On April 6, 2023, the President issued an Executive Order (E.O.) entitled “Modernizing Regulatory Review” (hereinafter, the Modernizing E.O.). The Modernizing E.O. advances the implementation of the Presidential Memorandum of January 20, 2021 (hereinafter, Presidential Memorandum), setting forth specific actions for Federal agencies and the Office of Information and Regulatory Affairs (OIRA) designed to modernize the regulatory process in order to advance policies that promote the public interest and address national priorities. The Modernizing E.O., among other things, amends Section 3(f)(1) of E.O. 12866 (Regulatory Planning and Review) to increase the monetary threshold for significance under that provision, amends Section 3(f)(4) to clarify what is significant under that provision, and encourages greater public participation during all stages of the regulatory process.

To assist agencies in their implementation of the Modernizing E.O., OIRA is issuing this Memorandum. OIRA has also prepared separate guidance pursuant to Section 2(e) of the Modernizing E.O. with respect to meetings requested by the public regarding the review of rules under E.O. 12866, for which OIRA is requesting public comment.¹

A. General

1. When does the Modernizing E.O. take effect?

   The Modernizing E.O. became effective when it was signed by the President on April 6, 2023.

2. How does the Modernizing E.O. advance implementation of the Presidential Memorandum?

   The Presidential Memorandum calls for the Director of the Office of Management and Budget (OMB), in consultation with agencies, to produce a set of recommendations for improving and modernizing regulatory review.² The Modernizing E.O. advances the implementation of that Memorandum in several ways. For example, the E.O.:

¹ That separate guidance is currently available for a 60-day public comment at Regulations.gov at the docket OMB-2022-0011.
• requires the OMB Director, through the OIRA Administrator, to issue revisions to OMB’s Circular A-4—as called for in the Presidential Memorandum—by April 6, 2024;

• reaffirms the principles governing regulatory review as set forth in E.O. 12866 (Regulatory Planning and Review) and E.O. 13563 (Improving Regulation and Regulatory Review), including that regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law, as contemplated by those Executive Orders and the Presidential Memorandum;

• calls for agencies to proactively engage interested or affected parties in order to inform the development of regulatory agendas and plans, which will facilitate OIRA taking “a more proactive role” in “partnering with agencies to explore, promote, and undertake regulatory initiatives that are likely to yield significant benefits”, and

• identifies reforms to reduce the risk or appearance of disparate and undue influence of outside parties who initiate a request to meet with OIRA about a regulatory action under OIRA review, which will help “promote the efficiency, transparency, and inclusiveness of the interagency review process.”

B. Improving the Effectiveness of the Regulatory Review Process (Modernizing E.O. Section 1)

1. When are regulatory actions significant under E.O. 12866 Section 3(f)(1)’s monetary threshold, as amended?

   If a regulatory action is otherwise subject to E.O. 12866 and the action’s likely effects—benefits, costs, or transfers—may be at least $200 million (adjusted for changes in nominal gross domestic product every 3 years) in at least one year, then the action is significant under Section 3(f)(1) of E.O. 12866, as amended by the Modernizing E.O. The word “or” in the previous phrase, “benefits, costs, or transfers,” is important: $200 million in annual benefits, or costs, or

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3 See id. § 2(b)(i), 86 Fed. Reg. at 7223 (calling for recommendations that “identify ways to modernize and improve the regulatory review process, including through revisions to OMB’s Circular A-4, Regulatory Analysis, 68 Fed. Reg. 58,366 (Oct. 9, 2003), to ensure that the review process promotes policies that reflect new developments in scientific and economic understanding, fully accounts for regulatory benefits that are difficult or impossible to quantify, and does not have harmful anti-regulatory or deregulatory effects”).

4 Id. § 2(b)(ii), 86 Fed. Reg. at 7223 (calling for recommendations that “propose procedures that take into account the distributional consequences of regulations, including as part of any quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities”); see Executive Order No. 12866, Regulatory Planning and Review § 1(b)(5), 58 Fed. Reg. 51,735, 51,736 (Oct. 4, 1993) (“In [designing its regulations], each agency shall consider . . . distributive impacts[] and equity.”); Executive Order No. 13563, Improving Regulation and Regulatory Review § 1(c), 76 Fed. Reg. 3821, 3821 (Jan. 21, 2011) (“Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity . . . and distributive impacts.”).


transfers is sufficient to make an action significant under Section 3(f)(1) (adjusted for threshold updates), consistent with practice to date. But $120 million in benefits and $120 million in costs, for example, is not sufficient, standing alone, to make an action significant under Section 3(f)(1).

Relatively, the threshold is measured in terms of gross, rather than net, effects. If an action, for example, had $250 million in benefits and $100 million in costs, for a net benefit of $150 million, it would still be significant under Section 3(f)(1) at the current threshold because there is a category of gross effect (benefits) exceeding $200 million. Consequential effects that may seem “indirect” or “ancillary” are relevant to this threshold determination. The potential importance of effects that are non-monetized is also relevant to this threshold determination. This threshold applies to all regulatory actions subject to E.O. 12866, including regulatory actions repealing or modifying existing regulatory actions.

Many regulatory actions will still continue to be significant under Section 3(f)(1); however, as a result of the amended threshold, fewer regulatory actions will be reviewed by OIRA under this section and fewer analyses will be required under E.O. 12866 Section 6(a)(3)(C). The threshold, which has not been changed since E.O. 12866 was promulgated in 1993, was amended to enable OIRA and agencies to prioritize their analytical resources more effectively.

While rules designated as meeting the monetary threshold under E.O. 12866 Section 3(f)(1) have often in the past been referred to as “economically significant,” going forward, the term “significant under Section 3(f)(1)” should be used, as it is more precise.\(^7\)

2. Have any changes been made to the factors in E.O. 12866 Section 3(f)(1) besides the monetary threshold?

In addition to the change in monetary threshold, the word “territorial” has been added to the list of potentially adversely affected groups or entities to be considered when determining whether a regulatory action is significant under Section 3(f)(1). Under E.O. 12866 Section 3(f)(1) as amended, a regulatory action can be significant if it is likely to result in a rule that may “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, territorial, or tribal governments or communities” (emphasis added). Territorial governments and communities include Puerto Rico, the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. The addition of “territorial” is considered a clarification, rather than a substantive change. Agencies and OIRA have long considered the impacts to territorial governments and communities in determinations of significance under Section 3(f)(1). Besides the revisions to the

\(^7\) Note that “significance” under Section 3(f)(1), as amended, consists of a number of sufficient criteria, including the monetary threshold. For example, a regulatory action can also be significant under Section 3(f)(1), as amended, if it is likely to result in a rule that may “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, territorial, or tribal governments or communities.” As discussed in the answer to Question B.2 below, the only text that has changed in the aforementioned clause is the addition of the word “territorial,” which is intended only as a clarifying edit. The remaining terminology and its application otherwise remain the same.
monetary threshold and the addition of the word “territorial,” the remaining criteria in Section 3(f)(1), as amended, otherwise remain the same in terminology and application.

3. What happens if my agency’s current regulatory action was designated as significant under Section 3(f)(1), but would no longer be, following an update to the monetary threshold?

In general, the new threshold applies to all regulatory actions, whether proposed, interim, or final, submitted to OIRA for review after the issuance of the Modernizing E.O. If, prior to the date of this order, you have submitted for review a non-final action, such as a proposed or interim rule, you should anticipate that significance under Section 3(f)(1) will be subject to reconsideration by OIRA upon submission of subsequent actions, such as a final rule. There will be instances in which a final rule does not receive a designation of significant under Section 3(f)(1) even if the earlier proposed or interim final rule was significant under the previous Section 3(f)(1)’s monetary threshold, and even though estimates (and more general assessments) of regulatory effects are unchanged. In these narrow circumstances, during this transition period, agencies should consult with OIRA and their offices of general counsel regarding any changes in the analytic content of their rulemaking packages.

4. Does the monetary threshold under E.O. 12866 Section 3(f)(1), as amended, affect regulatory designations under the Congressional Review Act (CRA)?

No. The new monetary threshold is specific to E.O. 12866, as amended by the Modernizing E.O., and has no effect on the statutory threshold for a “major rule” as that term is defined in the CRA. If any benefit, cost, or transfer estimate is at least $100 million in at least one year, OIRA will designate the associated rule as meeting the definition set forth in 5 U.S.C. § 804(2)(A). The term “major rule” as defined in the CRA is distinct from the definition of “significant regulatory action” under E.O. 12866 Section 3(f)(1), as amended.

5. Does the monetary threshold under E.O. 12866 Section 3(f)(1), as amended, affect agency obligations under the Unfunded Mandates Reform Act of 1995 (UMRA)?

No. The new monetary threshold is specific to E.O. 12866, as amended by the Modernizing E.O., and has no effect on agency obligations under UMRA. Title II of UMRA specifies analyses and consultations that agencies must undertake for “any general notice of proposed rulemaking” or “any final rule for which a general notice of proposed rulemaking was published” that includes “any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.” Agencies should continue to follow the

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9 See id.
UMRA-related directives set forth in OMB M-95-09, “Guidance for Implementing Title II of S.1.”

6. **How will the monetary threshold under E.O. 12866 Section 3(f)(1), as amended, be updated and where can information on the current threshold be found?**

The monetary threshold will be adjusted for changes in U.S. nominal gross domestic product (GDP), as estimated by the U.S. Bureau of Economic Analysis, every 3 years by the Administrator of OIRA. Regular updates will help enable OIRA and agencies to prioritize their analytical resources effectively. The first adjustment will occur in 2026, reflecting GDP in 2025, and further adjustments will take place every 3 years after that. These adjustments will account for real growth (or reduction) in GDP as well as growth (or reduction) in the GDP price deflator. The threshold will be adjusted from $200 million in proportion to GDP growth between 2022 and the calendar year preceding the update. For example, in 2029, the threshold will become $200 million multiplied by GDP in 2028 and divided by GDP in 2022 to ensure that the threshold increases by the same proportion that GDP increased over that time period. For ease of use, we currently plan to apply a rounding factor.

A memorandum explaining updates to the monetary threshold will be published in the *Federal Register*, as well as posted to the White House and OIRA websites, no later than June 1 in the year of scheduled updating.

7. **What other changes have been made to the criteria for a “significant regulatory action” under E.O. 12866 Section 3(f), as amended?**

While E.O. 12866 Sections 3(f)(2) and 3(f)(3) remain unchanged, there have been clarifying amendments made to Section 3(f)(4). Section 3(f)(4) previously provided that a “significant regulatory action” under E.O. 12866 included any regulatory action that was “likely to result in a rule that may . . . [r]aise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.” The terms “novel” and “arising out of,” however, required additional clarification. In addition, the term “legal mandates” is redundant given the reference to “legal issues.” Accordingly, these terms have been removed.

The new formulation of Section 3(f)(4) will improve the effectiveness of the regulatory review process. The amendments now clarify that this criterion is intended to cover regulatory actions that “raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this Executive order.” E.O. 12866 Section 6 specifies both the process and substance of centralized review. Section 6(a)(3)(B) makes clear that whether a regulatory action is “significant” under Section 3(f)(1)–(4) is “determined” by the Administrator of OIRA, a provision that is unchanged. The amendments to Section 3(f)(4) further clarify that with respect to Section 3(f)(4), as amended, the Administrator of OIRA shall “specifically authorize[]” these determinations “in a timely manner . . . in each case” given that the Administrator is best positioned to identify the President’s priorities and interpret the relevant

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principles of E.O. 12866. If necessary, the Administrator may delegate the authority to make such determinations only to a senior policy official within OIRA. These amendments are intended to further enable OIRA and agencies to prioritize their analytical resources effectively. They are expected to lead to fewer regulatory actions that are deemed significant under E.O. 12866 Section 3(f)(4), as amended.

C. Affirmative Promotion of Inclusive Regulatory Policy and Public Participation (Modernizing E.O. Section 2)

1. How can public participation opportunities “be designed to promote equitable and meaningful participation by a range of interested or affected parties, including underserved communities”?

The regulatory process benefits from broad public participation by interested and affected parties, permitting agencies to consider a range of relevant views on regulatory actions. Agency public engagement aiming to broaden participation in the regulatory process could take into account the barriers to participation that individual communities may face—for instance, differences in language; differences in familiarity with or trust in government agencies and programs; disabilities; transportation, childcare, or work obligations; or lack of access to the internet. Agencies could also use strategies that build on existing, trusted channels of communications with these communities by, for instance, fostering collaboration with existing organizations that have a presence in local communities.

While not every approach will be appropriate for every regulatory action, strategies agencies might consider for encouraging broader and more equitable public participation in the regulatory process, to the extent practicable and appropriate, include:

- assessing for a particular regulatory action which parties might be interested or affected, and planning corresponding outreach that takes into account those parties’ distinctive needs and potential barriers to participation;

- ensuring that agency policies on communication and engagement during rulemaking facilitate equitable and meaningful participation in the agency’s existing regulatory process, including by considering revisions to those policies that affirm the importance of proactive agency outreach consistent with other relevant agency policies;

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12 Similarly, under Section 3(f)(4), the Administrator must specifically authorize, in each case, the request for additional information from an agency if such information is necessary for the Administrator to make the “significance” determination under Section 3(f)(4).

• conducting outreach through online or in-person public hearings, listening sessions, and other consultations, including by making use of local agency field offices, which can help agencies reach communities using locally appropriate means of communication, as well as by ensuring that agency programming is sensitive to potential barriers to engagement communities might face;

• ensuring that engagement provides sufficient context and background information on a regulatory action so members of the public can provide informed feedback to agencies;

• including easy-to-understand language and analysis in the regulatory action that informs interested or affected members of the public of the expected effects of the regulatory action that may impact them;

• using online and alternative platforms and media to reach affected communities to share information on agency activities and regulatory actions, including short videos, infographics, and mobile-friendly content;

• ensuring that methods used for stakeholder engagement be accessible, to allow equitable participation by people with disabilities;

• developing plain-language guides to rulemaking and participation in the notice-and-comment process;\(^{14}\)

• expanding the use of public engagement tools, including requests for information, early in the regulatory planning process;\(^{15}\) and

• coordinating with community or membership-based organizations working with interested or affected communities to provide communication and engagement opportunities that can build on existing relationships that those organizations hold, subject to applicable policies, regulations, and statutes.

OIRA will release additional guidance and tools for agencies to help them to expand public participation in the regulatory process. While OIRA will not review individual agency regulatory actions pursuant to Section 2(a) of the Modernizing E.O., note that E.O. 12866 Section 6(a) continues to provide that “[e]ach agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process.”\(^{16}\)


\(^{16}\) Executive Order No. 12866 § 6(a), 58 Fed. Reg. at 51,740.
2. Who are members of “underserved communities”?

As defined by E.O. 14091 (Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government), the term “underserved communities” refers to “those populations as well as geographic communities that have been systematically denied the opportunity to participate fully in aspects of economic, social, and civic life, as defined in Executive Orders 13985 and 14020.” As stated in E.O. 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government) and E.O. 14020 (Establishment of the White House Gender Policy Council), examples of individuals who may have been systematically denied the opportunity to participate fully in aspects of economic, social, and civic life include members of the following communities: Black, Latino, Indigenous and Native American, Asian American, Native Hawaiian, and Pacific Islander persons and other persons of color; members of religious minorities; women and girls; LGBTQI+ persons; persons with disabilities; persons who live in rural areas; persons who live in U.S. Territories; persons otherwise adversely affected by persistent poverty or inequality; and individuals who belong to multiple such communities.

Vulnerabilities are often heightened by geographic location; linguistic isolation; or lack of access to affordable housing, transportation, health care, and energy.

3. How can agencies “proactively engage interested or affected parties” to “inform the development of regulatory agendas and plans”?

Agencies should, as practicable and appropriate, identify opportunities to increase public engagement early in the regulatory process, including when they are still considering regulatory options and developing priorities. Engagement at this stage makes it easier for more parties to raise views and considerations and provides greater opportunity for agencies to communicate about possible agency activities. Proactive engagement—outreach initiated by agencies to ensure engagement with specific communities, taking into account the needs and contexts of those communities—can help ensure that agencies hear from all interested and affected parties, not just those parties familiar with the regulatory process, when setting regulatory priorities.

Some important public communication tools that agencies have are their regulatory agendas and plans. “Regulatory agendas” refer to agency entries in the Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda), published twice a year, which lists regulatory actions under development. “Regulatory plans” refer to agency entries in the Regulatory Plan, usually included in the Unified Agenda’s fall edition, which serves as a statement of an Administration’s regulatory policies and priorities. When developing regulatory priorities for the Unified Agenda and Regulatory Plan, agencies shall endeavor, as practicable and appropriate, to proactively engage with a broad and diverse set of individuals and organizations, including parties that are likely to have an interest in or be affected by the regulatory action as well as those from underserved communities. This engagement can help

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inform agencies’ understanding of regulatory needs or problems, selection of potential regulatory actions, and prioritization of regulatory actions. In addition, agencies should also consider exploring opportunities for using the Unified Agenda as a tool for greater public engagement after its publication so that communities that might be affected by proposed rulemakings understand the options that agencies are considering and their opportunities for further input. When conducting this outreach, agencies should consider ways of proactively engaging all interested and affected parties to ensure a more equitable distribution of feedback, as practicable and appropriate. Some of those strategies are discussed in the answer to Question C.1 above.

OIRA will be releasing additional guidance and tools for agencies to implement these provisions to expand public participation in the regulatory planning and priority-setting process, while balancing the continued need for timeliness of the overall process.

4. **How can agencies “clarify opportunities for interested persons to petition for the issuance, amendment, or repeal of a rule under 5 U.S.C. 553(e)”?**

Agencies can clarify steps in their petitioning process under 5 U.S.C. § 553(e), a provision of the Administrative Procedure Act (APA), in a number of ways. This may involve improvements to agency websites to clarify how to file petitions or how to optimize their usefulness. It may involve clarifying official procedures for handling petitions. It may also involve better disseminating information on agency points of contact for questions on the petition process. Petitioners and agency personnel alike may benefit from greater clarity as to, for example:

- how petitions can be filed;
- the types of data and other information that make a petition more useful and easier for the agency to evaluate; and
- how petitions relate to other options available to members of the public for engaging with agency personnel on the need to issue, amend, or repeal rules (such as comments, when invited, on the Unified Agenda or Regulatory Plan).

5. **How can agencies “endeavor to respond to such petitions efficiently, in light of agency judgments of available resources and priorities”?**

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19 In addition to the APA’s provision authorizing rulemaking petitions, agencies may have particular statutes that provide more specific petition processes for certain kinds of rules. This guidance focuses on procedures under the APA, though agencies should consider whether any of this guidance may also be appropriate and useful to implement in connection with any other statute-specific petition processes. And as part of their efforts to “clarify” the petition process generally, agencies should explain to the public the relationship between any statute-specific petition processes and the more general right to petition under the APA. Many of the suggestions in this guidance draw from recommendations on best practices for public petitions for rulemaking issued by the Administrative Conference of the United States. See Admin. Conf. of the U.S., Adoption of Recommendations, 79 Fed. Reg. 75,114, 75,117–19 (Dec. 17, 2014) (Recommendation 2014-6); Admin. Conf. of the U.S., Recommendations of the Administrative Conference Regarding Administrative Practice and Procedure, 51 Fed. Reg. 46,986, 46,988–89 (Dec. 30, 1986) (Recommendation 86-6).
Each agency should decide what processes are most efficient in its situation, as consistent with law. Those processes should not result in delays that are longer than necessitated by agency resource constraints, competing priorities, related policy decisions, the number of active petitions, and other relevant considerations.

Agencies can also create internal processes to facilitate prompt reviews. For example, agencies may designate a particular person or office to receive and distribute all petitions for rulemaking, to ensure that each petition for rulemaking is expeditiously directed to the appropriate agency personnel for consideration and disposition.

6. What is a “log of . . . petitions received” and by when should agencies consider creating and maintaining one?

As stated in the Modernizing E.O., agencies shall, to the extent practicable and consistent with applicable law, “maintain, subject to available resources, a log of such petitions received.” Given the many relevant differences among agencies in terms of resources, capacity, and competing priorities, the petition logs that agencies develop may be organized in different ways. One suggestion is for the log to include a listing of all petitions, the date on which each was received, and the date of disposition. Logs may facilitate agencies’ responses to any OIRA requests for information on recent and pending petitions (see below). Subject to available resources, agencies should try to create and maintain the summary log prospectively, in other words, referencing petitions received after the creation of the log. To the extent practicable, agencies could include all new and pending petitions.

If the agency decides to develop a log, it should determine a timeline for doing so, taking into account the availability of resources, competing priorities, and the benefits of timely development of the log. Once established, regular updates will help maintain continued usefulness; quarterly updates are a reasonable frequency to aim for, but agencies should set their own schedules for updating consistent with their resources and the volume of petitions they receive.

7. What additional information might OIRA request on recently resolved or pending petitions?

To help identify regulatory priorities and ensure consistency with the requirements of the Modernizing E.O., OIRA may request information from agencies on recent or pending petitions. In connection with agencies’ development of their annual regulatory plans, OIRA may, for example, collect general information about the status of petitions responded to in the last year or those that are still pending and the general reasons why.

8. What are “mass comments, computer-generated comments (such as those generated through artificial intelligence), and falsely attributed comments”?

Technological advances can help improve agency ability to process, analyze, and consider public comments. Distinct, but related, challenges can often arise as a result of mass, computer-generated, and falsely attributed comments, and some comments may fall in more than one of these categories. While OIRA, in consultation with relevant agencies, may revisit these definitions, those offered by the Administrative Conference of the United States are a useful
starting point. Mass comments are “comments submitted in large volumes by members of the public, including the organized submission of identical or substantively identical comments.”

Computer-generated comments are “comments whose substantive content has been generated by computer software rather than by humans,” including through the use of artificial intelligence.

Finally, falsely attributed comments are “comments attributed to people who did not submit them.”

D. Improving Regulatory Analysis (Modernizing E.O. Section 3)

1. What are “distributive impacts and equity” in the context of regulatory analysis?

Circular A-4 currently defines “distributional effect” as “the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography).” As directed by the Modernizing E.O., proposed revisions to Circular A-4 address how agencies can better analyze the distributional effects of regulatory actions under consideration and potential alternatives, as consistent with applicable law. As part of their effort to account for equity in regulatory actions, agencies should consider which populations, including underserved communities, might be affected by regulatory actions, and what barriers those communities face to benefitting from those regulatory actions. As defined in E.O. 14091, equity means “the consistent and systematic treatment of all individuals in a fair, just, and impartial manner, including individuals who belong to communities that have often been denied such treatment.”

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21 Id.
22 Id.