underlying models publicly available, including that they may incorporate valuable proprietary information, or they may make it easier to personally identify participants in a study. The commenter argued that a researcher may not have the resources to publicly release underlying models in a safe manner, and may have legitimate concerns about allowing the EPA to release it, for example, without implementing all of the safeguards that the researcher deems necessary. The commenter stated that researches could worry about being held liable if the EPA releases the model in a manner that exposes CBI or PII. The commenter noted that the proposal does not indicate whether the EPA would indemnify a researcher who allows the EPA to release a model. The commenter also noted that researchers may be governed by Institutional Review Boards that must approve the disclosure of potentially sensitive information, and for studies involving multiple authors, it may be necessary to obtain unanimous authorization, even though they may be governed by Boards around the world and subject to a wide variety of privacy laws. The commenter argued that the EPA should also clarify whether it is required to release a model if a researcher allows it to do so. If the EPA neglects or declines to release a model for whatever reason, the EPA should indicate whether the model could still be utilized in its BCA, or whether the BCA would have to exclude consideration of the model. The commenter stated that the EPA's failure to consider these questions and propose a process for addressing them is arbitrary and capricious.

Another commenter argued that although in some cases the public's interest in transparency may outweigh either the third party's interest in confidentiality or the model's informative value, there may also be circumstances when certain data or models must remain more protected. The commenter argued that a blanket one-size-fits-all binary choice of either full disclosure or prohibition is likely not the proper solution to this issue.

Another commenter recommended that to enhance transparency, the EPA should require the disclosure of all sources of funding that sponsored any third-party models it uses. The commenter reported that the Occupational Safety and Health Administration's (OSHA) 2013 proposal on Occupational Exposure to Respirable Crystalline Silica offers a model for what such a requirement might look like, in which OSHA included the following instructions in the proposal:

> "If you submit scientific or technical studies or other results of scientific research, OSHA requests (but is not requiring) that you also provide the following information where it is available: (1) Identification of the funding source(s) and sponsoring organization(s) of the research; (2) the extent to which the research findings were reviewed by a potentially affected party prior to publication or submission to the docket, and identification of any such parties; and (3) the nature of any financial relationships (e.g., consulting agreements, expert witness support, or research funding) between investigators who conducted the research and any organization(s) or entities having an interest in the rulemaking."

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. The requirements in this final rule aim to provide appropriate access, to the extent permitted by law, to the information (including data and models) that was used in the

development of the BCA. The EPA will retain its data procedures in the final rule that are consistent with the principle of transparency discussed at length in OMB's Circular A-4 and EPA's Guidelines and as specified in EPA's "Strengthening Transparency in Pivotal Science Underlying Final Significant Regulatory Actions and Influential Scientific Information" rulemaking.

## 11.2 Benefits vs Ancillary Benefits

**Comment:** Commenters supported disaggregating benefits into those targeted and ancillary to the statutory objective of the regulation for at least one of the following reasons (presented in no particular order):

- It would ensure transparency and accessibility by clearly identifying to the public the benefits of a rule that pertain to the reduction of emissions targeted by the CAA provision at hand versus those benefits that occur coincidentally to the primary purpose of the rulemaking. It would give a clearer picture for policymakers, other regulators, and the public, of how well the rule accomplishes its intended regulatory goals.
- It would allow for accountability and further promote regulatory consistency by allowing stakeholders to understand and comment on how the EPA weighs benefits and costs across rules within a given CAA program (e.g., NESHAP).
- It would allow the EPA's authorizers and appropriators to evaluate whether the EPA is acting in a manner consistent with Congressional intent and statutory authorizations.
- It would cause the EPA to explore whether there may be more efficient, lawful and defensible, or otherwise appropriate ways of obtaining ancillary benefits. For example, when ancillary $PM_{2.5}$ reductions constitute nearly all quantified benefits, the rule is functionally a $PM_{2.5}$ reduction mandate, and this would be prohibited under CAA section 112(b)(2), which prohibits the EPA from listing as a HAP any air pollutant already listed for regulation under the NAAQS program in CAA section 108.
- It would allow all benefit and cost categories to be on equal footing.
- It would allow the EPA to regulate criteria pollutants more efficiently from stationary and mobile sources through the NAAQS, NSPS, PSD, SIP Requirements, Mobile Source, and Acid Deposition Control programs, instead of regulating $PM_{2.5}$ via non-PM statutes.
- It is consistent with contemporary BCA research, as many experts have expressed concern over inappropriate claims of co-benefits and unbalanced analyses.[58]

[58] See, e.g., Ana Maria Zarate Moreno, "Escaping the 'Smoke and Mirrors' in Benefit Cost Analysis," George Washington University, July 1, 2015. https://regulatorystudies.columbian.gwu.edu/escaping-smoke-and-mirrors-benefit-cost-analysis; "Perpetuating Puffery: An Analysis of the Composition of OMB's Reported Benefits of Regulation." https://link.springer.com/article/10.1057%2Fbe.2012.14.

- It would be consistent with peer-reviewed literature that indicates that some co-benefits are better regulated through separate policy or statutory provisions intended for them directly.[59]

Some of the commenters said that while they supported disaggregating benefits into those targeted and ancillary to the statutory objective of the regulation, it was critical that the EPA retain co-benefits in the total evaluation, and noted that research indicates that narrowing the scope of regulatory impact assessment to exclude co-benefits can lead to "policy errors and welfare losses" not to mention legal vulnerabilities, and proper BCA regulatory analysis should account for all quantifiable costs and benefits, including those intended and unintended by the regulatory action.[60] A commenter stated that recent the EPA decisions to exclude co-benefits from BCA have left experts concerned about the credibility of the EPA and may have increased legal risk unnecessarily.[61]

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. In addition, the final rule requires that the BCA include a description in the preamble of how the Agency considered the results of the BCA. The EPA believes these requirements will increase the consistency and transparency on these issues for considering benefit and costs in CAA rulemaking.

**Comment:** Commenters argued that regulatory decisions should be based on only the primary benefits; and the co-benefits or ancillary benefits should not be considered, or should not be the primary driver of the decision.

A commenter argued that, as the Supreme Court made clear in *EPA v. EME Homer City Generation*, 134 S.Ct. 1584 (2014), which involved a challenge to EPA's CSAPR, the EPA has no authority to require reductions in emissions of criteria pollutants below the level necessary to achieve the NAAQS. The commenter concluded that given this limitation on EPA's authority, in the programs designed to address NAAQS pollutants, the EPA cannot use ancillary benefits associated with reductions in NAAQS pollutants to justify regulatory requirements for HAPs or other non-criteria pollutants that are more stringent than required under the statute, if the

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[59] See, e.g., Susan Dudley et al., "Consumer's Guide to Regulatory Impact Analysis: Ten Tips for Being an Informed Policymaker," *Journal of Benefit- Cost Analysis* 8:2 (2017), pp. 187–204. https://www.cambridge.org/core/journals/journal-of-benefit-cost-analysis/article/consumers-guide-to-regulatory-impact-analysis-ten-tips-for-being-an-informed-policymaker/FAF984595B822A70495621AEA7EF7DEB; Adam Gustafson, "Testimony before the Subcommittee on Oversight & Investigations of the House Committee on Energy and Commerce," Hearing on Undermining Mercury Protections: EPA Endangers Human Health and Environment, 116th Congress, May 21, 2019. https://energycommerce.house.gov/committee-activity/hearings/hearing-on-undermining-mercury-protections-epa-endangers-human-health.

[60] John D. Graham et al., "Co-Benefits, Countervailing Risks, and Cost-Benefit Analysis," *Harvard Center for Analysis Risk Assessment, Economic Evaluation, and Decisions Workshop*, Sept. 26-27, 2019, p. 1. https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1273/2019/09/Graham-Wiener-Robinson-2019.pdf.

[61] See, e.g., Comments of Matthew Kotchen, "Has Good Benefit-Cost Analysis Been Swept under the MATS?", *Resources Radio*, April 15, 2020, (26:00). https://www.rff.org/news/press-releases/new-episode-resources-radio-has-good-benefit-cost-analysis-been-swept-under-mats-mary-evans-and-matthew-kotchen.

justification for doing so is based on ancillary benefits of reducing a criteria pollutant below the level of the NAAQS. The commenter also said that in CAA sections 109 and 110, Congress created a comprehensive and detailed statutory scheme for regulating emissions of criteria pollutants and their precursors in which the EPA sets the NAAQS and states are given the responsibility and almost complete discretion in how to meet those standards. See *Union Electric v. EPA*, 247 US 426 (1976). The commenter argued that when it comes to criteria pollutants, it is states that determine which existing sources to regulate and how to regulate them, and the EPA may take over this role only if a state is unwilling or unable to adopt a set of regulations (a SIP) that will bring a state into attainment and address that state's contribution to non-attainment in other states.

The commenter recommended that only potential coincidental reductions of criteria pollutants that are projected to occur in locations with ambient concentrations still above the NAAQS be considered for inclusion in a net benefits calculation, and any co-benefits that are calculated in locations with baseline concentrations below the NAAQS should not be included in a net total benefits calculation, nor presented in a summary net benefits presentation because they are inconsistent with legally binding statutory determinations and should not be considered reliable. The commenter provided a detailed appendix in which they explained how the past use of inconsistent assumptions about scientific uncertainties in estimating criteria pollutant health benefits has caused inclusion of those co-benefits in RIAs to have become unnecessarily controversial. The appendix provided by the commenter also explained how economists' formulations that claim to provide a theoretical basis for including co-benefits calculated to zero concentration are flawed because they too are based on assumptions inconsistent with the NAAQS regulatory judgment.

Similarly, another commenter added that if a given county or region is already in attainment for a NAAQS, which are themselves established such to protect public health and an adequate margin of safety, then any reduction of emissions of criteria pollutants that occur directly or indirectly as a result of a rulemaking in those same counties and regions should not be counted as having a positive public health benefit.

Commenters argued that, given that almost all ancillary benefits are derived from reductions in fine particulate matter, the EPA should explain how any additional reductions below the annual NAAQS are justified. Some of these commenters noted that only nine full counties and seven partial counties, out of more than 3,000, do not meet the most recent standards for fine particulate matter, for which the annual standard is considered requisite to protect the public health with an adequate margin of safety for susceptible populations. Other commenters noted that in 2017 the Office of Management and Budget noted that EPA rules yield over 80 percent of the monetized benefits (and over 70 percent of the monetized costs) of federal regulations, and that over 95 percent of those benefits are the result of air quality rules were "mostly" asserted to result from the reduction in fine particulates.[62] Similarly, another commenter argued that the EPA should not monetize $PM_{2.5}$ reductions below the NAAQS, or, at a minimum, discount the value of those reductions, because in many cases those reductions will

[62] See https://www.whitehouse.gov/wpcontent/uploads/2017/12/draft_2017_cost_benefit_report.pdf?_sm_au=iVV6k7TnsZM6Rq5q01TfKK3Qv3fc4

occur in areas that are already below the NAAQS. The commenter cited a study that estimated that 99 percent of the $PM_{2.5}$ reductions are projected to occur in areas where the $PM_{2.5}$ levels will already be below the $PM_{2.5}$ NAAQS of 12 $\mu g/m^3$.[63] The commenter argued that while it is theoretically possible that emission reductions below the NAAQS save lives, monetizing such reductions for BCA purposes is illegitimate because, by law, NAAQS must be set at a level "requisite to protect public health" with an "adequate margin of safety," and thus, the health benefits of $PM_{2.5}$ reductions below the NAAQS are less certain those achieved above the NAAQS. The commenter argued that if the science does not support a more stringent standard, then the EPA can have little confidence in the monetary value of reductions below the NAAQS. Another commenter noted that the EPA Clean Air Scientific Advisory Committee criticized the analyses used previously to justify regulation of fine particulates, in substantial part because the biological basis and the evidence on a causal relationship between fine particulates and death rates are much less clear than commonly asserted.[64]

A commenter argued that because American air quality has improved over recent decades, it is now difficult to justify new or tightened rules without the purported co-benefits. Another commenter asserted that there are two reasons that criteria pollutant emissions are already being over-regulated (reduced beyond the point where regulation achieves net benefits). The commenter argued that, first, in *Whitman v. American Trucking Associations* (2001), the Supreme Court upheld the appellate court's unanimous opinion that "the EPA may not consider the cost of implementing a NAAQS in setting the initial standard," and second, the statute is precautionary, directing the EPA to set the primary (health-focused) NAAQS at a level requisite to protect public health with an adequate margin of safety; i.e., when setting a NAAQS, the EPA must both ignore costs and err on the side of caution. The commenter argued that according to Smith (2011), "If a NAAQS has indeed been set to a point where it provides an adequate margin of safety, its RIA [regulatory impact analysis] should show that it fails a marginal BCA test," then consequently, the "co-benefits from any pollutant that is regulated as a criteria pollutant with a NAAQS that conforms with the requirements of CAA section 109 should not be included in the BCA of any other pollutant."[65]

Other commenters argued that based on the definition of "ancillary" in the dictionary, and as used in OMB's Circular A-4 ("[a]n ancillary benefit is a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking"), ancillary benefits are of lesser weight than direct benefits as it relates to the statutory purpose of a regulation, and the EPA should treat them accordingly. The commenters argued that it is misleading to use the term "co-benefits" as a synonym to describe ancillary benefits, because "co-benefits" suggests that direct benefits are equal to ancillary benefits, but this is not the case. The commenter added that when considering ancillary benefits, the EPA should not ignore the indirect costs. The

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63 Anne E. Smith, "Inconsistencies in Risk Analysis for Ambient Air Pollutant Regulations," Risk Analysis, 2015, pp. 6-7, http://www.globalwarming.org/wp-content/uploads/2016/06/Anne-Smith-Risk-AnalysisPerspectives-early-view-Nov2015.pdf

64 See https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/E2F6C717372016128525 84D20069DFB1/$File/EPA-CASAC-20-001.pdf

65 Anne E. Smith, An Evaluation of the $PM_{2.5}$ Health Benefits Estimates in Regulatory Impact Analyses for Recent Air Regulations, Final Report Prepared for the Utility Air Regulatory Group, NERA Economic Consulting, December 11, 2011, pp 11-12, https://www.nera.com/content/dam/nera/publications/archive2/PUB_RIA_Critique_Final_Report_1211.pdf

commenters stated that, unlike ancillary benefits that can be attributed to the non-targeted pollutants, indirect costs are not capable of being categorized in this manner, and the costs (direct and indirect) are connected to whatever is the regulatory requirement that has been imposed, and the EPA should properly count indirect costs without conflating them with direct costs (e.g. compliance costs are direct costs). The commenters noted that OMB has explained, "Consistency should also be kept in mind when assessing ancillary effects of a rule; estimating indirect benefits without attempting to estimate indirect costs, or estimating indirect costs without attempting to estimate indirect benefits, can yield very misleading results as regards rule-induced net benefits."

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. And as further described in Section V.D of the preamble to the final BCA rule, 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.

**Comment:** Commenters opposed disaggregating benefits into those targeted and ancillary to the statutory objective of the regulation. Many of the commenters argued that co-benefits are real and have valuable impacts on human health that must be accounted for in a benefits assessment and should not be excluded just because they may be "ancillary" rather than "targeted" benefits. Commenters said that disaggregating benefits may encourage decision-makers to downplay co-benefits when deciding whether a proposal is economically justified. The commenters argued that by not including co-benefits, such as $PM_{2.5}$ reductions, the EPA is abandoning past practices that considered co-benefits and is unreasonably tipping the balance against regulation by comparing artificially depressed benefits to a full set of costs. Commenters noted that the EPA has consistently taken indirect benefits into account when evaluating regulations,[66,67] and recognized that ancillary effects are part of any proper BCA; and although previous administrations have reviewed and modified EPA's cost-benefit processes from time to time, the EPA has not previously attempted to abandon the practice or guidelines underlying

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[66] *See e.g.*, 52 Fed. Reg. 25,399, 25,406 (July 7, 1987) (in issuing advance notice for new source performance standards for municipal waste combustors, noting intent to "consider the full spectrum of the potential impacts of regulation," including "indirect benefits accruing from concomitant reductions in other regulated pollutants"); 56 Fed. Reg. 24,468, 24,469 (May 30, 1991) (in proposing performance standards and emission guideline for landfill gases, justifying the regulation partly on "the ancillary benefit of reducing global loadings of methane"); 63 Fed. Reg. 18,504, 18,585-86 (Apr. 15, 1998) (analyzing the indirect benefits of reducing co-pollutants like volatile organic compounds, particulate matter, and carbon monoxide from emissions standards addressing HAP emissions from pulp and paper producers); 72 Fed. Reg. 8428, 8430 (Feb. 26, 2007) ("Although ozone and $PM_{2.5}$ are considered criteria pollutants rather than 'air toxics,' reductions in ozone and $PM_{2.5}$ are nevertheless important co-benefits of this proposal."); 75 Fed. Reg. 51,570, 51,578 (Aug. 20, 2010) (considering indirect benefits of regulating HAP emissions from combustion engines).

[67] U.S. ENVTL. PROT. AGENCY, EPA-230-05-85-006, COSTS AND BENEFITS OF REDUCING LEAD IN GASOLINE: FINAL REGULATORY IMPACT ANALYSIS VI1-74 (1985), https://yosemite.epa.gov/ee/epa/eerm.nsf/vwan/ee-0034- 1.pdf/%24file/ee-0034-1.pdf.

those BCAs, nor attempted to limit all of EPA's future CAA rulemakings through a one-size-fits-all cost-benefit process that excludes co-benefits.

Commenters opposed disaggregating benefits into those targeted and ancillary to the statutory objective of the regulation for at least one of the following reasons (presented in no particular order):

- Is biased, arbitrary, and capricious because it focuses inordinately on transparency and uncertainty related to benefits, but little to no time focusing on limitations, uncertainties, and potential lack of transparency in cost estimates.
- It is contrary to fundamental principles and best practices of BCA.
- It would allow the EPA to ignore significant environmental and public health impacts by slanting BCAs to support the EPA's preferred outcome.
- It would create confusion among stakeholders that industry groups would exploit in challenging new rules.
- It would set the stage for the EPA to subvert full consideration of regulatory benefits and improperly determine that regulation would be unjustified, similar to the EPA's recent reversal of its prior determination that regulating mercury emissions from power plants is "appropriate and necessary" considered total regulatory costs, which the EPA purported to be unable to disaggregate,[68] while, according to the commenter, the EPA disregarded many billions of dollars in annual benefits, and considered only the monetized benefit for avoided IQ loss in children from prenatal exposure via consumption of self-caught, freshwater fish.[69]
- It would be arbitrary and unlawful to ignore co-benefits or pretend they are not attributable to a rule, and the lives saved through reductions in a co-pollutant are no less valuable than those saved by reductions in the directly regulated pollutant. A BCA that looks at only a lopsided equation is arbitrarily one-sided and cannot be justified based on basic principles of economics, the EPA's public-health mission, or the law.
- It would be unnecessarily burdensome. EPA's proposed requirements contains analytical limitations that arbitrarily burden benefits estimates because it would require the EPA to compare quantified and monetized costs and benefits "to the extent supported by scientific literature as well as practicable in a given rulemaking,"[70] and to "quantify effects for endpoints which scientific evidence is robust enough to support such quantification."[71]
- It would make it harder for state and local agencies to meet federal air quality obligations and lead to requiring more time and money to create separate regulations

[68] 85 Fed. Reg. 31286 (May 22, 2020).

[69] Id.

[70] Id. at 35,626 (proposed § 83.3(a)(8)).

[71] *Id.* at 35,626 (proposed § 83.3(a)(7)(ii)).

and consent agreements (to separately reduce the emissions of the "ancillary" pollutants), including additional extensive negotiations between state officials and stakeholders.

- It point the EPA away from decisions that maximize social welfare and away from other "appropriate ways of obtaining ancillary benefits."
- It may lead to unsound decisions being made based on incomplete knowledge or hopes that future regulations may address the issue, even while changes in administration or funding may negate such opportunities.
- It is inconsistent with the Administrative Procedure Act because an agency must not ignore "an important aspect of the problem" when issuing a rule.[72]
- It is inconsistent with the CAA's first declared purpose which is "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[.]"[73]
- It is inconsistent with CAA section 111 because CAA section 111 shows Congress contemplated that the EPA would consider co-benefits when promulgating CAA rules, which reflect "the degree of emission limitation achievable through the application of the best system of emission reduction which (taking into account the cost of achieving such reduction and any non-air quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated,"[74] and the EPA "must exercise its discretion to choose an achievable emission level which represents the best balance of economic, environmental, and energy considerations."[75]
- It is inconsistent with CAA section 112(d)(1) and the legislative history (S. Rep. No. 101- 228, 1990 U.S.C.C.A.N. at 3557) which demonstrates that Congress expressly anticipated that implementing the Act's various provisions would lead to substantial ancillary benefits that must be considered by the EPA.
- It is inconsistent with CAA section 112(e)(2) because when Congress adopted the 1990 CAA amendments, it restructured Section 112 to direct the EPA to initiate standards for source categories rather than individual pollutants.
- It is inconsistent with the Senate Report accompanying the 1990 CAA amendments signaling that the EPA could account for co-benefits when setting standards for hazardous air pollutants.[76]

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72 State Farm, 463 U.S. at 43.

73 CAA section 101(b)(1).

74 CAA section 111(a)(1).

75 *Sierra Club v. Costle*, 657 F.2d 298, 330 (D.C. Cir. 1981).

76 S. REP. NO. 101-228, at 172 (1989) ("When establishing technology-based standards under this subsection, the Administrator may consider the benefits which result from the control of air pollutants that are not listed but the emissions of which are, nevertheless, reduced by control technologies or practices necessary to meet the prescribed limitation.").

- It is inconsistent with CAA section 112(m) because the EPA must consider that control measures are bound to have multipollutant impacts, and any emission standard that affects a fossil fuel combustion source will have impacts on the concentrations of more than one pollutant.

- It is inconsistent with CAA section 112(n)(1)(A) because CAA section 112(n)(1)(A) suggests Congress expected there to be significant co-benefits from co-pollutant reductions for various other CAA programs as well, and anticipates the potential for co-benefit HAP emissions reductions from the implementation of other provisions of the CAA at electric generating units (for example, the acid rain requirements), that are not specifically targeted at HAP emissions reductions.

- It is inconsistent with United States Sugar Corp. v. EPA. The U.S. Court of Appeals for the D.C. Circuit upheld EPA's consideration of co-benefits in regulating the effects of reducing HAP from boilers, process heaters, and incinerators. Specifically, the direct benefits of reducing HCl and the co-benefits of reducing other HAPs.[77]

- It is inconsistent with Michigan v. EPA. Justice Scalia's opinion for the Court highlighted the importance of conducting a balanced regulatory analysis when deciding whether to regulate power plants under Section 112 of the Act, and the Court reasoned that "[c]onsideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions."[78]

- It is inconsistent with several court decisions instructing agencies to consider indirect costs or co-benefits. [79] Legal decisions have criticized agencies when they "inconsistently and opportunistically frame[] the costs and benefits of the rule [and] fail[] adequately to quantify the certain costs or explain why those costs could not be quantified."[80]

- It is inconsistent with EPA's Affordable Clean Energy rule because the rule's preamble includes ancillary health impacts from concomitant variation in emissions of other pollutants, and indeed, ancillary impacts are key to EPA's determination that

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77 830 F.3d 591, 625 (D.C. Cir. 2016).

78 *Michigan v. EPA*, 135 S. Ct. at 2707.

79 See e.g. Am. Trucking Associations, Inc. v. E.P.A., 175 F.3d 1027, 1051–52 (D.C. Cir. 1999) (holding that when crafting a NAAQS that would reduce concentrations of ozone in the ambient air, EPA had to consider not only how the new standard would reduce tropospheric ozone's negative impacts on respiratory health, but also how it might reduce the pollutant's alleged positive health effects (as shielding from harmful ultraviolet rays), even though the latter effects were not the focus of the rule). See generally Kimberly M. Castle & Richard L. Revesz, Environmental Standards, Thresholds, and the Next Battleground of Climate Change Regulations, 103 MINN. L. REV., at 56-58 (2018) (forthcoming) (discussing various cases where the court required the Agency to consider co-benefits) [hereinafter "Castle & Revese] (Attach. D). See e.g. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1229-30 (5th Cir. 1991); and Competitive Enterprise Inst. v. Nat'l Highway Traffic Safety Admin., 956 F.2d 321 (D.C. Cir. 1991).

80 Bus. Roundtable v. SEC, 647 F.3d 1144, 1148-49 (D.C. Cir. 2011).

benefits exceed costs, given the minimal reductions in carbon pollution that the rule is expected to achieve.[81]

- It is inconsistent with the NAAQS program because when the EPA adopts a NAAQS, it identifies the "indicator pollutant" which is to be measured to assess whether air quality meets the standard (for example, ozone is the indicator for photochemical oxidants, and $PM_{2.5}$ is the indicator for a wide range of aerosol particles), and the "indicator pollutant" is not the only pollutant that will be affected by actions to ensure attainment. The EPA is currently reviewing ecological impacts in preparation for setting secondary ambient air quality standards for $NO_x$, $SO_2$, and particulate matter, and this multi-pollutant review will be supported by one Integrated Science Assessment, and argued that the EPA chose this approach in recognition of the sources, atmospheric chemistry, and ancillary effects that link these pollutants.

- It is inconsistent with the NESHAP program because when the EPA adopts a NESHAP, the EPA may group related pollutants (e.g., the EPA has done this for the Hazardous Organic NESHAP).

- It is inconsistent with the EPA, 2014, Guidelines for Preparing Economic Analysis[82] because the 2014 guidelines state that "An economic analysis of regulatory or policy options should present all identifiable costs and benefits that are incremental to the regulation or policy under consideration. These should include directly intended effects and associated costs, as well as ancillary (or co-) benefits and costs." The EPA should revise 40 CFR 83.3(a)(1) and 83.4(a) and 83.4(b)(1) to reflect the 2014 guidelines, and 40 CFR 83.3(a)(9)(iii)(B) should be amended to allow for consideration of information relative to ancillary or co-benefits. The guidelines instruct the EPA to assess "all identifiable costs and benefits," including both direct effects "as well as ancillary benefits and costs."[83] The assessment of both direct and indirect effects is needed to "inform decision-making" and allow meaningful comparisons between policy alternatives."[84]

- It is inconsistent with scientific literature[85] that suggest "BCAs should seek to account for all economic consequences of a regulation, relative to a baseline without the regulation. These include benefits and costs associated with changes in a directly targeted pollutant, as well as co-benefits or co-costs of changes in other pollutants. It is only through consistent and full recognition of all benefits and costs, including co-benefits and co-costs, that a BCA provides a comprehensive and transparent analysis to inform decision making."

- It does not consider the Science Advisory Board's report on the MATS rule, which states, among other things, that "The SAB notes that the EPA's BCA of the proposed

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81 84 Fed. Reg. 32,520, 32,562, 32,572 (July 8, 2019)

82 EPA, 2014, Guidelines for Preparing Economic Analysis, Updated May 2014, p. 11-2 https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf

83 *Guidelines* at 11-2.

84 Id. at 7-1.

85 Aldy et al., Science Vol. 368 Issue 6488, p. 247 (4/17/20).

action categorically excludes co-benefits. That departs from the EPA's long-standing practice and is contrary to both the EPA's guidance document on economic analysis and to the recommendations of the Office of Management and Budget" and "excluding co-benefits is a departure from the Board's recommended practice."[86]

- It does not consider the External Environmental Economics Advisory Committee ("E-EEAC") reported on the MATS rule, "When determining whether a policy promotes economic efficiency, properly estimated direct benefits and co-benefits (or costs) should count on an equal footing when making benefit-cost calculations,"[87] and "statements in EPA and OMB documents on including ancillary benefits in the assessment of the benefits and costs of regulations build on an extensive academic literature that is unambiguous on this point."[88]

- It does not consider the SAB Economic Guidelines Review Panel's recently published draft report recommending "explicit, consistent text throughout the report on the importance of accounting for all benefits associated with a regulation or policy, regardless of whether any given benefit was the intended target of the regulation."[89] The panel's draft comments on the 2020 EPA Draft Guidelines for Preparing Economic Analyses suggest that an analyst will likely already be focused on the direct costs and benefits from a rulemaking and the SAB comments ask for the EPA to include "strong language" that would direct the analyst to investigate and present information on ancillary benefits and costs.

- It does not consider OMB's 2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act, stated that "OMB encourages agencies to include in their analyses all reasonably foreseeable and reasonably expected ancillary effects, both benefits and costs."[90]

- Control technology commercialization relies on regulations that recognize the full spectrum of benefits and value of the technology, and the costs of a technology are more accurately represented when the complete benefit picture is assessed, and this helps to justify the business case for further innovation. Emission control technology suppliers spend R&D funds to innovate technologies that have greater value by delivering direct and indirect benefits. For example, catalysts are used to reduce emissions found in automobile exhaust, and diesel particulate filter technologies have

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86 https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonth BOARD/4908A62FD4C0DE228525854 9005B8797/$File/EPA-SAB-20-004+.pdf

87 External Environmental Economics Advisory Committee, *Report on the Proposed Changes to the Federal Mercury and Air Toxics Standards* (Dec. 2019), https://www.e-eeac.org/mats-report.

88 Id.

89 EPA Science Advisory Board, Draft SAB Peer Review of EPA's Revised Guidelines for Preparing Economic Analyses (June 2, 2020), https://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/40f2adc8d6e4bb868525857b007234d5/$FILE/6.2.20%20draft%20report.pdf.

90 The Report can be accessed at https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf.

been optimized over the past 20 years to increase criteria pollutant removal, overall durability, and fuel economy and reduce $CO_2$ emissions.

- It would break from longstanding best practices for the consideration of indirect effects under EO 12866, which makes no distinction between direct and indirect effects, instead instructing agencies to "assess all costs and benefits,"[91] and OMB's Circular A-4, which instructs agencies to apply "[t]he same standards of information and analysis quality" to both direct and indirect effects,[92] and notes that important indirect effects should carry enough weight that, just like direct effects, they can "change the rank ordering of the main alternatives in the analysis."[93] The OMB's Circular A-4 further suggests that it is appropriate to put ancillary benefits together with direct benefits on the same side of the ledger in a BCA,[94] and the ancillary benefits should be compared against direct costs and other effects.[95] OMB's Circular A-4 distinguishes categories of costs and benefits only by whether they are monetized or quantified or not—with no distinction between direct and indirect effects.[96]
- It would break from the requirements of EO 12291 in that "[r]egulatory objectives shall be chosen to maximize the net benefits to society."
- It undermines the consideration of co-benefits. Administrator Wheeler has publicly interpreted the proposed rule as barring the EPA from considering co-benefits in designing and selecting regulatory standards.[97]
- It may hamper EPA's own efforts to rely on co-benefits to justify rules, as the EPA did recently in its recently issued Boiler NESHAP.[98]

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. None of the comments received on the presentational requirements

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91 EO 12,866 § 1(a).

92 OMB's Circular A-4 at 26.

93 Id.

94 Id. (suggesting agencies might first subtract countervailing disbenefits from ancillary benefits before "put[ting] both of these effects on the benefits side"); see also id. at 3 ("Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.") (emphasis added).

95 Id. at 12 ("When you can estimate the monetary value of some but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost.").

96 Id. at 45, 47.

97 See Sean Reilly, EPA Limits Future Regs with Cost-Benefit Overhaul, E&E News PM, June 4, 2020.

98 U.S. Envtl. Protection Agency, National Emissions Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, EPA-HQ-OAR-2002-0058, RIN 2060-AU20 (Pre-Publication Federal Register Notice, Signed July 8, 2020), *available at* https://www.epa.gov/sites/production/files/202007/documents/frn_boiler_mact_nprm_20200629_admin.pdf. See also *In Remand Rule, EPA Tightens Boiler MACT with Reliance on Co-Benefits*, INSIDE EPA, July 9, 2020.

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) (or so-called "co-benefits") are not to be included or considered. The presentational requirements in the final rule do not bar consideration of any part of the BCA. Existing OMB and EPA guidance is clear that a BCA should endeavor to account for all benefits and costs of the regulatory action, including positive and negative welfare effects that do not stem directly from the statutory objective of the CAA provision under which a rule is promulgated. To enhance transparency about the extent to which a rule is achieving its statutory objectives, the final rule includes a requirement that BCAs will 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.

**Comment:** Commenters argued that the EPA should recognize the efficiencies achievable by control of multiple pollutants — concomitant controls can reduce the need for separate emissions controls for the ancillary pollutants, thereby saving costs. The commenters added that the EPA and state and local air agencies have examined and accounted for the co-benefits of air regulations for decades. The commenters concluded that seeking to downplay or exclude co-benefits now would be a dramatic departure from past actions and would serve to ignore real benefits and overstate regulatory costs. A commenter noted that the EPA has recognized the efficiency of controlling multiple pollutants with a single rule and cited the example of the "cluster" air and water rules controlling pollution from pulp and paper mills. A commenter stated that analyzing benefits of one pollutant at a time would create a systematic bias against comprehensive pollution reducing strategies, such as waste minimization.

A commenter stated that co-benefits are critical to health-protective policy, best exemplified by the MATS that the EPA issued for power plants in 2012, and noted that the MATS drove significant decreases in the releases of mercury and other toxic chemicals (such as fine particle pollution) from electric utility steam generating units (EGUs),[99] resulting in large benefits to public health, especially for children.[100] Other commenters argued the EPA dismissing the co-benefits of reduced particle pollution from MATS, while at the same time, declining to issue health protective standards for ambient air quality to target the pollutant directly, undermines any suggestion in the proposal that the EPA might compensate for the loss of co-benefits by directly regulating the other pollutant at issue.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. None of the comments received on the presentational requirements 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

[99] US EPA. (2018). Introduction to the Toxics Release Inventory and the 2016 TRI National Analysis Report. Washington, DC: US EPA. Available: https://www.epa.gov/sites/production/files/2018-01/documents/2016_trina_webinar.pdf

[100] Giang, A., & Selin, N. E. (2016). Benefits of mercury controls

other benefits (or disbenefits) are not to be considered. The presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter noted that the EPA also asked for comment on "alternative approaches to increasing transparency about the extent to which a rule is achieving its statutory objectives." The commenter contended that no such alternative approaches were necessary or appropriate since the EPA has not demonstrated any problems in regulatory transparency under the currently applicable guidance. The commenter stated that the EPA should, and already does, separate out different types of costs and benefits, but the task of designating some benefits or costs as "achieving statutory objectives" and others as not, was not necessary, not consistent with the economic principles governing BCA, may be impossible to do in a rational way or generally acceptable way because of statutory ambiguity, and may have the effect of biasing BCAs making them misleading for decision-making. Therefore, the commenter added that there was no need to have a table drawing this distinction between benefits or costs that achieve statutory objectives and those that do not or a presentation of all benefit or cost categories or other factors that are specifically listed as factors the EPA must consider under the relevant statutory provisions in the preamble to any rulemaking (85 FR 35624), and imposing such a requirement would be arbitrary and capricious.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter argued that disregarding reductions in emissions of non-target pollutants that occur as a direct consequence of the regulation leads to an unconscionable underestimation of the regulation's benefits. The commenter argued that reductions of criteria pollutant emissions that occur in areas that are attaining the NAAQS for that pollutant are still relevant to BCAs, because the NAAQS are not set at levels associated with zero risk of public and environmental harm. The commenter stated that this is particularly important for $PM_{2.5}$ and ozone, as recent health research continues to show the lack of a threshold for the health effects associated with exposure to these pollutants.101 Similarly, another commenter argued that reductions in PM pollution beyond the level required by NAAQS is an example of why co-benefits should be considered in EPA's BCAs. The commenter noted that the NAAQS do not require the elimination of all health risks from covered pollutants,[102] and some pollutants may

[101] Di, Q., et al. "Air pollution and mortality in the Medicare population." New England Journal of Medicine 376: 2513-2522 (2017), doi: 10.1056/NEJMoa1702747.

[102] See Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 494 (2001) (Breyer, J., concurring) (characterizing a zero risk ambient standard as "impossible and undesirable").

pose risks at all ambient concentrations.[103] The commenter noted that when the EPA revised the ambient standards for particulate matter in 2013, the EPA acknowledged the absence of a "discernible threshold" for the pollutant's negative health effects.[104]

Another commenter predicted that elimination or restriction of co-benefits consideration would harm air quality planning efforts because State and local air agencies rely on co-benefits for compliance planning, and they are often included as compliance strategies within State Implementation Plans for attaining and maintaining the NAAQS. The commenter stated that access to the co-benefits information in EPA's regulatory impacts analyses are an important tool for state and local air pollution control officials, and using separate presentation to eliminate, discount, or reduce them in future EPA BCAs would make it harder for state and local air agencies to meet their federal air quality obligations. Another commenter added that reducing consideration of co-benefits in regulatory decision-making would affect air quality planning because CARB and local air agencies employ the co-benefits analyses and information in the EPA's regulatory impacts analyses for compliance planning and development of state compliance strategies within SIPs for the NAAQS.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** Commenters argued that aspects of the proposal that would reduce the value of co-benefits in CAA programs could undermine the efforts of other environmental programs, such as efforts to restore the Chesapeake Bay, and to reduce haze and protect visibility in National Parks.

Commenters noted that if CAA programs are made less effective at reducing the atmospheric deposition of nitrogen to the Bay watershed, it will undermine the investments and commitments made by states and private parties to reduce their own nitrogen loads, and may require further reductions from certain sectors to account for any shortfall. Another commenter stated that a more limited consideration of CAA regulatory co-benefits will lead to increased air pollution in the Chesapeake Bay watershed, which could reduce the value of ecosystem services provided by the Bay in Charles County, MD, which have been estimated to be $577 million each

[103] See Michael A. Livermore & Richard L. Revesz, Rethinking Health-Based Environmental Standards, 89 N.Y.U. L. REV. 1184, 1186-87 (2014) ("Environmental pollutants often lack ambient concentrations below which there is no risk of negative health consequences. As a result, the complete elimination of health risks for these pollutants could be accomplished only by banning all emissions.").

[104] 78 Fed. Reg. 3086, 3161 (Jan. 15, 2013).

year.[105] A commenter noted that sources of air emissions of $NO_x$ contribute nitrogen to the Bay and its tributaries, with about half of the deposition loads of nitrogen coming from outside of the watershed, and $NO_x$ reductions have been codified into a Bay Total Maximum Daily Load (Bay TMDL) issued by the EPA and into the 2000 Chesapeake Bay Agreement, incorporated into amendments in section 117(g) to the Clean Water Act. 33 U.S.C. § 1267(g)(C). The commenter noted that the Bay TMDL's atmospheric deposition allocation for nitrogen relies on CAA programs, including programs focused on other pollutants (e.g., NAAQS, greenhouse gas regulations, etc.), and that failure to account for the co-benefit of reducing nitrogen deposition to the Bay undermines the TMDL's strategy, and CAA programs that are weakened because their co-benefits go unrecognized will threaten progress towards reducing atmospheric nitrogen and meeting TMDL goals. The commenter also noted that regulations that reduce GHG emissions also reduce $NO_x$ and other pollution to the Bay watershed, and any weakening of these climate-focused CAA programs will exacerbate the climate impacts in the Bay region and undermine Bay restoration.

A commenter argued that the proposed regulation would undermine the efforts and interfere with the protection of national parks and state implementation of the Regional Haze Rule. The commenter noted that the EPA estimated that in 2015, full implementation of the Regional Haze Rule nationally will prevent 1,600 premature deaths, 2,200 non-fatal heart attacks, 960 hospital admissions, and over 1 million lost school and workdays, and result in health benefits valued at $8.4 to $9.8 billion annually.[106] The commenter argued that the proposed regulation's attempt to disentangle benefits and co-benefits does not recognize the complex ways in which pollutants interact, both within and across environmental media, and the inter-relationship of government actions to address these harms. The commenter stated that using the Regional Haze Rule as an example, a discounting of benefits of national air standards would misconstrue the real world benefit of reducing fine particles for purposes of visibility, in part by pretending that other benefits are not of value to the regional haze program or, conversely, that benefits of reducing haze causing pollution do not hold value for national air standards.

The commenter reported that in developing their regional haze plans, states consider and incorporate the reductions of visibility impairing pollution benefits of other air regulations for many reasons, including reducing compliance costs for regulated entities by giving credit for emission reductions from other requirements. The commenter cited the example of coal-fired power plants which are significant contributors to visibility impairment and regulated under a number of existing or proposed CAA regulations. The commenter added that consideration of what the Proposal might deem an "ancillary benefit" is a critical component of achieving the visibility goals of the Regional Haze Rule, and by changing the way in which co-benefits are considered, the Proposal would substantively impact state interests under the regional haze program. The commenter concluded that to the extent that the Proposal would be used to try to justify a less stringent air emission standard, or a less stringent state haze plan, this would shift a

[105] DNR 14-392017 -651 https://dnr.maryland.gov/ccs/Documents/Charles_Co_Ecosystem_Service_Report_Final.pdf

[106] EPA, *Fact Sheet – Final Amendments to the Regional Haze Rule and Guidelines for Best Available Retrofit Technology (BART) Determinations* (2005), https://www.epa.gov/sites/production/files/2016-02/documents/fs_2005_6_15.pdf.

greater burden of meeting the Regional Haze Rule or other CAA programmatic requirements to states.

A commenter argued that there are two types of co-benefits that appear to be ignored and/or undervalued in the proposed rulemaking: not fully accounting for the benefits to other mediums of regulations designed to remove a pollutant from a single medium (e.g. considering $SO_x$ reductions in air only, while not accounting for the impacts of the same $SO_x$ on acid rain and water acidification), and not fully accounting for beneficial reductions in other pollutants when focused on a single target pollutant of a regulation even in the same medium (e.g. considering $SO_x$ reductions in air only, when the same regulation also results in reductions in other air pollutants such as $NO_x$, Particulate Matter, and air toxics).

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** Commenters stated that under no circumstance should disaggregated information be used to eliminate or in any way diminish the consideration of a CAA regulation's co-benefits. A commenter stated that EPA's focus on benefits "targeted by the statutory provisions that give rise to the regulation" is of major concern to the States because it may result in limiting health and welfare benefits to the atmospheric pollutant itself while negating any effects due to the atmospheric chemistry of the pollutant (e.g., ground-level ozone formation from $NO_x$ and VOCs). The commenter asked how the EPA would address limits on emitted $NO_x$ emissions if it could not include the health and welfare benefits due to lower ground level ozone?

Another commenter agreed that, from a transparency perspective, the proposed rule would help reduce an overreliance on ancillary benefits by "disaggregating benefits into those targeted and ancillary to the statutory objective of the regulation." However, the commenter argued that, by itself, this does not help promote transparency in terms of allowing the public to know how ancillary benefits play into regulatory decisions, and does nothing to develop consistency in how ancillary benefits will be applied across the CAA.

Another commenter said that the EPA incorrectly states that previous BCAs "clearly distinguish benefit categories in its regulatory documents," and noted that both the methods and results of individual benefit categories have always been well characterized and presented for all quantified benefits in regulatory analysis documents.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble

of significant regulations. None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter said discounting co-benefits from BCA for CAA regulation decision-making would render inaccurate results of the BCA, and would be directly harmful to human health. The commenter argued that discounting these savings in a BCA would undermine the value of the entire analysis by failing to factor in benefits with major economic impact. The commenter cited the CAA Acid Rain Program as an example which included a fine particulate matter co-benefit from acid gas scrubbers that economists estimate saved the United States $50 to $100 billion yearly.[107]

The commenter also argued that discounting of co-benefits would potentially create inaccurate assessments of future pollution baselines in later regulations by inhibiting the 'new,' reduced levels of ozone and particulate matter from being reported in the baseline, and would affect the cost effectiveness of future regulations.

The commenter argued that the consequences of inappropriately discounting co-benefits cannot be easily remedied by creating a subsequent rule with the focus on that ancillary benefit because co-benefits are achieved by the same mechanism as the targeted goal, often times those effects cannot be parsed out; in other words, creating a regulation to target the ancillary benefit in particular would be redundant, and runs the risk of counting that ancillary benefit twice. The commenter noted that whether or not this impact is recorded and utilized in the BCA, it will still exist, and ignoring this impact, and basing future baselines for subsequent regulations upon previous BCAs could result in targeting this pollutant more than once and increase the likelihood of cost inefficiency. The commenter recommended that a method of transparently depicting the motivations and impacts of given regulations, in theory, could be as simple as changing the names of the regulations to include these co-benefits in their stated purpose, so that these co-benefits were never something intended to be disguised, and their impact should be a clear objective in decision-making.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter argued that the proposed rule raises EJ concerns because the consideration of co-benefits is vital for the EPA to possess a complete understanding of the

[107] Aldy J, How a Minor Change to EPA Rules Could Slash Environmental Protection, EcoWatch, 2018.

environmental and health benefits that clean air regulations will provide, and those calculations are magnified for EJ communities due to the heavier pollution burden that they confront. The commenter argued that the proposed requirement to distinguish co-benefits from the "targeted" benefits of the CAA rulemaking would undermine the incorporation of co-benefits in CAA regulations, and have serious consequences for the communities that face the greatest danger from harmful air pollutants.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter stated that failure to consider all benefits of a regulation would deprive the public of fully understanding and recognizing the economic, engineering, physical, biological, and ancillary impacts of a new regulation, and keep them from using that information to craft better rules, such as market-based approaches for achieving more cost-effective outcomes. The commenter added that American businesses, entrepreneurs, and technology companies depend upon this information when considering market opportunities.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter said that the costs and benefits related to co-benefits should be fully disaggregated to increase regulatory transparency, but also stated that they take no position on how co-benefits should be factored by the EPA into regulatory decision-making regarding any specific program. The commenter stated that if the benefits of a specific regulatory proposal are heavily skewed towards co-benefits, that could be a significant indication that another program could be more suitable for additional regulation than the EPA’s proposed action. The commenter recommended that in those cases, the EPA should conduct a policy analysis either simultaneously or separately from the BCA for the proposed rule (e.g., primary pollutant of concern), to determine whether there is a more appropriate way or better-suited regulatory regime to obtain the unrelated co-benefits, considering the details of the rulemaking in question and the relevant CAA authorities.

**Response:** None of the comments received on the presentational requirements have led the EPA to materially change its views from the proposal. We note that the presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter recommended that to the extent that the EPA evaluates and reports co-benefits separately, the EPA should continue its practice of evaluating criteria co-benefits using the three different extrapolation endpoints of zero exposure; the lowest measured level (LML) in the selected studies from which the concentration-response function is based; and the level reflected in the NAAQS established for the criteria pollutant,[108] and only benefits at or above the relevant NAAQS should be given full weight. The commenter stated that this straight-forward analysis recognizes the inconsistency between assuming in benefit analyses consistent benefits per unit of concentration exposure reduced to zero, and EPA's regulatory decisions on establishing NAAQS that protect the public with an ample margin of safety. The commenter asserted that EPA's failure to bridge these inconsistencies has led to inflated co-benefit estimates that are directly at odds with the Administrators' own decisions.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. And as further described in Section V.D of the preamble to the final BCA rule, 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.

**Comment:** A commenter recommended that as the EPA develops the analysis to support a summary of overall BCA results, it could inject a BCA threshold test to determine if detailed co-benefits evaluation— potentially across multiple CAA provisions—is warranted. Furthermore, according to the commenter, the EPA could condition the nature and rigor of the disaggregation of co-benefits upon several parameters in the test. The commenter provided the following example:

- If either overall BCA metrics fail or, if they pass but co-benefits are not a deciding factor, then a rudimentary co-benefits analysis may suffice to suit informational purposes, as co-benefits would be less salient (if not immaterial) to the regulatory decision. In cases where direct BCA metrics fail but overall BCA metrics pass (i.e., co-benefits dependent BCA conclusion), further analysis of regulatory alternatives may be warranted.
- If co-benefits covered elsewhere under the CAA determine whether overall BCA metrics pass or fail, then an expanded array of BCA regulatory alternatives—

[108] See EPA's Regulatory Impact Analysis for the Repeal of the Clean Power Plan, and the Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units, EPA-452/R-19-003 at ES-9 (June 2019), available at https://www.epa.gov/sites/production/files/2019-06/documents/utilities_ria_final_cpp_repeal_and_ace_2019-06.pdf.

including those provision(s) of the CAA that co-benefits are treated as the primary objective—may inform the regulatory decision.

- If these co-benefits do not fall under the CAA, then their consideration would be non-decisional for the EPA. However, the informational value of evaluating them may inform other policymaking and regulatory decisions outside of EPA's authority. In this case, a higher-quality co-benefits analysis may prove fruitful but require coordination between the EPA and external parties (or perhaps across the EPA offices if the co-benefits fall under other environmental statutes).

The commenter stated that the threshold test has an advantage in simplicity and decisiveness, but it has major limitations. The commenter noted that even if a direct BCA passed, it would remain possible that more exhaustive BCA analysis across CAA provisions with more nuanced metrics may reveal a preferable set of alternative regulatory actions. The commenter stated that the threshold test may also place too much decisional emphasis on BCA analysis, and it is not an infallible tool (because for example, it overvalues readily quantifiable benefits and costs relative to under-quantified ones), nor is it an exhaustive one, as it does not necessarily encompass all elements a regulator should factor into decisions.

The commenter recommended that the EPA could add increased procedural scrutiny for any existing and proposed rules with poor direct/targeted BCA metrics; for example, if a proposed rule had poor direct BCA metrics but positive overall ones, the EPA could institutionalize a protocol for additional evaluation of co-benefits and rebound effects. The commenter contended that this could provide the grounds for coordinating rulemakings, such as adjusting criteria pollutant levels under NAAQS in lieu of economically inferior rules under HAPs justified primarily by their co-benefits. The commenter stated that this is consistent with recent research which advises that regulators should consider regulating co-benefits directly when they yield higher net benefits than another statutory provision.[109]

Another commenter recommended that when co-benefits dominate the benefits side of the equation, the EPA can:

- Support research to reduce the uncertainty surrounding the impact of ancillary benefits, as recommended by OMB and the National Research Council;[110] and
- Strongly consider an alternate regulatory approach that would achieve these benefits more directly in manner consistent with statutory intent. Instead of regulating the pollutant as a co-benefit, the EPA should consider regulating the pollutant under the statutory provision established by Congress under the CAA for its regulation.

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[109] Graham et al. https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1273/2019/09/Graham-Wiener-Robinson-2019.pdf.

[110] See, e.g., OMB, 2017 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act (Feb. 23, 2018) at 12, available at http://www.whitehouse.gov/wp-content/uploads/2017/12/draft_2017_cost_benefit_report.pdf; National Research Council, Estimating the Public Health Benefits of Proposed Air Pollution Regulations (2002), available at https://doi.org/10.17226/10511.

Another commenter argued that the EPA should finalize a very clear requirement that, when future rules rely in whole or in part on ancillary or incidental benefits, the Administrator shall make this clear and explain why this is appropriate in statutorily-relevant terms. The commenter also recommended that the EPA should explain why, if a given regulation targeted at achieving specific outcomes only becomes net beneficial when ancillary benefits are included, the EPA is not pursuing a more targeted and cost-effective alternative to deal with the problem at hand.

Similarly, a commenter recommended that the EPA provide for a separate analysis of whether the statutory objective benefits alone justify the rule's costs (absent co-benefits), rather than merely requiring that the statutory objective benefits be "presented." The commenter argued that requiring this additional analytical step would further increase regulatory transparency and consistency and also preserve the statutory intent behind the CAA.

Likewise, another commenter stated that the EPA should give special consideration when primary benefits do not exceed primary costs because it is a strong signal that an alternatives analysis is required. The commenter argued that because the EPA retains numerous other regulatory authorities and implementation plans for achieving required emission reductions in the most cost-effective manner possible, ancillary "co-benefits" often represent a significant net opportunity cost, not a net benefit, and if the EPA could achieve the same reductions in emissions at half the cost under separate authority, then the "co-benefits" to reducing the targeted pollutant are negative.

Another commenter argued that the any final rules should provide a clear, reasonable standard as to how ancillary benefits will be used in deciding whether to move forward with a rulemaking, especially when ancillary benefits are greater than the direct benefits, because in such a case, the stated purpose of the rule cannot reasonably be claimed to be the true purpose of the rule. The commenter suggested that the EPA can consider ancillary benefits when comparing the total benefits to cost, but the EPA would not be able to exceed 25 percent of the total benefits for some other objective, yet significant amount of total benefits.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. And as further described in Section V.D of the preamble to the final BCA rule, 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.

**Comment:** A commenter argued that the EPA has a history of abusing ancillary benefits, and cited the MATS rule as the prime example, among others.[111] The commenter argued that

[111] Anne E. Smith, "An Evaluation of the $PM_{2.5}$ Health Benefits Estimates in Regulatory Impact Analyses for Recent Air Regulations," NERA Economic Consulting (December 2011), https://www.nera.com/content/dam/nera/publications/archive2/PUB_RIA_Critique_Final_Report_1211.pdf

unless limits are placed on this overreliance on ancillary benefits, the EPA could use a statutory section to regulate one pollutant as a pretext to regulate another pollutant it otherwise may not regulate beyond what is specifically authorized under the CAA. The commenter presented three possible options to address ancillary benefits abuse:

- Option 1: The commenter argued that at a minimum the majority of total benefits should not be ancillary benefits. The commenter argued that it is arbitrary and capricious to justify a rule based on benefits that have nothing to do with the targeted pollutant and statutory section authoring the rule.
- Option 2: The commenter argued that ancillary benefits may not constitute more than a marginal amount of the total benefits. One of the problems with the first option, according to the commenter, is that it gives too much weight to ancillary benefits, and it treats direct benefits and ancillary benefits as close to being equal as possible without actually requiring ancillary benefits and direct benefits to each represent 50 percent of total benefits, and benefits and costs can easily be "fudged," especially to make such a small adjustment that can lead to a desired result.
- Option 3: The commenter argued that direct benefits should exceed costs. The commenter argued that the benefits from regulating a targeted pollutant should by itself exceed the costs (excluding indirect costs). The commenter stated that ancillary benefits could still play a significant role in determining whether to move forward with a rule, and if direct benefits exceed costs among different regulatory options, the ancillary benefits can help to inform the best regulatory alternative.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. And as further described in Section V.D of the preamble to the final BCA rule, 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.

**Comment:** A commenter argued that because BCA is not the objective for determining the level of stringency under most segments of the CAA, net targeted benefits should be given the primary attention in a discussion of the justification for each significant regulatory action and should be presented as an integral part of the first table summarizing the analysis results. The commenter recommended that presenting the targeted components of net benefits in the executive summary would be an improvement over most of past practice, but the use of two tables, even if required to be presented in immediate sequence, unacceptably diminishes the importance of clarifying to policy makers and the public how well the regulation serves its statutory objectives. The commenter added that it would also be very confusing, as is evident

from a review of the RIA for the final ACE rule[112] which the commenter stated appears to meet the intent of the proposed rule's presentation requirements.

The commenter recommended a one-table format with the following structure:

- Its rows would report benefits and associated net benefits in three distinct layers of relevance to the policy evaluation.
- It would start with a summary of the aggregated targeted benefits, then incorporate aggregated ancillary benefits for co-incidental effects not tied to health effects of criteria pollutant, and end with aggregated benefits for criteria pollutant co-benefits that are calculated only for baseline ambient concentrations above the NAAQS (i.e., using assumptions consistent with those used for each respective criteria pollutant's NAAQS regulatory determinations).
- The calculated cumulative net benefits as of each incremental row of the table would be provided in an additional column, so that the top row would provide the net targeted benefits, and the bottom row would present the net total benefits that are required under EO12866.

The commenter provided an illustrative example of the recommended single-summary table presentation, based on the present value estimates of benefits and costs that are reported in the first two tables in the executive summary of the RIA for the final ACE rule.

The commenter recommended that the summary table include an intermediate row for ancillary benefits estimates other than those for criteria pollutant health effects, allowing for recognition that there are more forms of ancillary benefits than those associated with reductions in criteria pollutants below their NAAQS levels, and to keep those less controversial forms of ancillary benefits in a separate category when moving from net targeted benefits to net benefits that includes the consistently-calculated criteria pollutant health co-benefits. The commenter recommended that if any other estimates of co-benefits that violate the consistency assumption were to be calculated, they should be required to be reported separately and not shown in the summary table that would be mandated under the final rule. The commenter recommended that it would be perfectly reasonable to add descriptors and notes where significant forms of unquantified benefits are believed to exist. The commenter stated that the recommended summary table does not provide disaggregated details of all the underlying benefits that are accounted for in the column of "quantified estimates," because these can be provided in a more detailed format following the provision of this high-level summary of the key outcomes of the BCA calculations.

**Response:** None of the comments received on the presentational requirements have led the EPA to materially change its views from the proposal. As discussed in Section V.F of the

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

preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations.

**Comment:** A commenter said that the preamble language at 85 F.R. 35622 is in some respects clearer than the proposed rule text in section 83.4, and recommended that the regulatory text be improved by including words almost verbatim from what is at 85 F.R. 35622, specifically that BCAs must "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 commenter also recommended that the text should clarify that BCAs should delineate between health benefits and non-health welfare benefits, and that it should do that for both benefits of the reduced emissions targeted by the statutory provision giving rise to the regulation, and the co-benefits.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule.

**Comment:** A commenter stated that the requirements in the proposed rule 40 CFR 83.4(b) may obscure the overall results of the BCA, and create confusion and therefore be at odds with the 40 CFR 83.3(a)(11)(i) requirement to "present the overall results of the BCA (benefits, costs, and net benefits of each regulatory option evaluated in the BCA) in a manner designed to be objective, comprehensive, reproducible to the extent reasonably possible, and easily understood by the public." The commenter argued that if aggregate benefits are obscured within the BCA by giving additional weight to targeted pollutant benefits and presenting co-benefits as secondary, or by failing to clearly and prominently communicate aggregate benefits, it could result in the under-regulation of pollution relative to the benefits of improved air quality. The commenter stated that even stronger concerns arise should the EPA disregard co-benefits as the EPA has begun to propose in specific contexts such as in the analysis that underlies the MATS.

Another commenter said the requirement in proposed 40 CFR 83.3(a)(11)(i) that CBAs be "reproducible to the extent possible" is consistent with the directives in OMB's Circular A-4 regarding the transparency of RIAs by clearly describing assumptions and methods and discussing uncertainties associated with estimates of costs and benefits.

**Response:** We considered the comments submitted and we are finalizing the proposed rulemaking with some revisions, which are discussed in the preamble to the final rule. 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter recommended that the EPA be required to prepare a short, standardized summary in both the preamble to a proposed rule and the RIA that: clearly summarizes the results of the BCA (including relevant cost/benefit ranges and the extent to which the rule results in ancillary benefits); lists key assumptions that drive its BCA (including assumptions related to ancillary benefits); discusses the level of uncertainty of the BCA

(including any underlying risk assessments); describes how dependent the analysis is on these assumptions; and provides a brief overview of the key imitation in inherent in the analysis.

**Response:** None of the comments received on the presentational requirements have led the EPA to materially change its views from the proposal. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations.

**Comment:** A commenter stated that the proposal does not address how costs and benefits would be handled under this new approach in deregulatory actions in which health benefits become the costs (avoided benefits) and the regulatory costs become the benefits (avoided costs). The commenter questioned whether the EPA intends in those situations to limit the benefits (avoided costs) to those only directly targeted by the statutory language guiding the deregulatory action, or does the EPA intend to adhere to its motives to limit only health impacts while incorporating the broadest possible view of impacts to regulated industries. The commenter stated that the failure to discuss this challenge to the ethic of this proposal, makes it clear that this proposal is not intended to increase transparency or improve economic efficiency, but it is rather designed to tilt the balance away from public health benefits and towards benefits and economic well-being of regulated entities.

**Response:** None of the comments received on the presentational requirements have led the EPA to materially change its views from the proposal. The EPA disagrees with the comment and notes the presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter suggested that with respect to PM emission reductions that are a co-benefit of limiting another pollutant, the EPA may be confronting what economists call a "joint-cost problem," in which one set of costs – e.g., installing scrubbers at power plants – may achieve multiple agency objectives. The commenter suggested that if different pollutants are regulated in separate rulemakings, there needs to be some mechanism to allocate the joint costs across multiple BCAs, and because the efficient frontier will involve balancing marginal benefits and costs, a simple allocation rule will not suffice. The commenter suggested that in such cases, it might make more sense to do some of the BCA in the context of a strategic plan, where the EPA is able to look across the range of available tools and multiple objectives, and choose the combination of actions that makes the most sense.

**Response:** None of the comments received on the presentational requirements have led the EPA to materially change its views from the proposal. The EPA disagrees with the comment and notes the presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter argued that although Administrator Wheeler has suggested in his public comments that counting the ancillary or co-benefits is "dishonest" [EPA News Release, June 4, 2020], it would actually be dishonest and deceitful not to count the fine particulate reductions as a benefit of a regulatory action. The commenter stated that the EPA's own Science Advisory Panel criticized the EPA for ignoring its previous advice and failing to

consider the full health benefits of reducing mercury and fine particle exposures when finalizing the EPA's 2020 MATS rule.

The commenter noted that in this proposed rule, as well as in its most recent draft of EPA's economic guidelines (sent to the SAB panel for review), the EPA says that an economic analysis of a regulation must address alternative ways of capturing the co-benefits using measures other than the proposed rule under consideration. The commenter stated that the implication is that it may be possible to get the same benefits at lower cost by regulating the targeted and ancillary pollution reductions separately, but warned that it will not suffice to point out other ways to reduce the ancillary pollutants if those alternative means are not implemented, and that does not provide a justification for regulating neither the targeted nor ancillary pollutant(s). The commenter argued that, in the example of the MATS rule, the Administrator said it was "dishonest" to count reductions of fine particles when regulating mercury emissions, suggesting by this logic that fine particles should be regulated separately in some other way. However, according to the commenter, when given the opportunity to gain these benefits by revising the fine particle air quality standard, the Administrator chose not to revise the standard to further protect public health, as recommended by EPA's own science policy experts. The commenter concluded that pointing out an alternative way to get ancillary benefits (presumably at lower cost) is of no use if no action is taken to attain those benefits.

Another commenter argued that the proposed rule does not appear to allow for the consideration of co-benefits or cumulative impacts and takes a narrow and harmful approach to the knowledge that could be gained from conducting a thorough BCA and in doing so neglects many of the resultant health benefits, and their contribution to the economy.

Another commenter said that a CBA requires a full presentation of the benefits and costs for it to be useful, which entails considering a broad range of alternatives, taking uncertainty seriously, and including effects that cannot be quantified.

**Response:** None of the comments received on the presentational requirements 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 included or considered. The presentational requirements in the final rule do not bar consideration of any part of the BCA. Existing OMB and EPA guidance is clear that a BCA should endeavor to account for all benefits and costs of the regulatory action, including positive and negative welfare effects that do not stem directly from the statutory objective of the CAA provision under which a rule is promulgated. To enhance transparency about the extent to which a rule is achieving its statutory objectives, the final rule includes a requirement that BCAs will 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.

**Comment:** A commenter stated that the issue of exploring "whether there may be more efficient, lawful and defensible, or otherwise appropriate ways of obtaining ancillary benefits" must be further fleshed out in the final rule, and at the very least, the final rule should require the EPA to consider whether the regulation is justified based on the specific statutory authority being

invoked and describe if there are other statutory authorities through which the claimed ancillary benefits could be achieved.

**Response:** None of the comments received on the presentational requirements have led the EPA to materially change its views from the proposal. As discussed in Section V.F of the preamble to the final BCA rule, the EPA is codifying in the final rule a standardized presentation of the results of the BCA in the preamble of significant regulations. The EPA disagrees with the comment and notes the presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter argued that the proposed rule's suggestion that, in any rulemaking with co-benefits, the EPA should "explore whether there may be more efficient, lawful and defensible, or otherwise appropriate ways of obtaining ancillary benefits"[113] is problematic for multiple reasons. The commenter argued that undertaking multiple regulations, each focused on individual pollutants rather than a unified, multi-pollutant regulatory strategy, may carry additional costs, such as designing and issuing multiple regulations; paperwork costs from implementing and complying with multiple regulations; and any lost efficiencies that a multi-pollutant compliance strategy may achieve that distinct pollutant-specific rulemakings might preclude. The commenter added that any analysis of a regulatory alternative that requires a separate rulemaking would have to consider the realistic probability of whether such alternate or separate rulemakings could actually occur, as well as the forgone benefits during any delay in waiting for the additional rulemakings. The commenter argued that such an analysis could prove vexing if not impossible when different authorities span across different agencies or different offices within an agency. The commenter also noted that courts have reminded agencies that the existence of overlapping authorities does not excuse an agency from rationally implementing all of its statutory mandates: "The two obligations may overlap, but there is no reason to think the two agencies cannot both administer their obligations"[114]; and "Just as the EPA lacks authority to refuse to regulate on the grounds of [the existence of another] statutory authority, the EPA cannot defer regulation on that basis." Coalition for Responsible Regulation v. EPA, 684 F.3d 102, 127 (D.C. Cir. 2012).[115]

**Response:** None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter noted that the rule itself does not discuss approaches for considering ancillary benefits or ways that the disaggregation of ancillary and direct benefits will lead to more efficient means for obtaining these co-benefits. The commenter stated that the proposal's requirement that the EPA should make an additional presentation in the preamble discussions for its rules that is limited to benefits that "pertain to the specific objective ... of the CAA provision or provisions under which the rule is promulgated" implies that co-benefits will

[113] 85 Fed. Reg. at 35,622.
[114] Massachusetts v. EPA, 549 U.S. 497, 532 (2007).
[115] Coalition for Responsible Regulation v. EPA, 684 F.3d 102, 127 (D.C. Cir. 2012).

be disregarded or minimized. The commenter added that the proposed rule provides no guidance on determining which benefits relate to the "specific objectives" of the CAA provision at issue, and without such guidance, decisions as to what to exclude may often be arbitrary and capricious.

**Response:** None of the comments received on the presentational requirements have led the EPA to materially change its views from the proposal. The EPA disagrees with the comment that in distinguishing the benefits pertaining to the CAA statutory objective to be presented in the future rulemaking preamble means that other benefits (or disbenefits) are not to be considered. The presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** Commenters stated that the EPA's proposal calling for transparency in detailing benefits of proposed rules is problematic because it does not make the same demand for the estimation of costs, and seems to emphasize the consideration of costs and minimize the consideration of benefits and co-benefits. The commenters argued that fundamental weakness of BCA not addressed by this proposal is that they tend to underestimate benefits, and cannot estimate all the benefits.

A commenter argued that this is particularly concerning because costs are consistently found to be significantly lower than initial estimates, and cited the example that the costs for the MATS rule have been found to be billions of dollars lower than the EPA and industry initially estimated, and which the EPA ignores in its 2020 decision to scrap the appropriate and necessary finding.[116,117]

Commenters also asserted that recent rulemakings by the current EPA have not applied the same principles of consistency being proposed, and the EPA has excluded co-benefits when it wants to abandon a rule and to include them when it wants to write a preferred rule. As an example, the commenters noted that the EPA argued against the inclusion of co-benefits in its decision to scrap the appropriate and necessary finding from the MATS, but argued for the inclusion of co-benefits in its ACE regulation, even though in both cases, the inclusion of co-benefits was needed to justify promulgation of each rule.[118] The commenters also asserted that the Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule also did not apply the principles being proposed because costs and benefits were not shown accurately, and not all relevant data and analyses were considered.[119,120]

Another commenter noted that in the EPA's October 2017 proposal to repeal the Clean Power Plan (CPP) (82 FR 48035), the EPA conducted sensitivity analyses in which health co-

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116 National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units — Reconsideration of Supplemental Finding and Residual Risk Technology Review 85 Fed. Reg. 32186; 31306-07 (May 22, 2020)

117 Environmental Defense Fund, Power Companies' Declining Estimates of the Compliance Costs of the Mercury, and Air Toxics Standards (MATS), http://blogs.edf.org/climate411/files/2014/05/Declining-costs-of-MATS-compliance.pdf?_ga=1.64911789.383468789.1454952534

118 Chemnick, Jean. October 9, 2019. "EPA — Agency's been all over the map on 'health co-benefits'. Climatewire.

119 Eilperin, Juliet and Dennis, Brady. "Trump promised his mileage standards would make cars cheaper and safer. New documents raise doubts about that." Washington Post, Jan. 23, 2020.

120 Eilperin, Juliet and Dennis, Brady. "EPA staff warned that mileage rollbacks had flaws. Trump officials ignored them." Washington Post, May 19, 2020.

benefits were excluded from the analysis, because the targeted pollutant of the CPP was carbon dioxide, not the other health-damaging criteria pollutants (sulfur dioxide and nitrogen oxides) that would also be reduced as a result of the rule. The commenter noted that in the EPA's justification for repealing the CPP, it relied heavily on the benefits versus costs comparison without the health co-benefits, but in order to justify the Affordable Clean Energy (ACE) rule in July 2019 (84 FR 32520) – the CPP replacement – the EPA did use the resulting co-benefits in order for its total benefits to exceed its costs and, thus, to justify the rule.

Commenters argued that the calculation of benefits can be more difficult and less straightforward than the calculation of costs, and cited as an example, that in several instances in the RIA for the MATS rule, the EPA acknowledged that it did not have enough information on the effects of mercury and other hazardous air pollutants to make quantitative benefits analyses, even though these pollutants cause significant impacts on human health, even if the EPA does not estimate those monetary values. The commenters argued that exclusion or diminishment of these benefits and adoption of rules based strictly on monetized costs versus benefits would expose the public to impacts that are not widely understood and could be harmful to human health and well-being.

Another commenter argued that, in the case of clean air programs, the costs of regulations are often easier to identify and estimate for regulated entities than are the public health costs borne by the public, and this makes it even more important that potential health benefits be comprehensively identified and carefully analyzed to provide the EPA and the public with a complete and full understanding of both costs and benefits. The commenter asserted that without a more sophisticated approach from EPA, many significant health costs borne by the public may remain excluded from future analyses. The commenter cited as an example, that ambulance deployments that do not result in hospital stays have important cost impacts to those who experience them and are excluded from EPA's cost-benefit accounting.

A commenter stated that the treatment of co-benefits and co-costs should be symmetric; that is, while it is important to include co-benefits when they occur, analysts should also make sure that any indirect costs are also included.[121] Another commenter added that the lack of clarity in the proposal surrounding what is to be counted as a direct benefit versus what is to be counted as a co-benefit opens the door for degrading the BCA process.

**Response:** None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

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[121] Dudley, S., Belzer, R., Blomquist, G., Brennan, T., Carrigan, C., Cordes, J., Cox, L.A., Fraas, A., Graham, J., Gray, G., Hammitt, J., Krutilla, K., Linquiti, P., Lutter, R., Mannix, B., Shapiro, S., Smith, A., Viscusi, W.K., Zerbe, R. (2017). Consumer's Guide to Regulatory Impact Analysis: Ten Tips for Being an Informed Policymaker. Journal of Benefit-Cost Analysis, 8(2), 187-204. doi:10.1017/bca.2017.11. https://www.cambridge.org/core/services/aop-cambridge-core/content/view/FAF984595B822A70495621AEA7EF7DEB/S2194588817000112a.pdf/consumers_guide_to_regulatory_impact_analysis_ten_tips_for_being_an_informed_policymaker.pdf

**Comment:** Commenters argued that the proposed rule should not have different standards for the estimate of costs and benefits of a proposed rule and that the EPA should consider all co-benefits in the BCA. Commenters argued that partially considering benefits while fully considering costs is both inappropriate for economic analysis and unlawful,[122] as it results in significant underestimation of the benefits of environmental regulations. The commenter argued that full estimation of co-benefits of regulatory actions is critically important to ensuring appropriate actions are taken to comprehensively improve air quality and mitigate climate change. Another commenter said that any limitation in the scope of benefits should be accompanied by a corresponding limitation in costs, which is not a part of this proposal.

A commenter noted that the heavier pollution burden imposed upon EJ communities makes it even more crucial to those communities that BCAs consider the best available science in calculating both the benefits and the costs of a proposed regulation. The commenter asserted that the proposed rule creates different standards for the scientific data used to inform benefits and costs by applying a more stringent "fitness for purpose" test only in the case of benefits, but not to costs, with the proposal asserting that "strength of scientific evidence should be strongest when the benefits are estimated." The commenter argued that this will increase the likelihood that certain studies may not be deemed "robust enough" to justify their consideration in a BCA benefit assessment and CAA regulations could be arbitrarily distorted towards higher ratios of costs to benefits by excluding scientific data related to environmental and health benefits. The commenter argued that the "fitness for purpose" test's uneven application to benefits would lead to heavier air pollution burdens on vulnerable communities from weaker pollution standards.

**Response:** None of the comments received on the presentational requirements 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 presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** Commenters argued that the proposal would reduce the EPA's consideration of costs and benefits that cannot be easily monetized. Commenters stated the proposal ignores important qualitative health benefits of clean air regulations and will undercount qualitative health benefits that do not have monetary value attached, including those health costs on Native American Tribes and migrant communities that have disproportionate rates of poverty, lack of access to water sanitation, and access to health care. A commenter said that acting to clean up air pollution only if the monetized benefits exceed costs would clearly favor industry interests over fulfilling EPA's legal duty of protecting public health; and this approach seems tone-deaf to the mental health benefits that arise from being able to breathe fresh air, see and experience green grass and plants, and feeling the warmth of the sun. Another commenter argued that EPA's proposal (that BCAs will qualitatively characterize benefits that cannot be quantified or monetized) implies that the scope of benefits assessment will be limited to the pollutant analyzed

[122] *E.g., Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008) ("Even if NHTSA may use a cost-benefit analysis to determine the 'maximum feasible' fuel economy standard, it cannot put a thumb on the scale by undervaluing the benefits and overvaluing the costs of more stringent standards. NHTSA fails to include in its analysis the benefit of carbon emissions reduction in either quantitative or qualitative form. It did, however, include an analysis of the employment and sales impacts of more stringent standards on manufacturers.").

in the study (for example, in regulating mercury emissions from coal-fired power plants, the proposal would not account for the co-benefits to society of improved control of PM emissions that would not otherwise have occurred). A commenter cited as an example not accounting for improved birth outcomes that result from reducing particle pollution, such as reducing the number of preterm births and the number of low birth weight babies do not get counted when the EPA considers rules that would reduce particles. The commenter also asserted that particle pollution is associated with tens of thousands of deaths each year, causes heart disease, diabetes, lung cancer and lung disease, and increases the risk of lung infections, an important point as we are in the midst of a respiratory pandemic.

Another commenter argued that in the proposed analytic approach, the non-monetized benefits to public health and the environment would get short shrift as the ancillary benefits of CAA rules associated with fine particulate matter reduction. The commenter stated this was the same process to devalue such ancillary benefits in the EPA's recent supplemental proposal to limit EPA's consideration of longstanding scientific studies, and in the EPA's recent reversal of the appropriate and necessary funding for the mercury and air toxic standards or MATS. The commenter stated that while the current proposal notes concerns about overestimation of benefits and underestimation of costs, it does not concern itself with the EPA's overestimation of costs and underestimation of benefits.

A commenter argued that distinguishing between benefits "targeted by the statutory provision" versus "other welfare effects" can be a complex, controversial, and ultimately fruitless endeavor because a regulation can have multiple statutory authorities and have multiple objectives. The commenter stated that analysts should not assume, absent explicit statutory language, that any statute has the objective of barring consideration of important indirect effects, and any broad statutory language, like "reasonable" or "appropriate," should be read broadly to authorize consideration of all important effects, whether direct or indirect. The commenter noted that in interpreting the phrase "appropriate and necessary" under Section 112 of the CAA, the Supreme Court noted that it would not be appropriate to ignore indirect costs to human health.[123] Similarly, according to the commenter, distinguishing between direct and indirect effects may turn on questions of law and science, and, for example, the benefits that come from reducing particulate matter when regulating mercury and other toxic pollutants under Section 112 of the CAA are directly relevant to the evaluation of whether it is "appropriate and necessary" under Section 112 to regulate power plants, and some components of particular matter also meet the definition of hazardous air pollutants.[124]

The commenter argued that even if it were possible to always distinguish between pollutants that are the "statutory objective" and those that are "other," doing so could lead to an inappropriate belittlement of key effects if the sufficient context is not provided, which is more

[123] Michigan v. EPA, 135 S.Ct. 2699, 2707 (2015) (after noting it would be irrational to ignore whether compliance technologies imposed countervailing risks to human health that more than offset the benefits of emissions reductions, concluding that "[n]o regulation is 'appropriate' if it does significantly more harm than good").

[124] See Policy Integrity, Comments to SAB on Scientific and Technical Basis of EPA's Proposed Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review at 3 (Jan. 10, 2020), https://policyintegrity.org/documents/J_Lienke_-_written_statement_for_SAB_re_MATS_Reconsideration_-_January_2020_%28signed%29.pdf.

likely to occur in a presentation in a summary table in a preamble without requiring an additional presentation to provide that context.

**Response:** None of the comments received on the presentational requirements have led the EPA to materially change its views from the proposal. We note that the presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter noted that in some cases, a qualitative assessment might be sufficient for the EPA to conclude with high confidence that a rule's benefits exceed its costs, and in other cases, many provisions under the CAA prohibit consideration of costs or prescribe a limited role for the consideration of costs.[125] In these circumstances, significant expenditures to quantify or monetize the rule's benefits and costs would not necessarily be useful and could result in unnecessary delays.

The commenter added that the proposal fails to identify measures to ensure that unquantified and unmonetized benefits and costs are given equal weight, because in many instances the environmental costs and benefits are not easily or feasibly monetized, for example, when impacts are borne disproportionately by EJ communities. The commenter concluded that the EPA has failed to propose or solicit comment on any aspect of distributional analysis.

Another commenter argued that whenever permissible, the EPA should give strong weight to unquantified health and environmental risks and to unquantified benefits of regulatory action because many important human health and environmental benefits of reducing pollution cannot be quantified.

**Response:** None of the comments in the proposal's solicitation for additional public comments have led the EPA to materially change its views from the proposal. We note that the presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter argued that like other benefits and costs, an effort should be made to quantify and monetize ancillary benefits and countervailing risks, and if monetization is not feasible, quantification should be attempted through use of informative physical units. The commenter added that if both monetization and quantification are not feasible, then these issues should be presented as non-quantified benefits and costs. The commenter also noted that the same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks.

**Response:** None of the comments in the proposal's solicitation for additional public comments have led the EPA to materially change its views from the proposal. We note that the presentational requirements in the final rule do not bar consideration of any part of the BCA.

## 11.3 Non-domestic Benefits

**Comment:** Commenters supported reporting domestic benefits separately from benefits unrelated to the statutory objective of the regulation. In general, commenters argued that the EPA

[125] Congressional Research Service, *Cost and Benefit Considerations in Clean Air Act Regulations* (2017), https://crsreports.congress.gov/product/pdf/R/R44840/4.

should report these benefits separately for at least one of the following reasons (presented in no particular order):

- Reporting separately would allow stakeholders (including all Americans since they are paying for the benefits of the regulations) to understand who would experience the costs and benefits before regulatory action is taken. By employing an analytical approach that fails to quantify domestic benefits, the EPA risks overlooking the real costs on American competitiveness, employment, investment, and productivity.
- Reporting separately helps ensure that any comparisons of benefits and costs are made on an equivalent basis; and is more reliable and reflective of true costs and benefits .
- Reporting separately would assist the EPA in transparently fulfilling the CAA's primary purpose "to protect and enhance the quality of the Nation's air resources."
- Reporting separately is consistent with guidance in OMB's 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."
- Reporting separately is consistent with EO 12866 which makes clear that "the American people deserve a regulatory system that works for them, not against them." The EO further explains in the "regulatory philosophy and principles" section that "[f]ederal agencies should promulgate only such regulations as are required by law…to protect or improve the health and safety of the public, the environment, or the well-being of the American people".
- Blanket incorporation of non-domestic impacts ignores and confuses the role of internationally focused provisions of the CAA, including Title VI, Section 115, Section 179B, and Section 103.
- Recent practice has relied heavily on global benefits while ignoring the costs of shifting production to less efficient and, in most cases, more polluting firms overseas.
- Using any global benefits estimates to justify domestic actions could fail to consider whether those benefits are real, vis-à-vis the 'leakage' effect, as well as the opportunity costs of not pursuing any more cost-effective benefits--whether domestically or internationally--or other benefits, whether through private market activity or government regulation. For example, the EPA cannot count highly uncertain non-domestic benefits while ignoring the known social costs of the adverse effects on the unemployed worker (that are not captured by accounting only for workers' wages).
- It is long-standing federal regulatory policy for agencies to issue regulations only upon a "reasoned determination" that the benefits "justify" the costs. A decision to issue a regulation with substantial domestic costs based on a finding that benefits to

non-US countries "justify" such costs would not be a reasoned determination and thus, would not be within EPA's authority.

Some of these commenters said domestic costs have been inappropriately compared to global benefits in the use of the social cost of carbon; and some suggested that the EPA use an appropriate discount to represent willingness of American citizens to pay when presenting benefits and costs from an international perspective.

A commenter said they do not object to reporting separately, as long as all of the benefits are accounted for accurately and reported fully, particularly with regard to climate change, which has and will also disproportionately negatively impact AN/AI populations and lands.

**Response:** 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)). 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. The final rule includes a presentational requirement 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. We note that the presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** Commenters opposed reporting domestic benefits and costs of significant impacts separately from non-domestic benefits and costs of regulations for at least one of the following reasons (presented in no particular order):

- Reporting separately is unnecessary and counterproductive.
- Reporting separately is arbitrary and capricious. Simply "reporting" non-domestic benefits and costs separately to provide greater transparency may not present an issue; however, 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. For example, the United States remains connected to Canada, Mexico, and other countries by transboundary transport of air pollution.
- If the EPA adopts an approach that values only domestic benefits, this would allow the EPA to disregard the changes in climate that affect directly U.S. citizens who reside abroad, property owned by U.S. citizens and residents outside the territorial United States, and U.S. military assets overseas.
- Reporting separately is not consistent with the CAA section 302(h) which takes a broad view of air pollutant impacts, including its expansive language that defines welfare effects to specifically include global considerations such as climate.

- Reporting separately is not consistent with the CAA section 312(b) which states that "a default assumption of zero value shall not be assigned to such benefits unless supported by specific data." For example, a solely-domestic SCC that treats global impacts as having zero value would ignore this statutory guidance and fail to acknowledge the spillover effects of damages that occur abroad. This would result in an erroneously lower estimate of actual damages in the United States.
- Both the CAA and OMB's Circular A-4 support the inclusion of global impacts as best practices that the EPA should implement in future rulemakings.
- Certain classes of effects cannot be meaningfully disaggregated. Reporting separately is not consistent with the recent federal court decision in *California vs. Bernhardt*.[126] EPA's recent decisions to ignore the scientifically supported and peer-reviewed global cost of greenhouse gas emissions (ignoring the relevant consequences that climate change impacts outside of the United States will have on the United States), and instead limit its analysis to an unscientific interim measure of domestic costs of greenhouse gases are unlawful.
- Reporting separately is not consistent with the National Academies findings that the calculation of a domestic social cost of methane cannot be credibly done using current models, as they ignore important spillover effects given the global nature of climate change.[127]
- Reporting separately invites adverse reciprocity by providing a disincentive to other countries to reduce their air pollutant emissions that adversely affect the United States.
- Reporting separately and excluding non-domestic considerations would provide lower accuracy in articulating the effects of the rule than broadening it to account for the true scope of the action. There are no physical borders in the air. Reductions in air emissions- like climate-warming greenhouse gases – within the United States serves the American people and the greater good by slowing the pace of climate change.
- Reporting separately might be used to devalue certain subcategories of benefits and to obscure the central role of aggregate benefits in BCAs.
- Public Law 115-91, Defense Authorization Act of 2018, December 12, 2017, 131 Stat. 1283, § 335 makes clear that maximizing the welfare of U.S. citizens and

[126] See *California v. Bernhardt*, No. 18-5712 (N.D. Cal. July 15, 2020). Commenters said that the federal court affirmed that a purported estimate of the domestic social costs of greenhouse gases that omits impacts to U.S. citizens (including U.S. military service members) who live abroad and/or have significant investments abroad, omits potential impacts to trade flows and global commodity markets that affect the U.S. economy, omits impacts to U.S. military sites abroad, and/or omits other risks to national security with significant potential costs, violates the APA by "failing to consider ... important aspect[s] of the problem" and "run[ning] counter to the evidence before the agency." See *California v. Bernhardt* at *27, citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983).

[127] National Academies of Sciences, Engineering, and Medicine, *Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide,* 53 (2017).

residents involves considering climate impacts beyond U.S. borders, as does appropriate regulatory analysis.

- 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'. 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 EPA's obligations to use the 'best available science' and reasoned decision-making. The U.S. Government Accountability Office report, *Social Cost of Carbon: Identifying a Federal Entity to Address the National Academies' Recommendations Could Strengthen Regulatory Analysis* (see GAO-20-254, June 2020, p. 29) affirms that EPA's domestic SC-GHGs does not account for the 'best available science,' in violation of EOs 12688 and 13783, and OMB's Circular A-4, which the EPA claims as the basis for the proposed regulation.
- Identification and communication of subcategories of benefits (such as co-benefits or benefits accruing outside the United States), where practical, is already accommodated and frequently done under existing procedures.

**Response:** Separate reporting of domestic and non-domestic benefits and costs 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. The final rule includes a presentational requirement 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. We note that the presentational requirements in the final rule do not bar consideration of any part of the BCA.

**Comment:** A commenter argued that the current federal administration's withdrawal of the Interagency Working Group (IWG) on the Social Cost of Greenhouse Gases reports[128] as no longer representative of federal policy does not call into question the validity and scientific integrity of this work. The commenter argued that the IWG's work remains relevant, reliable, and appropriate for use for these purposes. The commenter said they support continued use of the IWG social cost of GHG values and strongly suggests that the EPA support and promote these values, which would increase transparency and consistent high quality of regulatory analyses vastly more than any of EPA's current proposals. Another commenter said that abandoning the global values estimated in 2016 by the IWG in favor of a so-called "domestic only" calculation of climate damages, or else relegating consideration of global effects to an appendix or sensitivity analysis, arbitrarily excludes or devalues climate damages that directly and indirectly affect the United States and its citizens and residents. Another commenter cited EPA's Overview

[128] The commenter said IWG was convened in 2009 by the President's Council of Economic Advisors and OMB, and originally titled the Interagency Working Group on the Social Cost of Carbon.

of Greenhouse Gases report[129] and said that according to EPA, "these [greenhouse] gases remain in the atmosphere long enough to become well mixed, meaning that the amount that is measured in the atmosphere is roughly the same all over the world, regardless of the source of the emissions." The commenter argued that any country's domestic carbon emissions impose damages on other countries, places, and persons, regardless of political borders; therefore, the EPA must look at both benefits and costs worldwide to account for scale of the pollution problem.

**Response:** The final rule allows for reporting of non-domestic impacts and therefore addresses the commenter's concern regarding accounting for impacts on other countries. We note that the presentational requirements in the final rule do not bar consideration of any part of the BCA.

## 11.4 Retrospective Analysis

**Comment:** Commenters supported retrospective review of historical BCA of other EPA promulgated rules. A commenter pointed out that retrospective review has been a bipartisan goal for every Administration since President Ronald Reagan. Other commenters encouraged the EPA to focus on individual major, economically significant rules; and another commenter encouraged the EPA to phase-in the requirements for retrospective review, starting with Agency actions having the most widespread effects and the least transparent by the modernized criteria. Other commenters suggested that the EPA should only focus its retrospective reviews on regulations recommended by the public, the regulated community, and independent reviewers. A commenter added that the EPA may lack the resources and incentives to determine which regulations would benefit the most for such reviews and rules vary significantly in terms of how burdensome or subject to improvement they are and the industry being regulated would know best about such matters. The commenter said that where multiple rules are directed toward the same objective, it may be sensible to review them collectively, to evaluate how well they accomplish that objective.

A commenter recommended that the EPA ensure that the impacted industry is interested and willing to participate in a retrospective review prior to beginning the information collection process because compliance cost information can be very sensitive and is typically treated as highly confidential business information that will need to be managed in a particularly sensitive manner by EPA. The commenter recommended that the EPA first notice and convene a workshop with the impacted industry to ensure that a retrospective review can be supported by the impacted industry. Another commenter contended that the EPA should provide the public with an analysis of the actual costs and benefits of a rule's implementation and compare them to the estimates of costs and benefits projected in the rulemaking that promulgated the rule.

Commenters generally said that retrospective review is valuable for at least one of the following reasons (presented in no particular order):

- Retrospective review can help cut down on the trend of an ever-growing regulatory state.

[129] https://www.epa.gov/ghgemissions/overview-greenhouse-gases

- Retrospective review would improve outcomes for a number of regulations that were based on flawed BCAs; because in the past, the EPA has undercut its BCA type of analyses by grossly underestimating impacts in an initial rulemaking and then relying solely on an "incremental" BCA type of analysis for all related future rulemakings.
- If a regulation was not fully effective in achieving its intended objectives, then retrospective review can help to reveal the factors that were responsible for the regulation's failure. This information can be used to improve both the design of future regulations and ex ante RIAs.
- Retrospective review can help correct for past mistakes by providing appropriate transparency for the actual cost of implementing regulatory mandates under the CAA. Actual costs may differ from ex ante estimates because of unforeseen behavioral adaptations by consumers or firms, shifts in government policy, and other exogenous changes (e.g., changes in energy prices). Recognizing the effect of these changes can improve the design of future regulations and ex ante RIAs, will enhance the benefit-cost rule's goals of consistency and transparency, and will keep the EPA accountable to the public for the integrity and accuracy of its estimates.
- Retrospective review may make it possible to obtain causal estimates of a regulation's benefits or its effects on outcomes other than economic efficiency—for example, the impacts of the regulation on employment.
- Retrospective review can generate data that are useful for estimating the cost savings and foregone benefits of repealing a regulation. For instance, if the costs of the regulation since its implementation are known, they can help in estimating the remaining costs of the rule, which in repeal terms would be the cost savings of repeal. Over the long term, retrospective review can support the type of institutional learning needed to sustain agency legitimacy.
- Examining the cumulative benefits and costs of a set of rules or a broader program invites the bundling of a variety of provisions in a way that obscures the opportunity to obtain cost savings or additional benefits at a low additional cost from specific rule requirements
- Comparing a rule's original cost-per-ton estimate with subsequent data will help the EPA improve cost estimation over time and facilitate public understanding of and engagement in the regulatory process.
- Retrospective review would enhance the benefit-cost rule's goals of consistency and transparency.
- It will keep the EPA accountable to the public for the integrity and accuracy of its estimates.

A commenter said that the defining characteristic of retrospective review is that a new rule would include a retrospective review plan that would specify regulatory objectives; define the metrics (ideally, evidenced-based public health or environmental outcomes) the EPA would use to evaluate how well the rule accomplishes those objectives; outline how the EPA would

collect data on these metrics; and specify a time frame for conducting the retrospective analysis (e.g., 5-10 years after the rule is promulgated). The commenter said that a draft retrospective review plan should be issued along with the proposed rule and should be as specific as possible regarding the data and methods it will use to evaluate the rule's true ex-post impact. The commenter said such specificity would provide multiple benefits, including:

- Ensuring the EPA appropriately considers how best to measure the rule's effect before moving forward.
- Allowing for public input that could produce higher-quality metrics for use in the retrospective review.
- Allowing regulated entities to comment on the information collection burdens imposed by particular metrics, thereby enabling the EPA to take steps to minimize those burdens while collecting the necessary data.
- Allowing the EPA to comply with the Paperwork Reduction Act (PRA) in the course of the rulemaking, rather than having to conduct a separate PRA approval process later.
- Enabling the EPA and regulated entities to determine monitoring or other information collection requirements up-front, while the rule is being developed, rather than having to search for or estimate data after the fact.

In addition, a commenter pointed out that the EPA itself concluded in 2014 that "retrospective assessments were challenging to conduct and were often limited by a paucity of comprehensive cost information on treatment technologies and mitigation strategies. Commenters stated that disentangling the expenditures made expressly for required pollution control from other investments made at the same time was a challenge for several of the case studies." A commenter said that before setting mandatory requirements for itself for all of its CAA regulatory actions, EPA's expectations should be set realistically about what is possible given available data. Another commenter said that it is very difficult to calculate ex post costs that can reliably be compared to ex ante compliance cost estimates. The commenter pointed out that EPA's Science Advisory Board (SAB) noted this difficulty in 2012 when it was asked to review and comment on the Retrospective Cost Study of the Costs of EPA Regulations: An Interim Report of Five Case Studies (March 2012) (RCS).[130] As a means to also improve EPA's ability to evaluate costs retrospectively, the commenter recommended that the EPA focus on improving the EPA's consideration of potential secondary costs in BCAs incurred by the control technology's interference with other functions of the total plant system or the long-term macroeconomic impacts on overall economic productivity. Moreover, the commenter said that if the EPA decides to conduct retrospective costs analyses and/or further evaluate its ability to conduct meaningful comparisons of ex ante and ex post costs, it should specifically seek out ex post evidence of unanticipated indirect cost and economy-wide impacts that may have been incurred.

[130] The RCS was composed of five case studies developed by EPA's National Center for Environmental Economics (NCEE) to investigate how well the Agency has predicted the costs of regulatory compliance by comparing EPA's cost estimates to ex post costs.

**Response:** 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. We also agree that 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. The SAB, during its review of the forthcoming update of EPA's Guidelines, 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.

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 establishing best practices for conducting retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures.

**Comment:** Commenters said that retrospective review should be bidirectional; thus, not biased toward less (or more) regulation. One of these commenters said that identifying opportunities for achieving benefits at low cost should be as important as identifying wasteful or poorly designed regulations. The commenter said that retrospective review of historical BCA should be a key part of an initiative to revise or withdraw an existing rule. The commenter said that there is a need for data collection efforts after a rule is implemented to help determine the effectiveness of the rule, the costs incurred (including sunk costs), and to what extent non-compliance is occurring.

**Response:** EPA agrees that retrospective analysis should not be biased toward less or more regulation. Conducting retrospective analyses of an implemented regulation can provide valuable information that, if considered, can more fully inform public decision-making. Retrospective analyses may also lead to improved methods for prospective analysis and ultimately improvements in regulatory design. 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 establishing best practices for conducting retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures.

**Comment:** Some commenters provided suggestions to improve access to the key data needed for a retrospective review. A commenter said that the EPA should continue to assure existing data collection efforts within the EPA and by other Federal government agencies (e.g., EIA, DOE, and USDA); however, in a number of cases, new data are required. The commenter stated that OMB could streamline data collection under the Paperwork Reduction Act, as it has already been done for research-related information. In addition, commenters said that in an effort to further institutionalize retrospective review of environmental regulations, it is critical that the EPA adopt specific guidance establishing a retrospective review process within its rulemaking procedures; 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. The commenters said that the plan for ex post review should identify at the time of rulemaking the measurable outcomes to be chosen for retrospective review; and it should also stipulate the relevant control group, the associated data requirements to measure both compliance costs and environmental impacts, a power calculation of a minimum sample size necessary to identify regulatory outcomes, and the time period for the evaluation.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. 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 establishing best practices for conducting retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures.

**Comment:** A commenter supported applying retrospective analysis to more than specific provisions of the CAA.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. 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 establishing best practices for conducting retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures.

**Comment:** A commenter said the EPA should include in the final BCA regulation a requirement to consider the aggregate future and retrospective costs of any significant California mobile-source regulation for which a preemption waiver is sought to determine whether the putative benefits of that regulation outweigh its aggregate nationwide costs, and so warrant the issuance of a preemption waiver under the enhanced BCA criteria that the EPA will codify under this rulemaking. In that regard, the commenter said it agrees that any such analysis should include "a review of the cumulative burden of the set of [California] rules regulating the same or related entities." (85 FR at 35624).

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. 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 establishing best practices for conducting retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures.

**Comment:** Commenters opposed retrospective review of historical BCA of other EPA promulgated rules for at least one of the following reasons (presented in no particular order):

- Retrospective review is time-intensive and fraught with many practical challenges and complexities, a waste of resources, and could lead to unacceptable regulatory and legal uncertainty. With a greater demand on resources, a supplemental retrospective review requirement might affect the timeline of other significant rulemakings and enforcement and compliance activities that impact public health, the economy, and the environment. The EPA already faces a large and growing number of duplicative and wasteful "lookback" or "retrospective review" requirements that serve to inhibit effective implementation and enforcement of its statutory authorities.
    - The Regulatory Flexibility Act requires agencies to review every rule that has "a significant economic impact upon a substantial number of small entities" within 10 years after the final rule is published.
    - EO 12866 requires agencies to develop a program "under which the EPA will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated."
    - EO 13563 adds more time-consuming and resource-intensive procedures for carrying out the lookback program on an ongoing basis.
    - The CAA already requires the EPA to review and update its NAAQS every five years.
    - The CAA already requires the EPA to conduct risk and technology reviews.
    - The EPA reviews its existing regulations even when it is not mandated by a particular program – that is, because it has independently recognized that such a review is a good idea in certain circumstances.[131]
    - CAA section 312 requires the EPA to "conduct a [periodic] comprehensive analysis of the impact of this chapter on the public health, economy, and environment of the United States. In performing such analysis, the Administrator should consider the costs, benefits and other effects associated with compliance with each standard."

[131] As Michelle Sager, the Director of Strategic Issues at the U.S. Government Accountability Office (GAO), testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, "Reviews mandated by requirements in statutes or executive orders and related OMB memorandums were sometimes the impetus for reviews, but agencies more often exercised their own discretionary authorities to review regulations." Significantly, according to Ms. Sager's testimony, the GAO found that "[a]gencies noted that discretionary reviews generated additional action more often than mandatory reviews, which most often resulted in no changes." Before the Subcommittee on Efficiency & Effectiveness of Fed. Programs & Fed. Workforce, S. Comm. on Homeland Security & Gov't Affairs,113th Cong., Hearing on a More Efficient and Effective Government: Improving the Regulatory Framework, Mar. 11, 2014, available at: http://www.hsgac.senate.gov/subcommittees/fpfw/hearings/a-more-efficientandeffective-government-improving-the-regulatory-framework

- Retrospective review would create the opportunity for regulated industries to challenge certain regulations that have been in place for years; and could end with regulated industries being permitted to emit more air pollution, harming health.
- Retrospective review has the potential for stranded investment, which in some cases can lead to subsequent higher cost for electricity consumers, should previously implemented regulation be undone and past investment based on those regulatory decisions be undermined or reversed. Some commenters pointed out that the retrospective review of the Mercury and Air Toxics Standard (MATS) in light of the Supreme Court's decision in *Michigan v. EPA* has sparked controversy as to whether regulated electricity providers should have to pay back to customers the hundreds of millions of dollars captured in rate increases to comply with the MATS (now that the EPA has determined that the standard's direct benefits were not economically justified).
- Retrospective review would undermine the CAA and the benefits to be gained through those duly promulgated regulations.
- Retrospective review could be misused to undermine the environmental progress from policies that increase the use of renewable fuel. For example, if a BCA analysis is done on the 2017 RVO, the results of the analysis could potentially be used to retroactively alter the blending obligations in past years, which could create market volatility, and needlessly depress demand for renewable fuels and associated crops. The proposal does not provide a clear roadmap for how disaggregation should be applied in the context of the RFS reset or in post 2022 annual RVOs, both of which require the EPA to consider and weigh six statutory factors, some of which do not have straightforward cost or quantitative metrics. It is also unclear how the proposal would affect accounting for GHG impacts of ethanol compared to gasoline.
- EPA's proposal is too vague; the EPA has not proposed a retrospective review requirement with enough specificity to allow for meaningful comment. Any such potential requirements should be concretely proposed in a separate notice that fully explains the need specifically for a rule-based solution to this matter (as opposed to relying on existing or new guidance on retrospective review) and that allows a new and adequate opportunity for public comment.

A commenter said that the EPA should clarify whether retrospective review would be different from the current comprehensive analysis, and if so, how might this contribute to CAA's purpose of protecting and enhancing the quality of the Nation's air resources. The commenter contended that under section 312 of the CAA, the EPA must conduct a periodic comprehensive analysis on public health, economy, and environment. The commenter concluded that the additional requirement in the BCA would affect the timeline of other significant rulemaking and enforcement and compliance activities that impact public health, the economy, and the environment.

Another commenter argued that it is difficult to determine why regulated businesses take specific actions (e.g., was an action taken to comply with the rule under consideration, another recently passed rule, or simply for other business reasons). The commenter pointed out that

businesses are reluctant to share accurate data due to lack of incentives, proper record keeping, and confidentiality. The commenter said that other regulatory agencies (EPA included) have tried to conduct retrospective reviews; however, there has not been a single successful effort despite countless hours of work. The commenter said it is better use of EPA's time to continue to invest in high-quality, robust economic analyses using best-available science and following best economic practices than to spend countless hours and resources going down the rabbit hole of retrospective review. The commenter argued that the idea of turning retrospective review into a regular or required practice does not have any semblance of Congressional authorization, nor can it be justified as "necessary" in the meaning of CAA section 301. The commenter said that the Second Prospective Report on Benefits and Costs of the CAA, 1990-2020, that was issued in 2011 under CAA section 312 had documented a central benefits estimate that exceeds costs by a factor of more than 30 to one. The commenter argued that there is no rational basis, much less any authorization, for making a new rule that the CAA's tremendous, cumulative benefits (nearing trillions of dollars) should be individually validated or revalidated on some retrospective, rule-by-rule basis. The commenter also stated that the CAA already assigns recurrent rulemaking responsibilities across a number of program; and the EPA is also accountable to administrative petitions for CAA rulemakings; therefore, nothing prevents a petitioner from claiming or showing that some past-promulgated rule is not or was not economically justified.

A commenter opposed any retrospective analysis requirement using cumulative burden/cost as a way to say that no emission controls are needed. The commenter added that when a CAA regulation is market forcing and has both spurred the development of cleaner facilities that are more cost effective and forced older, dirtier, and more costly facilities to close, then revisiting this outcome is inappropriate. The commenter also added that regulated industries, in implementing controls and continuing to operate, have in effect stated that the controls were not an economic burden. The commenter concluded that these industries must be excluded from any retrospective analysis.

Another commenter added that studies have shown that even without the proposed rule, the EPA tends to undercount the overall benefit of CAA regulations. The commenter stated that retroactively applying a rule that systematically underestimates such benefits may subject existing regulation to rescission on the basis of skewed analysis.

A commenter contended that the EPA should regulate if it has statutory authority to do so and if the regulation would solve actual problems demonstrated in the administrative record of the rule making, based on a record of assessment of the problems and analysis of how the problems would best be solved. The commenter added that it is not sufficient for the EPA to just say that some stakeholders submitted comments and therefore the EPA would conduct retrospective reviews.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. 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 establishing best practices for conducting

retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures.

**Comment:** A commenter contended that retrospectively eliminating co-benefits from analysis would counter the very consistency necessitated by the Proposed Rule and imbalances the BCA of future regulations. The commenter stated that by eliminating or separating co-benefits from BCA, the Proposed Rule runs the risk of anti-regulatory bias. The commenter added that a foundational goal of BCA is to analyze which policy choices will produce the greatest net benefits to society, and to achieve this goal, agencies must consider benefits and costs consistently and holistically.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. 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 establishing best practices for conducting retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures.

**Comment:** Commenters stated that because no details were provided, they could not submit comments. A commenter contended that because the EPA did not provide a sufficiently detailed proposal, it cannot adopt retrospective analysis requirements in the final rule. The commenter added that a final rule is not a logical outgrowth of the proposal if a new round of notice and comment would "provide commenters with 'their first occasion to offer new and different criticisms which the EPA might find convincing.'" The commenter concluded that such a vague proposal cannot provide sufficient notice as is required by the Administrative Procedure Act or CAA.

The commenter stated that if the EPA does intend to move forward with instituting a retrospective analysis requirement for CAA rules, the EPA should: (1) establish a separate docket for that proposal; (2) develop a concrete proposed rule or set of alternative proposed rules for public comment, including: details on the purpose and intended effect of the review; the need to establish a new, CAA-specific retrospective review process; the selection criteria for rules to be reviewed; and public participation opportunities within the selection and analysis process; and (3) take public comment on the concrete proposal.

The commenter stated that to the extent the EPA implies that it might be appropriate to assess the "cumulative burden of a set of rules" on an industry, it would also be necessary to evaluate the cumulative benefits achieved by reducing air pollution from that industry under the same rules. The commenter added that the EPA offers no reason why a retrospective analysis focusing exclusively on one class of regulated entities would be useful in examining the benefits and costs of a rule or set of rules. Without an adequate explanation, any policy on retrospective analysis that exclusively examines the costs, or costs and benefits, of regulating a single industry would be arbitrary.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. 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 establishing best practices for conducting retrospective analysis and how to plan for different types of retrospective analysis within its rulemaking procedures.

## 11.5 Making Information Public

**Comment:** Commenters supported the proposal in that it should require full disclosure of raw data as part of its study selection process. A commenter said transparency is essential to reproducibility. A commenter added the proposal would provide transparency in the weight assigned to factors used in the analysis, increasing consistency in the interpretation of terminology used, and promoting adherence to best practices in conducting the technical analysis and presenting it to the American people. A commenter contended that the EPA must be fully transparent in its analysis and not utilize entrenched policy beliefs to measure a benefit or cost without considering other scientific data, no matter the source.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. These revisions include requirements to ensure that information used in the development of BCAs are publicly available to the extent permitted by law, and where information is proprietary EPA will make available underlying inputs, assumptions, equations, and methodologies. In making these revisions the Agency is making the final rule consistent with applicable portions of the EPA's "Strengthening Transparency in Pivotal Science Underlying Final Significant Regulatory Actions and Influential Scientific Information" rulemaking in terms of making information publicly available. Further, the rule also contains requirements that evaluation processes must emphasize transparency and replicability.

**Comment:** Commenters opposed the proposal in that it should not require full disclosure of raw data as part of its study selection process. A commenter said transparency is unnecessary to assure data quality. The commenter stated that well-established scientific practices and norms already exist for assessing the quality of raw data that do not involve disclosure and betrayal of confidentiality agreements. The commenter suggested that the EPA assure the quality of the data it uses through existing well-established scientific practices and norms for assessing the quality of raw data that do not involve disclosure and betrayal of confidentiality agreements, rather than relying on arbitrary transparency requirements that would do more harm than good. Another commenter stated that transparency considerations must be governed by the principles of protecting privacy, following the science underlying the CAA, and continuing to include epidemiological studies that are based on aggregated personal health data.

A commenter contended that the proposal may require the EPA to rely on rigorous data and models that cannot feasibly or lawfully be released publicly. The commenter added that elements of the proposal pertaining to the public availability of data and models resembled EPA's separate proposal restricting the scientific information upon which the EPA relies when

setting public health and environmental protections. The commenter also incorporated by reference the comments to EPA's proposed rule "Strengthening Transparency in Regulatory Science."

The commenter contended that the EPA must explain the relationship and intent of the BCA proposal and EPA's proposed "Strengthening Transparency in Regulatory Science" (STRS) rule (85 FR 15396) to provide the public with adequate notice to develop informed comments. The commenter requested clarification whether the EPA would expect the rules to operate independently, or if restrictions on using scientific information would affect (directly or indirectly) which information the EPA can consider in BCAs. The commenter stated that it was unclear whether the two proposals would impact the same information or would expand upon each other. The commenter urged the EPA to explain whether the BCA proposal was an effort to implement some of the objectives of the STRS proposal, or if not, what other purpose was being served by replicating elements of that proposal. The commenter concluded that finalizing a rule that would impose some of the same counterproductive measures was arbitrary, capricious, and an abuse of the EPA's discretion.

Similarly, another commenter added that many organizations and academics raised significant concerns with EPA's "Strengthening Transparency in Regulatory Science" (STRS) rule that also apply to the BCA proposal, particularly to the proposed rule's request (85 FR 35622) for additional comments on whether additional study selection criteria were appropriate, and the commenter incorporated those STRS comments by reference.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. EPA has made these revisions to make the final rule consistent with the EPA's "Strengthening Transparency in Pivotal Science Underlying Final Significant Regulatory Actions and Influential Scientific Information" rulemaking in terms of making information publicly available.

**Comment:** A commenter did not support the proposed use of anonymizing methodologies or other techniques to protect Personally Identifiable Information (PII). The commenter stated that even if such methodologies or techniques were used, such a requirement would serve to exclude earlier seminal studies (and new studies that use previously-gathered data), in which the participants were promised that the data would not be made publicly available and signed informed consent agreements to that effect, because the authors of those studies could not feasibly go back and alter those consent agreements or otherwise reacquire the same raw data. The commenter added that such a requirement similarly would exclude new studies that use previously gathered human health information. The commenter stated that anonymizing techniques would not address the chilling effect that a data disclosure requirement would have on securing participants for future health studies, particularly from within tribal, immigrant, and EJ communities. The commenter noted that members of these communities are often already understandably wary of the research establishment, given historical abuses (e.g., experienced by American Indian people and African American people) and ongoing discrimination and that there could be ripple effects that would extend beyond the data-gathering that informs environmental standard-setting, if the resulting distrust were to undermine efforts to address public health deficits in these communities more generally.

Similarly, another commenter contended that EPA's general failure to consider how they could implement the proposed procedures for protecting CBI, PII, and other privileged, non-exempt information, particularly in light of the many foreseeable obstacles, was arbitrary, capricious, an abuse of the EPA's discretion, and otherwise contrary to law. The commenter pointed out that the proposal (85 FR 35627) did not explain what the EPA meant by "appropriate protection" regarding CBI, PII, and other privileged, non-exempt information, much less how the EPA would assure this protection. The commenter noted that the proposal offered no information on where the raw data collected would reside, how the resources to manage the data would be obtained, or how the EPA would deal with legally and ethically protecting confidential or sensitive data.

The commenter asserted that the EPA did not seriously consider the issues involved with redacting data, such as the fact that simply redacting a name or a few pieces of information will not adequately protect an individual's identity, and that a simple anonymization process is at odds with the legal and ethical frameworks developed to protect human participants in scientific studies and was inadequate to protect personal data since simple steps like an Internet search or database query search can re-identify research participants. Furthermore, the commenter stated that release of underlying human health data may include participants who cannot consent to such a process, like those who have died or cannot be located, and it may discourage people to sign up for future research studies. The commenter added that the EPA is statutorily responsible for characterizing pollutant exposure to at-risk subpopulations, such as the elderly, young people, indigenous people, and people of color and that, if subjected to the rigid transparency requirements outlined by the proposal about scientific studies, many studies of at-risk groups, particularly cohort studies which can rely on small populations with unique characteristics, would have raw data that could not be made available because it would too easy to identify individuals, even with redactions of some personal information.

The commenter contended that it would be nearly impossible for the EPA to strike an appropriate balance between redacting data to protect privacy and maintaining its utility. The commenter added that the EPA had not explained how it would pay to make all of the data and models publicly available, which can be a complex and technical undertaking and almost certainly be a significant cost especially at a time when EPA's budget and capacity are under strain. The commenter noted that the proposal was silent on what would happen if neither the EPA nor the researchers have the resources to make data and models publicly available, and specifically, what impact that would have on the EPA's BCAs or other scientific and public health determinations.

Another commenter noted that the proposed rule (85 FR 35622) explained that "[i]f the data and models are proprietary," then the EPA will protect confidential business information, personally identifiable information, and other privileged information from disclosure, but the commenter stated that the proposed rule did not make clear whether personally identifiable information will also be appropriately protected if the data are not specifically "proprietary" but are still privileged or otherwise in need of protection, nor did the proposed rule explain the consequences if underlying data is simply infeasible to disclose.

**Response:** We considered the additional comments submitted on this solicitation and we are finalizing the proposed rulemaking with some revisions. EPA has made these revisions to

make the final rule consistent with the EPA's "Strengthening Transparency in Pivotal Science Underlying Final Significant Regulatory Actions and Influential Scientific Information" rulemaking in terms of making information publicly available.

# 12.0 Executive Orders

## 12.1 Executive Orders 12866, 13563, 13771, 12898, UMRA

### *12.1.1 EO 12866 (Regulatory Planning and Review)*

**Comment:** Commenters contended that EPA's proposed rule does not comply with Executive Order (EO) 12866 regarding economic and fiscal impacts and that this failure demonstrates that the proposal was arbitrary. The commenter stated that the EPA failed to conduct the RIA required by EO 12866 or provide a rational explanation for not doing so, even though the EPA determined the proposal to be a "significant regulatory action." The commenter also noted that the EPA failed to assess their own likely costs to administer a significant proposed regulation as required by EO 12866 in section 6, paragraph(a)(3)(C)(ii). The commenter noted that the proposal preamble (85 FR 35624) claimed that the EPA did not need to evaluate the costs of the proposal under EO 12866 because "EPA does not anticipate that this rulemaking will have an economic impact on regulated entities."

**Response:** 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. EPA will implement the requirements of the procedural rule in the future when it develops BCA in the CAA rulemaking process for that future action. Further, many of the procedures in this rule are consistent with best practices established under OMB's Circular A-4 and EPA's Guidelines, and therefore are not expected to impose additional costs on the agency.

**Comment:** A commenter stated that the proposed regulation was not needed and opened an avenue for the EPA to avoid the EO 12866 requirement of "[maximizing] net benefits (including potential economic, environmental, public health and safety, and other advantages, […])". The commenter noted that the proposal (85 FR 35620) says that, in a BCA, "the pollutant analyzed in the study matches the pollutant of interest in the regulation." The commenter said that this stipulation would apparently prevent the EPA from including the many health co-benefits from other pollutants that would also be reduced at the same time the regulation is implemented, thereby eliminating adverse health effects from the benefits side of the analysis and inappropriately reducing the financial justification of an environmental protection required under EO 12866. For example, most emissions control options for removing mercury from the exhaust of a coal-fired power plant would also remove health-damaging particulate matter that would otherwise not be controlled. Because the health benefits of the control of one pollutant are far larger than just the pollutant that is the direct aim of the regulation alone, the commenter contended that the EPA should fully include all of the health benefits and their valuations in the estimated benefits of a regulation. The commenter added that forcing the EPA to ignore the air quality benefits of co-control of other pollutants inappropriately prevents the EPA from valuing the full range of potential health benefits, including those where the evidentiary base is suggestive, which effectively assumes that there is zero benefit to reducing these health effects, in violation of widely accepted economic principles.

**Response:** The final rule does not limit how BCAs may be used in decision-making. The final rules codifies procedures that are already being followed in guidance documents and OMB's Circular A-4. The final rule does not exclude any benefit categories from consideration, the provisions in the final rule in this regard are presentational requirements that will increase transparency.

**Comment:** A commenter noted that EPA's proposal ignored the requirement in EO 12866 to assess distributive impacts and equity in analyzing rule impacts. The commenter stated that EPA's description in the proposal preamble (85 FR 35620) of the methods for analyzing benefits is limited to quantifying health endpoints and, where necessary, discussing qualitatively those benefits that are difficult to quantify. The commenter contended that the preamble discussion did not recognize the need to evaluate the distributive impacts of regulation and equity as potential benefits. The commenter asserted that the EPA should explain how it plans to perform these types of analyses, which are required by EO 12866.

**Response:** EPA acknowledges the need to analyze distributional impacts consistent with OMB's Circular A-4, particularly in the EIA for a rulemaking. However, this rulemaking is focused on BCA, and does not address EIA or other types of analysis conducted pursuant to executive orders or statutory requirements.

**Comment:** A commenter said that the proposed rule's suggestion that the Administrator could use his or her discretion to designate a rulemaking, other than one that meets the criteria of EO 12866, seemed oddly amorphous, and the proposal provided little discussion of how the Administrator's discretion would be used in this fashion. Thus, the commenter asserted that finalizing the rule as proposed likely would fail the arbitrary and capricious test. In addition, the commenter said it could not comprehend why some regulations might be significant and others that have similar monetary benefits and costs might be deemed insignificant. The commenter said that if the public perceived that the rule was not being used consistently, either to absolve the EPA from doing a CBA or adding to the cost of agency rulemaking by adding a CBA, it would compromise the requirement. For these reasons, the commenter believed that final action on this proposed rule should not provide discretion to the Administrator over its use.

**Response:** In the final rule we are promulgating the proposal definition of significant regulation as "a proposed or final regulation that is determined to be a 'significant regulatory action' pursuant to EO 12866 or is otherwise designated as significant by the Administrator." We have reviewed the commenters' suggestions, and concluded that the definition of significant regulatory action in EO 12866 is the most appropriate definition for the BCA rulemaking. We also maintain that the requirement provides adequate protections for small businesses when combined with the regulatory Flexibility Act, and as discussed, the Administrator also has discretion to require a BCA for rulemakings that may affect small entities and businesses, if needed.

**Comment:** A commenter asserted that presidential administrations of both political parties have followed recognized economic principles and practices by requiring analysis of co-benefits to ensure that regulatory analyses focus on the overall societal costs and benefits (including indirect benefits and costs) expected to result from regulatory action. The commenter stated that EO 12866 highlights the need for agencies to "assess *all* costs and benefits of

available regulatory alternatives, including the alternative of not regulating" and to consider non-quantifiable effects including potential economic, environmental, public health, and safety benefits. The commenter added that EO 12866 also recognizes that as "some costs and benefits are difficult to quantify, [each agency shall] propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs," to the extent permitted by law and where applicable. Therefore, while quantified benefits do not have to outweigh costs under EO 12866, the commenter contended that an agency must consider all regulatory benefits in deciding whether regulation is justified. The commenter noted the EO 13563 reaffirmed the principles of EO 12866 and directs agencies to "select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)."

**Response:** We have reviewed the commenters' suggestions, and concluded that codifying best practices in this rule demonstrate consistency with The final rule codifies best practices consistent with EPA's Guidelines and the OMB's Circular A-4.

**Comment:** A commenter stated that the EPA should clarify that the consistency and transparency measures would apply to actions taken by EPA regional offices, such as federal implementation plan (FIPs), that meet the requirements in section 3(f) of EO 12866, regardless of whether the rules have general applicability or are limited in scope to specific affected facilities or a discrete geographic area such as a single state.

**Response:** We view the rule as only requiring a BCA for a significant rulemaking under the CAA. A BCA would be prepared in accordance with the requirements of this rule if it is considered a significant rulemaking action under the definition provided in section IV of the preamble.

**Comment:** A commenter urged the EPA to reprint EO 12866 in an appendix to the final rule to support the dual principles of transparency and certainty in this rulemaking. The commenter added that the EPA should consider whether to reproduce OMB's Circular A-4 in the final rule.

**Response:** We disagree with the commenters. In the proposed and final rule EPA has laid out clear procedures for rulemakings to be more transparent and consistent and to incorporate the best practices.

### *12.1.2 EO 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations)*

**Comment:** Commenters contended that EPA's proposed rule does not consider EO 12898 and the EPA failed to evaluate the EJ impacts on communities of color and low-income communities. Commenters said that this failure demonstrates that the proposal is arbitrary. Commenters said that by its own admission (85 FR 35625), the EPA ignored its obligation to assess the EJ implications of the rule prior to issuing the proposal, dismissively stating that the action is not subject to EO 12898 "because it does not establish an environmental health or safety standard." The commenters noted that EO 12898 and other documents call for proposed rules to advance EJ, but the commenters questioned how the proposed rule advances EJ noting that the proposal preamble does not mention EJ at all (e.g., the proposal does not include requirements to

identify and quantify risks to sensitive subpopulations, including the "minority populations, low-income populations, and workers who may be exposed to substantial environmental hazards" that are identified in the EO; and the proposed requirements say absolutely nothing about analyzing the distributional impacts of clean air protections as part of future BCAs—the question of who benefits from a decision to regulate (or not), and who is burdened). The commenters said that EPA's failure to consider the distributional impacts of the proposal or to consider distributional equity in the benefit-cost requirements in the proposal is contrary to accepted practices in regulatory analysis, and that the EPA has repeatedly performed this sort of assessment when acting under the CAA, Clean Water Act, and other statutes.

Commenters stated the following points regarding EO 12898 in reference to the proposal (presented in no particular order):

- EO 12898 does not apply only to "standard[s]," but rather to all "programs, policies, and activities." EO 12898 directs each federal agency, including EPA, to make EJ part of its mission regardless of whether the programs, policies, and activities are substantive or procedural in nature. EPA's failure to consider the distributional impacts of the proposal or to consider distributional equity in the benefit-cost requirements in the proposal is contrary to accepted practices in regulatory analysis.
- By altering BCAs for CAA protections in a way that might make the benefits of these protections more difficult to demonstrate—as well as creating new administrative and litigation-related hurdles to these protections—the proposal puts at risk these vital protections and the progress they have yielded in overburdened communities.
- The proposed rule would preclude the EPA from fully considering the substantial health and economic impacts to disadvantaged communities that would fall in the "upper-bound" risk estimates including both the disproportionate impacts of exposure to pollution from nearby sources and the increased rates of illness and death from heightened vulnerability to the effects of pollution.
- If the proposed rule is finalized, then the EPA will be required to regard the balance sheets of wealthy industries as being no less important than the health and welfare of frontline communities which is manifestly arbitrary and unjust.
- The issue of EJ cannot be made to disappear at the EPA's discretion and that EPA's failure to consider EJ is a serious omission and renders the rule legally defective.
- Failure by the EPA to conduct an EJ analysis for the proposed regulation is particularly egregious in view of the numerous studies that demonstrate disproportionate air pollutant health impacts in the very populations that the EO is designed to protect.
- The proposal's restrictions on use of epidemiological studies, primarily excluding epidemiological studies that do not demonstrate causality, would severely limit understanding of impacts on vulnerable communities, and many, if not most, epidemiology studies could be excluded based on this criterion alone. Additional restrictions on epidemiological studies would further limit use of research to characterize conditions in marginalized communities and the proposal would permit

only the consideration of studies whose location is "appropriately matched to the analysis" and whose "study population characteristics [are] sufficiently similar to those of the analysis;" these provisions would largely exclude consideration of studies that demonstrate health impacts to vulnerable communities, which categorically receive less research attention and funding.

- The EPA recognized in its EJ FY2017 Progress Report[132] that minority, low-income, and tribal communities "may face greater risks" to their health and environment (e.g., disproportionate exposure to lead, particulate matter, and other hazardous air pollutants) "because of proximity to a contaminated sites or because fewer resources are available to avoid exposure to pollution. "

A commenter appreciated EPA's organizational recognition that more needs to be done to afford EJ to the inequitably under-protected, as demonstrated by its ongoing commitment to operating EPA's Office of Environmental Justice; however, the commenter noted that creating a regulatory requirement that may perpetuate systemic injustice undermines that commitment. The commenter said that the EPA should proceed carefully and not constrain itself to the rigid operational requirements of the proposal, instead maintaining flexibility to apply the right frameworks to the situation as warranted to best serve its mission.

A commenter said that the proposal should address EO 12898 by codifying an analytical framework for performing EJ impact analyses which would assist North Carolina and other states that need to perform EJ impact analyses of state regulations that implement Federal statutory/regulatory requirements. The commented noted that maximizing net benefits is not the only metric to consider when developing policies that may have important distributional effects, such as large health impact inequities. In such a case, the appropriate policy might be the one that maximizes benefits to a specific group and/or one that does not impose unduly high costs on another group.

**Response:** 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 ensure 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 support the consistency and transparency of EO 12898 activities. The additional information available as a result of compliance with this final rule's requirements will support future EO 12898 analyses and will further the understanding of the underlying issues highlighted by the commenters.

### *12.1.3 EO 13771 (Reducing Regulation and Controlling Regulatory Costs)*

**Comment:** A commenter stated that the proposal did not comply with EO 13771 regarding economic and fiscal impacts regarding economic and fiscal impacts. The commenter said that this failure demonstrates that the proposal is arbitrary.

[132] https://www.epa.gov/sites/production/files/2018-04/documents/usepa_fy17_environmental_justice_progress_report.pdf

Another commenter stated that the EPA wrongly sought to excuse itself from compliance with EO 13771 by claiming, without explanation, that the regulatory action relates only to "agency organization, management or personnel" (85 FR 35624). The commenter said that the proposal failed to present any information about the type or magnitude of the new and costly duties and their attendant costs imposed on EPA staff, despite requiring EPA staff to conduct BCAs. The commenter cited EO 13771 which requires agencies to assess and consider the costs of regulatory actions when making regulatory decisions, and specifically noted that section 3(d) of EO 13771 requires the Director of OMB to identify to agencies, including EPA, a total amount of incremental costs (or "regulatory cap" as stated in section 2) for all EO 13771 actions finalized during the fiscal year (the total incremental cost imposed by each agency cannot exceed the EPA's allowance for that fiscal year, unless required by law or approved by the OMB Director). The commenter said that despite imposing new and costly duties on EPA staff to conduct BCAs, the Proposal fails to present any information about the type or magnitude of those duties and their attendant costs.

**Response:** 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, we have clarified in the preamble that this action is not subject to Executive Order 13771 because this final rule is a rulemaking of agency organization, procedure, or practice.

## 12.2 Other Executive Order Comments

### *12.2.1 EO 13045 (Protection of Children from Environmental Health Risks and Safety Risks)*

**Comment:** Commenters stated that the proposal did not comply with EO 13045 regarding environmental health and safety risk to children. A commenter said that this failure demonstrates that the proposal is arbitrary. Another commenter asserted that EPA's argument that the proposed regulation is not subject to EO 13045 because it does not establish an environmental health or safety standard is specious. Another commenter said the EPA must account for children's health in BCAs under the CAA. Commenters contended that, if the EPA planned to proceed with adoption of the proposed rule, then the EPA must first conduct "an evaluation of the environmental health or safety effects of the planned regulation on children" and provide "an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives," as required in EO 13045.

**Response:** 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. 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. As this action is a procedural rule, it is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

### *12.2.2 EO 13132 (Federalism)*

**Comment:** Commenters said that the EPA arbitrarily and capriciously failed to conduct analyses and consultation required by EO 13132 regarding federalism implications. A commenter noted that, contrary to EPA's unsupported, cursory assertion (85 FR 35624-25), the proposal indisputably had substantial federalism implications because states and local communities are directly and significantly impacted by health and risk-based standards established by EPA. The commenter stated that the proposal would unquestionably affect EPA's decision-making when considering adoption of CAA standards, and despite the substantial impact the proposal would have on states and local governments, the EPA did not seek any input from states and local governments in developing the proposal, in violation of EO 13132. The commenter asserted that the EPA must engage in the required consultation with state and local officials, as required by EO 13132, before proceeding further.

Another commenter argued the proposal would disrupt the cooperative relationship between the federal government and California to implement federal environmental laws, including potentially undercutting state-level air quality standards under the CAA. The commenter stated that a requirement to generate a BCA for NAAQS barred from incorporating costs is likely to generate confusion and disagreements between California Air Resources Board (CARB) (and its counterparts in other states) and the EPA and the commenter said that this would likely harm the cooperative relationship between the EPA and state air agencies, in addition to hindering the ability of the EPA and CARB to meet the obligations of the CAA, and, ultimately, harming public health through the setting of substandard NAAQS. The commenter added that this instability could also create significant liabilities, and hence reliance risks, for states including California. The commenter said that EPA's failure to consult with the states on the impacts of the proposal was also inconsistent with EPA's own primary goal set forth in its 2018-2022 Strategic Plan[133] to create more effective partnerships with the states, among others, in carrying out shared responsibilities and communicating results to all Americans.

**Response:** 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. This action does not have federalism implications. As it is a procedural rule applicable to Agency best practices in conducing BCA under the CAA, 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.

### *12.2.3 EO 13175 (Consultation and Coordination with Indian Tribal Governments)*

**Comment:** A commenter said that the AN/AI populations in America suffer disproportionately from health discrepancies that leave them more vulnerable to impacts from pollution. The commenter contended that, not only did the EPA ignore these implications, but the EPA did not offer Tribal consultation on this proposal, in direct disregard for EO 13175.

**Response:** 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

[133] https://www.epa.gov/sites/production/files/2019-09/documents/fy-2018-2022-epa-strategic-plan.pdf

with an aim to ensure consistency and transparency for these BCA analyses. As this action is a procedural rule applicable to EPA as it conducts BCA under the CAA, this action does not have tribal implications as specified in Executive Order 13175. However, the EPA asserts that with the focus on ensuring transparency and providing access to the underlying data as provided in this final rule's provisions, the requirements will ensure the understanding of future rulemakings.