

Chapter 2

Executive Order and Statutory Requirements for Conducting Economic Analyses

Federal agencies are subject to executive orders (EOs) and statutes that direct them to conduct specific types of economic analyses. Many of these directives are potentially relevant for all U.S. Environmental Protection Agency (EPA) programs, while others target individual programs. This chapter identifies directives for conducting economic analyses that may apply to all EPA programs (see Table 2.1 - Overview of Executive Orders and Statutes). Although not discussed here, analysts should carefully consider the relevant program-specific statutory requirements when designing and conducting economic analyses, recognizing that these requirements may mandate specific economic analyses.

The scope of the requirements for economic analyses in these directives varies substantially. In some cases, the language in a statute or EO may limit its applicability to only those regulatory actions that exceed a specified threshold in significance or impact. To determine whether a regulatory action meets such a threshold and is covered by the statute or EO, the agency may need to conduct a brief economic analysis. Covered regulatory actions may be subject to additional requirements, such as:

- economic analysis (e.g., analysis of benefits and costs as required by EO 12866, “Regulatory Planning and Review”),
- procedural steps (e.g., consultation with affected state and local governments as required by EO 13132, “Federalism”) or
- a combination of both an economic analysis and procedural steps.

This chapter identifies the thresholds that trigger an economic analysis or additional procedural requirements for a regulatory action, summarizes the general requirements for economic analyses contained in selected statutes and EOs contingent on the thresholds and provides further direction for analysts seeking guidance on compliance with the statute or EO.¹ It also provides references to applicable Office of Management and Budget (OMB) and EPA guidelines for each EO or statute discussed. For further information about the type and scope of analysis required, the program’s Office of General Counsel (OGC) attorney is a good resource.² This chapter does not address provisions of the statutes and EOs that do not require economic analysis.

¹ Note that for some statutes and EOs, requirements for proposed regulatory actions may vary slightly from the requirements for final regulatory actions.

² For OGC’s reference guide on cross-cutting statutory and executive order reviews that may apply to rulemakings, see U.S. EPA (2003c, 2005a).

2.1 Executive Orders

2.1.1 Executive Order 12866,³ “Regulatory Planning and Review”

Threshold: Significant regulatory actions as defined by the EO. A “significant regulatory action” is defined by Section 3(f)(1)-(4) as any regulatory action that is likely to result in a rule that may:

- “Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities;
- 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 EO.”

EO 12866 does not distinguish between regulatory and deregulatory actions.⁴ Meeting one or more of the threshold criteria triggers the classification of a regulatory action as “significant.” OMB categorizes a regulatory action that meets the first criteria as “economically significant.”⁵ The determination of economic significance is multi-faceted. Rules that have an annual effect that meets the \$100 million threshold are deemed economically significant. This threshold is interpreted by OMB as being based on the annual costs, benefits or transfers of the proposed or finalized option in any one year.⁶

The word “or” is important: \$100 million in annual benefits, or costs or transfers is sufficient to meet the threshold.⁷ For example, suppose Congress passes a new law that requires the EPA to collect user fees from an industry that manufactures chemicals. The user fees will be used to defray the costs associated with an existing obligation for the EPA to conduct risk evaluations of new chemicals. Previously, the EPA’s costs to conduct these evaluations were provided by Congress through its annual congressional appropriation. This new rule requires the EPA to recoup these costs from industry. Assume that the fees to be collected from industry total \$120 million per year. In this case, no new burden is being placed on society. The \$120 million is simply a transfer of payments from businesses to government;⁸ however, because the transfer is more than \$100 million annually, this action is economically significant.

In addition, rules that “adversely affect in a material the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities” are also deemed economically significant. These criteria do not depend on the \$100 million threshold to trigger the “economically significant” designation. There are no fixed rules for interpreting this criterion. OMB offers an example: a regulation that would (1) impose \$98 million in first-year costs

3 EO 13563, “Improving Regulation and Regulatory Review,” issued in January 2011, supplements and reaffirms the provisions of EO 12866. It emphasizes the importance of reducing regulatory costs and burdens and maintaining flexibility and freedom of choice. See Section 2.1.7 in this chapter for more information on EO 13563.

4 See EO 13771 “Reducing Regulation and Controlling Regulatory Costs” for more information on deregulatory actions.

5 See OMB Circular A-4 (September 17, 2003).

6 See OMB (2011b), “Regulatory Impact Analysis: Frequently Asked Questions (FAQs),” p. 1, Question 1.

7 OMB explicitly clarified this in OMB (2011b), “Regulatory Impact Analysis: Frequently Asked Questions (FAQs),” p.1, Question 1.

8 See (OMB (2011b), “Regulatory Impact Analysis: A Primer.”

Table 2.1 - Overview of Executive Orders and Statutes

Executive Order/Statute	Economic Threshold*	Guidance/ Information Available
EO 12866, Regulatory Planning and Review (1993)	Specific	EPA, OMB
EO 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (1994)	General	EPA
EO 13045, Protection of Children from Environmental Health Risks and Safety Risks (1997)	Specific	EPA
EO 13132, Federalism (1999)	Specific	EPA
EO 13175, Consultation and Coordination with Indian Tribal Governments (2000)	General	EPA, OMB
EO 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (2001)	Specific	OMB
EO 13563, Improving Regulation and Regulatory Review (2011)	Specific	OMB
EO 13707, Using Behavioral Science Insights to Better Serve the American People (2015)	General	White House Memo
EO 13771, Reducing Regulation and Controlling Regulatory Costs (2017)	Specific	OMB
EO 13777, Enforcing the Regulatory Reform Agenda (2017)	General	OMB
EO 13783, Promoting Energy Independence and Economic Growth (2017)	General	OMB
EO 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents (2019)	Specific	OMB
Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)	Specific	EPA
Unfunded Mandates Reform Act of 1995 (UMRA)	Specific	EPA, OMB
Paperwork Reduction Act of 1995 (PRA)	Specific	EPA, OMB
The Foundations for Evidence-Based Policymaking Act of 2018	None	OMB

* Economic Threshold: "Specific" if EO or statute provides specific numeric threshold or detailed criteria; "General" if EO or statute provides only general description or statement.

for pollution control equipment, with lower annual costs thereafter, (2) disproportionately and adversely affect a small sector of the economy and (3) threaten to create significant job loss, would be considered economically significant.⁹

It is important to note that meeting the \$100 million threshold can include consideration of unquantified effects as well as quantified effects. There may be impacts that are unquantified due to lack of data or valuation methods, but if the judgement of the EPA and OMB is that the combined quantified and unquantified effects are likely to exceed \$100 million, the regulation would be considered economically significant.

In practice, while the threshold for economic significance is important, the level of analysis is somewhat of a continuum; OMB clarifies, “The level of detail in the analysis can vary with the expected effects of the rule...”¹⁰

EO 12866 does not provide for or adjust the \$100 million threshold for inflation.¹¹ As such, nominal values have been used in practice, implying that as inflation increases, the threshold becomes more stringent. OMB has applied the economic significance trigger using current dollars.¹²

Requirements contingent on threshold: Regulatory actions designated “significant” are subject to EO 12866 review by OMB. The process of making this determination is discussed in “EPA’s Action Development Process: Guidance for EPA Staff on Developing Quality Actions.”¹³ For all significant regulatory actions, the agency shall provide to OMB a statement of the need for the proposed action and an assessment of potential benefits and costs (Section 6(a)(3)(B)). The requirements for the analysis of benefits and costs increase in complexity and detail for economically significant rules (i.e., those that fall under the definition in the first bullet above). For these rules, the EO requires that in addition to assessing potential costs and benefits, agencies must include the underlying analysis informing that assessment, quantify benefits and costs to the extent feasible, assess the benefits and costs of potentially effective and reasonably feasible alternative approaches and provide the underlying analysis of that alternatives assessment (Section 6(a)(3)(C)).¹⁴ OMB’s Circular A-4 (discussed below) states that analysts should generally analyze at least three options: the proposed or finalized option; a more stringent option; and a less stringent one.¹⁵

Guidance: OMB’s Circular A-4 (2003) provides guidance to federal agencies on the development of regulatory analysis of economically significant rules as required by EO 12866. More specifically, Circular A-4 is intended to define good regulatory analysis and standardize the way benefits and costs of federal regulatory actions are measured and reported. Parts of Circular A-4 guidance are standardized. For example, agencies are asked to provide a clear executive summary of their central conclusions, including a prominent standardized accounting statement, with one or more tables summarizing costs and benefits (both quantitative and qualitative), and transfers, at both 3% and 7% discount rates.¹⁶ In other respects,

9 OMB (2011b), p. 1, Question 1.

10 OMB (2011b), p. 5, Question 8.

11 OMB (2011b), p. 2, Question 1.

12 Circular A-4 states that all costs and benefits should be reported in 2001 dollars, but most economic analyses report results in a more recent base year. OMB states that you should use the gross domestic product (GDP) deflator to convert dollars to a different year. The Annual OMB Report to Congress on Benefits and Costs of Federal Regulations began to report estimates in both 2001 and 2010 dollars in the 2014 report. See OMB (2003) and OMB (2015).

13 EPA’s Action Development Process Guidance for EPA Staff on Developing Quality Actions, U.S. EPA (2018).

14 EO 13422 and amended EO 12866 formerly required analysts to “identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem” and extended the benefit-cost analysis (BCA) requirement to “significant” guidance documents. Although EO 13497, issued in January 2009, revoked EO 13422 together with any “orders, rules, regulations, guidelines or policies” enforcing it, a subsequent memo issued by then Director of OMB Peter R. Orszag offering guidance on the implementation of the new EO indicated that “significant policy and guidance documents ... remain subject to Office of Information and Regulatory Affairs’ (OIRA’s) review.”

15 See Section E “Identifying and Measuring Benefits and Costs; 3. Evaluation of Alternatives” of OMB Circular A-4 (September 17, 2003).

16 See Chapter 11 of this document, Presentation of Analysis and Results, for agency guidance on presenting economic analysis results.

OMB has stated that “[t]he level of detail in the analysis can vary with the expected effects of the rule; you should use more rigorous analytical approaches, and more comprehensive sensitivity analysis, for rules with especially large consequences.”¹⁷ To help clarify the requirements of EO 12866 and the guidance in Circular A-4, OMB has also issued supplemental references on regulatory analyses for agencies.¹⁸

The *Guidelines* provide more in-depth Agency guidance, building on the OMB’s guidance with a focus on approaches and methods that are relevant to environmental regulations. Chapters 3 through 8 of this document provide more detailed guidance for meeting the EO 12866 benefit-cost analysis requirements, consistent with provisions in OMB’s Circular A-4. Chapters 9 and 10 provide guidance on addressing distributional effects of environmental regulation, with a focus on economic impact analysis examining compliance costs effects (e.g., profitability, employment, prices) in Chapter 9 and on environmental justice and life stage considerations in Chapter 10.¹⁹

2.1.2 Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations”

Threshold: No specific threshold; agencies are directed to “...identify and address disproportionately high and adverse human health or environmental effects of its programs, policies and activities [including rulemaking] on minority populations and low-income populations...”

Requirements contingent on threshold: No specific analytical requirements in the EO. However, a presidential memorandum that accompanied EO 12898 directed federal agencies to analyze environmental effects of federal actions, including human health, economic and social effects.

Guidance: The EPA’s “Technical Guidance for Assessing Environmental Justice in Regulatory Analysis” (U.S. EPA 2016) is designed to help EPA analysts understand how to evaluate potential environmental justice (EJ) concerns associated with EPA regulatory actions. The Agency also has guidance for considering environmental justice in the Action Development Process (U.S. EPA 2010) which provides direction on when EJ should be considered during rulemaking. The EPA and the Council on Environmental Quality (CEQ) have prepared guidance for addressing environmental justice concerns in the context of National Environmental Policy Act (NEPA) requirements [U.S. EPA (1998a) and CEQ (1997)]. These materials provide guidance on key terms in the EO. Chapter 10 of this document addresses environmental justice analysis, including guidance on consideration of relevant benefits and costs when evaluating impacts on these specific populations.

2.1.3 Executive Order 13045, “Protection of Children from Environmental Health Risks and Safety Risks”

Threshold: Economically significant regulatory actions as described by EO 12866 that involve environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.

¹⁷ OMB (2011b), p. 5, Question 8.

¹⁸ The supplemental OMB references are:

- 2010 Agency Checklist for Regulatory Impact Analyses (RIAs) (OMB 2010a).
- 2011 FAQ on Regulatory Analysis (OMB 2011b).
- 2011 Primer on RIAs per Circular A-4 (OMB 2011c).
- 2012 statement to clarify what should go in Executive Summaries for RIAs with a suggested template; “Clarifying Regulatory Requirements: Executive Summaries.” Memorandum for the Heads of Executive Departments and Agencies. (OMB 2012).

¹⁹ In its Statement of Regulatory Philosophy, EO 12866 states that agencies should consider the distributional and equity effects of a rule (Section 1(a)).

Requirements contingent on threshold: An evaluation of the health or safety effects of the planned regulation on children. The agency shall also provide an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives the agency is considering.

Guidance: The EPA has prepared guidance to assist EPA staff on the implementation of EO 13045 (U.S. EPA 2006b). The EPA's Children's Health Valuation Handbook (U.S. EPA 2003b) discusses special issues related to estimation of the value of health risk reductions to children. The Office of Children's Health Protection also provides online information with links to resource materials on guidance and tools.²⁰ Guidance in Chapter 10 of this document addresses analyses of impacts on children.

2.1.4 Executive Order 13132, "Federalism"

Threshold: Rules that have "federalism implications" that either impose substantial compliance costs on state and local governments or preempt state or local law. According to EPA policy, rules are considered to impose substantial compliance costs if:

- the action is likely to result in the expenditure by state and local governments, in the aggregate, of \$25 million or more in any one year; or
- the action is likely to result in expenditures by small governments that equal or exceed 1% of their annual revenues.²¹

Exception: An action that imposes substantial compliance costs (meets the \$25 million threshold or the 1% test) does not have a federalism implication if: (1) the action is expressly required by statute (without any discretion by the EPA); or (2) there are federal funds available to cover the compliance costs.

Requirements contingent on threshold: Actions with federalism implications require pre-proposal consultation with elected state/local officials or their representative national organizations. Rules must include a Federalism Summary Impact Statement in the preamble, and a signed Federalism Certification from the Agency's designated official should be provided to OMB along with any written communications that the EPA received from state or local officials.

Guidance: Specific guidance on EO 13132 can be found in the internal EPA document "Guidance on Executive Order 13132: Federalism" (U.S. EPA 2008c).²²

2.1.5 Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments"

Threshold: Regulations that have substantial direct effects on one or more American Indian tribes, on the relationship between the federal government and tribes, or on the distribution of power and responsibilities between the federal government and tribes and that: (1) impose substantial direct compliance costs on Indian tribal governments that are not required by statute, or (2) preempt tribal law.

Requirements contingent on threshold: To the extent practicable and permitted by law, the Agency must either provide the funds necessary to pay the tribal governments' direct compliance costs, if applicable, or prior to the formal promulgation of the regulation, consult with tribal officials early in the process of developing the proposed regulation and include in the preamble of the regulation a Tribal Summary Impact

20 See <https://www.epa.gov/children/guidance-tools-and-glossary-key-terms> (accessed January 8, 2021).

21 U.S. EPA (2008c). Internal EPA document located at <http://intranet.epa.gov/actiondp/documents/federalismguide11-00-08.pdf> (accessed January 8, 2021).

22 U.S. EPA (2008c).

Statement. The Statement must include a description of the extent of the Agency’s prior consultation with tribal governments; a summary of the nature of the tribe’s concerns and the agency’s position supporting the need to issue the regulation; and a statement of the extent to which the concerns of tribal governments have been met.

Guidance: OMB issued Guidance for Implementing EO 13175 in 2010, to provide direction for compliance and documentation.²³ The EPA issued Policy on Consultation and Coordination with Indian Tribes (2011) to establish national guidelines and institutional controls for consultation across the EPA. This policy states, “EPA’s policy is to consult on a government-to-government basis with federally recognized tribal governments when EPA actions and decisions may affect tribal interests” [emphasis added].²⁴ Chapter 10 of this document addresses distributional analyses focusing on minority, low-income and Indigenous populations.

2.1.6 Executive Order 13211, “Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use”

Threshold: Rules that are significant regulatory actions under EO 12866 and that are likely to have significant adverse effects on the supply, distribution or use of energy.

Requirements contingent on threshold: Submission of a detailed Statement of Energy Effects to OMB. The Statement of Energy Effects must address any expected adverse effects on energy supply, distribution or use, the reasonable alternatives to the action, and the expected effects of such alternatives on energy supply, distribution and use.

Guidance: OMB has guidance for implementing EO 13211.²⁵

2.1.7 Executive Order 13563, “Improving Regulation and Regulatory Review”

Threshold: Significant regulatory actions under EO 12866 (reaffirms EO 12866 and adds additional requirements).²⁶

Requirements contingent on threshold: As mentioned, EO 13563 supplements and reaffirms the provisions of EO 12866. EO 13563 states, “Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.” It emphasizes the importance of reducing regulatory costs and burdens and maintaining flexibility and freedom of choice. The EO highlights the importance of scientific integrity, and retrospective analyses of existing rules.

Among other requirements, agencies must use best available techniques to quantify costs and benefits, give the public meaningful opportunity to comment online, include relevant scientific and technical findings in the rulemaking docket, consider the combined effects of their regulations on particular sectors and industries and promote coordination across agencies. Agencies are required to develop plans for retrospective review of significant rules. Per OMB guidance, agencies are particularly encouraged to identify

23 See OMB’s Guidance for Implementing E.O. 13175, OMB (2010b).

24 U.S. EPA (2011a), p. 1.

25 See OMB’s guidance for implementing EO 13211, OMB (2001).

26 See OMB’s guidance memo for implementing EO 13563, OMB (2011a).

actions for review that will significantly reduce existing regulatory burdens and promote economic growth and job creation. Chapter 5 includes a discussion of retrospective review and analysis; see Text Box 5.1 on Retrospective Analysis.

Guidance: OMB issued implementation guidance in three memos: M-11-10 February 2, 2011; M-11-19 April 25, 2011; M-11-25 June 14, 2011.²⁷

2.1.8 Executive Order 13707, “Using Behavioral Science Insights to Better Serve the American People”

Threshold: No specific threshold; the EO encourages agencies to “identify policies, programs, and operations where applying behavioral science insights may yield substantial improvements in public welfare, program outcomes, and program cost effectiveness...”

Requirements contingent on threshold: Agencies are encouraged to use behavioral science insights when designing policies and specifically when determining access to programs, presenting information to the public, structuring choices within programs and designing incentives.

Guidance: The White House Social and Behavioral Sciences Team issued implementation guidance in a memo on September 15, 2016.²⁸ Chapter 4 of this document includes a discussion of behavioral responses.

2.1.9 Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs”

Threshold: OMB Guidance defines an EO 13771 regulatory action as “a significant regulatory action as defined in Section 3(f) of EO 12866 that has been finalized and that imposes total costs greater than zero;” and defines an EO 13771 deregulatory action [as] “an action that has been finalized and has total costs less than zero.”²⁹

Requirements contingent on threshold: For every new EO 13771 regulatory action proposed, the agency must identify at least two prior regulations to be repealed. The agency must also offset any incremental costs associated with the new regulation in order to meet a cost allowance set by OMB each fiscal year. Agencies are directed to calculate the present value (as of 2016) of costs for EO 13771 regulatory actions and cost savings for EO 13771 deregulatory actions over the full duration of the expected effects of the actions using both 3% and 7% end-of-period discount rates.³⁰

Guidance: OMB issued guidance on implementing the EO on April 5, 2017, in the form of Questions and Answers for agencies as well as interim guidance for implementing the EO on February 2, 2017.³¹ The guidance notes that EO 12866 remains the primary governing EO regarding regulatory planning and review.

²⁷ See EO 13563 and implementation guidance.

²⁸ Executive Office of the President, Office of Science and Technology Policy. 2016. “Implementation Guidance for Executive Order 13707: Using Behavioral Science.” Memorandum for the Heads of Executive Departments and Agencies.

²⁹ See OMB (2017b); “Guidance Implementing Executive Order 13771, Titled ‘Reducing Regulation and Controlling Regulatory Costs.’” Memorandum for Regulatory Policy Officers. OMB (2017).

³⁰ OMB (2017b), p. 11, Question 25.

³¹ OMB (2017a and 2017b); The interim guidance (2017a) issued in February 2017 supplements the April 2017 guidance from OMB.

OMB's guidance also notes that agencies may proceed with significant regulatory actions that need to be finalized in order to comply with an imminent statutory or judicial deadline even if they are not able to identify offsetting regulatory actions by the time of issuance but must subsequently identify other regulations to be repealed to meet the requirements of the EO.³²

2.1.9 Executive Order 13777, “Enforcing the Regulatory Reform Agenda”

Threshold: No specific threshold; agency's Regulatory Reform Task Force is charged with making recommendations to agency head on repeal, replacement or modification of existing rules.

Requirements contingent on threshold: To make recommendations, the Task Force is to evaluate existing regulations to identify those that, among other things, “(i) eliminate jobs, or inhibit job creation; (ii) are outdated, unnecessary, or ineffective” or “(iii) impose costs that exceed benefits.”

Guidance: OMB issued a guidance memo on regulatory reform accountability on April 28, 2017.³³ The memo states that “agencies should establish and report other meaningful performance indicators and goals for the purpose of evaluating and improving the net benefits of their respective regulatory programs (i.e., all of the existing regulations in place that address a specific regulatory objective).” See also Chapter 9 of this document for a discussion of analysis of economic impacts.

2.1.10 Executive Order 13783, “Promoting Energy Independence and Economic Growth” (Sections 1 and 2)

Threshold: All existing regulations, orders, guidance documents, policies and any other similar agency actions (collectively, agency actions) that potentially burden the development or use of domestically produced energy resources, with particular attention to oil, natural gas, coal and nuclear energy resources.

Requirements contingent on threshold: Agencies are to develop and submit a review plan to OMB and CEQ, conduct the required review and issue a report which “shall include specific recommendations that, to the extent permitted by law, could alleviate or eliminate aspects of agency actions that burden domestic energy production.”

Guidance: OMB issued guidance for Section 2 of the EO which covers review of actions that “potentially burden the safe, efficient development of domestic energy resources.”³⁴ The review should include “any quantitative analysis (e.g., costs, lost production) the agency plans to perform,” and the report should include “preliminary estimates by agency action of the costs and cost savings, increased production, or other beneficial effects, that may be achieved by implementing each recommended action,” using the guidance for EO 13771 and Circular A-4.

2.1.11 Executive Order 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents”

Threshold: According to OMB, “[a]n analysis is required for any guidance document that may bring about \$100 million in benefits, costs, or transfer impacts in at least one year (i.e., in one consecutive 12-month period), or that otherwise qualifies as economically significant under Executive Order 12866.” OMB

³² OMB (2017a), p. 5.

³³ OMB (2017c).

³⁴ OMB (2017d).

guidance further provides that, in determining whether a guidance document is significant, agencies should provide at least the same level of analysis that would be required for a major determination under the Congressional Review Act.

Requirements contingent on threshold: Agencies are to conduct a Regulatory Impact Analysis for economically significant guidance documents of the sort that would accompany an economically significant rulemaking, to the extent reasonably possible. In addition, agencies are to explain how the guidance document maximizes net benefits and any alternatives considered.

Guidance: OMB issued a guidance memo on October 31, 2019 (OMB 2019). The RIA for a significant guidance document should generally follow the principles of Circular A-4, although there may be some differences in estimating behavior change due to the non-binding nature of guidance and in considering baseline considerations. The memo also discusses the definition of guidance document, waivers and exemptions.

2.2 Statutes

2.2.1 Regulatory Flexibility Act of 1980 (RFA), as Amended by The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601-612)

Threshold: Regulations that may have a “significant economic impact on a substantial number of small entities,” (SISNOSE), including small businesses, governments and non-profit organizations. The RFA does not define the terms significant or substantial.

Requirements contingent on threshold: For rules that are expected to have a SISNOSE, agencies are required to prepare an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) examining potential adverse economic impacts on small entities and complying with a number of procedural requirements to solicit and consider flexible regulatory options that minimize adverse economic impacts on small entities and address significant issues raised in public comments. The IRFA and FRFA are published with the proposed and final rules, respectively,

Guidance: The EPA has issued specific guidance for complying with RFA/SBREFA requirements in the “EPA Final Guidance for EPA Rulewriters: Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act” (U.S. EPA 2006e). See also Chapter 9 of this document on economic impact analysis.

The guidance offers approaches for determining whether a specific rule may have a SISNOSE but provides flexibility to use alternative methods or reach different conclusions where appropriate in the context of a specific rule.

2.2.2 Unfunded Mandates Reform Act of 1995 (UMRA) (P.L. 104-4)

Threshold one (Sections 202 and 205 of UMRA): Regulatory actions that include federal mandates “that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.”³⁵ An action contains a federal mandate if it imposes an enforceable duty on state, local or tribal governments or the private sector.

³⁵ Note that the threshold in this case is “adjusted annually for inflation,” as opposed to the threshold under EO 12866.

Requirements contingent on threshold one: Section 202 of UMRA requires preparation of a written statement that includes the legal authority for the action; a BCA; a distributional analysis; estimates of macroeconomic impacts; a description of an agency's pre-proposal consultation with elected representatives of the affected state, local or tribal governments; and a summary of concerns raised and how they were addressed. Section 205 of UMRA requires an agency to consider a reasonable number of regulatory alternatives and select the least costly, most cost-effective or least burdensome alternative, or to publish with the final rule an explanation from the agency head of why such alternative was not chosen.

Per OMB's Circular A-4, the analytical requirements under EO 12866 are similar to the analytical requirements under Sections 202 and 205 of UMRA, and thus the same analysis may permit compliance with both analytical requirements.

Threshold two (Section 203 of UMRA): Regulatory requirements that might "significantly" or "uniquely" affect small governments. Small governments include governments of cities, counties, towns, townships, villages, school districts or special districts with a population of less than 50,000.

Requirements contingent on threshold two: Agencies must solicit involvement from, and conduct outreach to, potentially affected elected officers of small governments (or their designated employees) during development and implementation.

Guidance: The EPA has issued "Interim Guidance on the Unfunded Mandates Reform Act of 1995" (1995), and OMB issued a memo on "Guidance for Implementing Title II of S.1" that provides general guidance on complying with requirements contingent on each of the two thresholds under UMRA (U.S. EPA 1995; OMB 1995).

2.2.3 The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501)

Threshold: Any action that includes record-keeping, reporting or disclosure requirements or other information collection activities calling for answers to questions seeking the same information imposed upon or posed to 10 or more persons, other than federal agency employees.³⁶

Requirements contingent on threshold: The agency must submit an information collection request (ICR) to OMB for review and approval and meet other procedural requirements including public notice. The ICR should: (1) describe the information to be collected, (2) give the reason the information is needed and (3) estimate the time and cost for the public to answer the request.

Guidance: Both guidance and templates for completing an ICR and associated Federal Register (FR) notices can be found on the EPA's intranet site, "ICR Center."³⁷

2.2.4 The Foundations for Evidence-Based Policymaking Act of 2018 (Public Law No: 115-435)

Threshold: No specific threshold.

³⁶ Note that Section 1320.3(c)(4)(ii) states that "any collection of information addressed to all or a substantial majority of an industry is presumed to involve ten or more persons." However, OMB guidance on this issue indicates that if agencies have evidence showing that this presumption is incorrect in a specific situation (i.e., fewer than 10 persons would be surveyed), the agency may proceed with the collection without seeking OMB approval. Agencies must be prepared to provide this evidence to OMB on request and abide by OMB's determination as to whether the collection of information ultimately requires OMB approval.

³⁷ See <http://intranet.epa.gov/icrintra/> (accessed January 8, 2021, internal EPA document).

Requirements contingent on threshold: The Foundations for Evidence-Based Policymaking Act of 2018 (“Evidence Act”), statutorily mandates federal evidence-building activities, where evidence is broadly defined and includes foundational fact finding, performance measurement, policy analysis and program evaluation (OMB M19-23). The act does not specify what evidence-building activities agencies should conduct but instead calls on agencies to significantly rethink how they currently plan and organize evidence building, data management and data access functions to ensure they have the evidence they need for informed decision making. Prospective and retrospective economic analyses of agency programs and regulations are evidence-building activities under the Evidence Act and data used or produced in economic analyses may be subject to Title II of the Evidence Act (the Open Government Data Act), including the requirement of being open by default.

Guidance: In July 2019, OMB issued a memorandum on Phase 1 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Learning Agendas, Personnel and Planning Guidance. OMB notes that in their annual evaluation plans, “agencies should also discuss any evaluation activities that relate to its proposed regulatory actions in the Unified Agenda of Federal Regulatory and Deregulatory Actions, recognizing that these activities often need to occur well before the development of economically significant regulatory actions” (OMB M19-23).