EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
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M-25-24

MEMORANDUM FOR: REGULATORY POLICY OFFICERS AT EXECUTIVE DEPARTMENTS AND AGENCIES AND MANAGING AND EXECUTIVE DIRECTORS OF CERTAIN AGENCIES AND COMMISSIONS

FROM: Jeffrey B. Clark, Acting Administrator
Office of Information and Regulatory Affairs

SUBJECT: Interim Guidance Implementing Section 3 of Executive Order 14215, Titled "Ensuring Accountability for All Agencies"

The entire "executive Power" belongs to the President alone. But because it would be "impossib[le]" for "one man" to "perform all the great business of the State," the Constitution assumes that lesser executive officers will "assist the supreme Magistrate in discharging the duties of his trust." 30 Writings of George Washington 334 (J. Fitzpatrick ed. 1939). These lesser officers must remain accountable to the President, whose authority they wield.
– *Seila L. LLC v. Consumer Fin. Prot. Bureau*, 591 U.S. 197, 213 (2020)

For the Federal Government to be truly accountable to the American people, officials who wield vast executive power must be supervised and controlled by the people's elected President. Therefore, in order to improve the administration of the executive branch and to increase regulatory officials' accountability to the American people, it shall be the policy of the executive branch to ensure Presidential supervision and control of the entire executive branch.
– Executive Order 14215, *Ensuring Accountability for All Agencies*

I. Introduction

A. Purpose

Interim Guidance Focused on EO 12866. This document provides initial implementation guidance for historically independent regulatory agencies to comply with the required regulatory provisions in Section 3. OIRA Review of Agency Regulations found in Executive Order 14215, *Ensuring Accountability for All Agencies* (EO 14215).[1] EO 12866 establishes clear regulatory principles and procedural requirements that agencies are directed to integrate into their rulemaking and administrative processes. This interim guidance clarifies independent regulatory agency obligations under EO 12866 and sets forth compliance expectations;

[1] Subsequent guidance to implement Section 4. Performance Standards and Management Objectives; Section 5. Apportionments for Independent Regulatory Agencies; and Section 6. Additional Consultation with the Executive Office of the President will be issued at a future date.

issuance of revised guidance is likely as OIRA and other relevant agencies gain experience with the implementation of EO 14215.

Centralized Review. EO 14215 seeks to ensure Presidential supervision of the Executive Branch. EO 14215 amends Executive Order 12866 (EO 12866), *Regulatory Planning and Review*, to include historically independent regulatory agencies. Pursuant to EO 12866 these agencies must now participate in centralized regulatory review led by the Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget. All agencies not explicitly exempted by EO 12866, as amended by EO 14215, are subject to the requirements of EO 12866, including submission of draft regulatory actions to OIRA prior to publication in the *Federal Register*.

B. Implementation Timeline

Agencies should adhere to the following implementation timeline:

Requirement	Deadline
Begin submitting significance determination requests for any regulatory action your agency will publish on or after April 21, 2025	On or after April 17, 2025
Identify Regulatory Policy Officer/Regulatory Second	On or before April 21, 2025
Begin full compliance with EO 12866	No later than April 21, 2025

C. Structure of this Guidance

This guidance is organized as follows:

- Section II – General Questions
- Section III - Scope
- Section IV – Centralized Review of Regulations
- Section V – Accountability and Transparency
- Section VI – Additional Guidance to Agencies
- Section VII – For Further Information

II. General Questions

Q1: What is EO 14215, and what does it require for regulation?
A: EO 14215 amends EO 12866 to require the submission of all stages (e.g., advanced notice of proposed rulemaking (ANPRMs), proposed (NPRMs) and final rules) of regulatory actions promulgated by independent regulatory agencies to OIRA for a

significance determination and potential EO 12866 review. If a regulatory action is deemed significant, EO 12866 review ensures compliance with the regulatory principles of EO 12866 and the priorities of the President. The EO 12866 process can include interagency review.

Q2. What are the objectives of EO 12866?
A: The objectives of EO 12866 include enhancing planning and coordination with respect to new and existing regulatory actions; making the regulatory process more accessible to the public; ensuring the regulatory decision-making process is consistent with Federal agencies' authorities and the priorities of the President; and limiting regulations, where consistent with statute, to those that provide net benefits to the American people.

Q3: What is the regulatory philosophy of EO 12866?
A: Federal agencies should promulgate only such regulatory actions as are required by law, are necessary to interpret the law, or are made necessary by compelling public 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.

Q4: How does cost-benefit analysis apply to the regulatory philosophy under EO 12866?
A: In deciding whether and how to regulate, to the extent permitted by law and where applicable, agencies should assess both the costs and benefits of an intended regulatory action, as well as available regulatory alternatives, including the alternative of not regulating. Analysis of costs and benefits should utilize the best reasonably available scientific, technical, economic, and other information. Further agencies' analysis submitted to OIRA should include both quantifiable measures and qualitative measures of costs and benefits that are difficult to measure. Additionally, in choosing among regulatory approaches, agencies should select those that maximize net benefits unless a statute requires otherwise. *See generally Michigan v. EPA*, 576 U.S. 743 (2015) (establishing as a general default rule that, as a basic feature of rational regulation, federal rulemaking must consider not just benefits but also regulatory costs).

Q5: What best practices does EO 12866 seek to promote?
A: A more detailed discussion of these best practices can be found in Section 1(b) of EO 12866. EO 12866 seeks to ensure that, among other things, when developing regulatory actions, agencies:

a) identify the problem the regulatory action seeks to address and its significance;
b) assess whether existing regulations created, or contributed to, the problem the new regulation intends to correct;
c) identify and assess available alternatives to direct regulatory action;
d) choose the regulatory approach, when regulation is necessary, that is most cost-effective to achieve the regulatory objective and safeguards innovation;

e) assess the costs and benefits of an action and propose or adopt a regulatory action upon a reasoned determination that the benefits of the intended regulatory action justify its costs;
f) base decisions on the best scientific, technical, economic and other information concerning the need for and consequences of the action;
g) seek and incorporate, as appropriate, the costs and benefits to state, local and tribal communities;
h) prevent the adoption of inconsistent, incompatible or duplicative regulations based upon the current regulatory landscape;
i) tailor any regulatory action to minimize the burden to society, including individuals, businesses of differing sizes, and other entities (including small communities and government entities); and
j) draft simple, plain language actions to minimize uncertainty and litigation risk.

III. Scope

Q6: What agencies are newly subject to EO 12866, as amended by EO 14215?
A: EO 14215 amends EO 12866's definition of an "agency" to read "any authority of the United States that is an 'agency' under 44 U.S.C. 3502(1), and shall also include the Federal Election Commission."[2] As a result, the Federal Election Commission and independent regulatory agencies are newly subject to EO 12866. Under 44 U.S.C. 3502(5), "independent regulatory agency" means the:

Board of Governors of the Federal Reserve System,[3]
Commodity Futures Trading Commission,
Consumer Product Safety Commission,
Federal Communications Commission,
Federal Deposit Insurance Corporation,
Federal Energy Regulatory Commission,
Federal Housing Finance Agency,
Federal Maritime Commission,
Federal Trade Commission,
Interstate Commerce Commission,
Mine Enforcement Safety and Health Review Commission,
National Labor Relations Board,
Nuclear Regulatory Commission,
Occupational Safety and Health Review Commission,
Postal Regulatory Commission,
Securities and Exchange Commission,
Bureau of Consumer Financial Protection,
Office of Financial Research,

[2] https://www.govinfo.gov/content/pkg/USCODE-2023-title44/pdf/USCODE-2023-title44-chap35-subchapI-sec3502.pdf
[3] Note, however, that EO 14215 exempts the Board of Governors of the Federal Reserve System and the Federal Open Market Committee in one key respect—those bodies' conduct of monetary policy. See Question 7 for more information about excepted agencies. However, the regulation of financial institutions by these bodies is covered by EO 14215.

Office of the Comptroller of the Currency, and
any other similar agency designated by statute as a Federal independent regulatory agency or commission.

With this amendment to the definition of the term "agency" in EO 12866, ***all agencies*** are subject to the requirements of EO 12866 unless otherwise explicitly exempt in EO 12866 or EO 14215 (as discussed in Question 7, below).

Q7: What is an "excepted" agency in EO 12866, as amended by EO 14215?
A: EO 14215 section 3(a) expressly excepts "the Board of Governors of the Federal Reserve System or to the Federal Open Market Committee in its conduct of monetary policy" from the scope of EO 12866 as amended. EO 14215 further clarifies that EO 12866 as modified "shall apply to the Board of Governors of the Federal Reserve System only in connection with its conduct and authorities directly related to its supervision and regulation of financial institutions."

By cross reference to 44 U.S.C. 3502(1), the term "agency" in EO 14215 also does not include: the Government Accountability Office; the governments of the District of Columbia and of the territories and possessions of the United States, and their various subdivisions; or Government-owned contractor-operated facilities, including laboratories engaged in national defense research and production activities.

Q8: What is a "regulatory action" subject to the requirements of EO 12866?
A: A "regulatory action" is defined in Section 3(e) of EO 12866, which states:

> "'Regulatory action' means any substantive action by an agency (normally published in the *Federal Register*) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking." This definition includes policies with impacts that are regulatory, deregulatory, or transfer resources from one entity to another.

This definition also includes agency "guidance documents", whether published in the *Federal Register* or elsewhere. "Guidance document" has the same meaning as the definition in Section 2(b) of EO 13891, *Promoting the Rule of Law Through Improved Agency Guidance Documents,* which states:

> 'Guidance document' means an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation, but does not include the following:
> (i) rules promulgated pursuant to notice and comment under section 553 of title 5, United States Code, or similar statutory provisions;
> (ii) rules exempt from rulemaking requirements under section 553(a) of title 5, United States Code;
> (iii) rules of agency organization, procedure, or practice;

(iv) decisions of agency adjudications under section 554 of title 5, United States Code, or similar statutory provisions;
(v) internal guidance directed to the issuing agency or other agencies that is not intended to have substantial future effect on the behavior of regulated parties; or
(vi) internal Executive Branch legal advice or legal opinions addressed to Executive Branch officials.

The scope of Section 3(e) of EO 12866 can include additional "substantive actions" where the effect of the action has general applicability.

Q9: What exemptions to the definition of "regulation" or "rule" exist under EO 12866?

A: Per section 3(d) of EO 12866, the following actions are not included in the definition of "regulation" or "rule" under that EO:

1) "Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;
2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;
3) Regulations or rules that are limited to agency organization, management, or personnel matters; or
4) Any other category of regulations exempted by the Administrator of OIRA."

IV. Centralized Review of Regulations

A. Agency responsibilities

Q10: **Who within the agency is responsible for communicating with OIRA and ensuring agency compliance with the principles of EO 12866?**

A: Each agency newly coming into compliance with EO 12866 should designate employees to fulfill two positions:

1) Regulatory Policy Officer

The Regulatory Policy Officer is a role that is defined in EO 12866 itself in Section 6(a)(2).

> …each agency head shall designate a Regulatory Policy Officer who shall report to the agency head. The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

As a direct report to the agency head, the RPO will generally be a political appointee with the authority to approve (or obtain the approval of) policy positions on behalf of the agency. The RPO should generally be knowledgeable about all regulatory actions and policymaking the agency is actively pursuing and should be available to discuss such

actions as needed. Many agencies designate a politically appointed General Counsel to serve as the RPO.

2) Regulatory Second

The Regulatory Second is a less formal but crucial role played by a senior agency official (traditionally a career employee) who coordinates or leads an office in coordinating agency work on all regulatory actions reviewed under EO 12866. In this role, the Regulatory Second will have an agency-wide and crosscutting view of agency priorities and be able to work within their agency to obtain an agency-wide position on all areas of active discussion. This work includes both the submission and review of regulatory actions the agency itself promulgates, as well as agency review of regulatory actions from other agencies. In most agencies, this position is a repository of institutional knowledge on administrative law and process, serving as a trusted advisor to agency leadership. To that end, OIRA recommends that the role be a career position, typically within the Senior Executive Service, that is situated in a centralized office (such as the Office of General Counsel) and thus well-positioned to coordinate agency positions.

Importantly, prior to submitting draft regulations to OIRA for significance determinations under EO 12866, the Regulatory Second should conduct a review of the draft regulatory action to ensure compliance with the Administrative Procedure Act (APA), EO 12866, OMB Circular A-4, and all other applicable laws and executive orders. In many agencies, the Regulatory Second has policy, legal, and analytical staff to support them in this duty.

The Regulatory Second or that person's delegated team usually will be the main point of contact for the OIRA Desk Officer for all steps of EO 12866 review and, ideally, for Congressional Review Act determinations. EO 12866 review may necessitate regular communication exchanges between the agency and OIRA to adjudicate interagency comments; this process is coordinated by the Regulatory Second and their staff to ensure that agency speaks with one voice throughout the EO 12866 process.

We request agencies provide the name and contact information for the Regulatory Policy Office and Regulatory Second for your agency on or before April 21, 2025.

Q11: If an agency has non-statutory policies in place that are barriers to implementation of EO 12866 regulatory review, what should it do?

A: For non-statutory policies that present barriers to implementation with the regulatory review requirements of EO 12866, including policies that would infringe on the Executive Branch's legal authority to preserve the confidentiality of deliberative materials consistent with the deliberative process privilege and/or lawyer-client privilege, etc., agencies should explore and exercise any discretion available to them to facilitate EO 12866 regulatory review. To the extent that such discretion is foreclosed by existing agency policy, agencies should promptly move forward with amending their policies to better align with the EO 12866 regulatory review processes, consistent with agency

statutory obligations. Generally, regulations amending agency processes to facilitate EO 12866 review will not be subject to. Executive Order 14192, Unleashing Prosperity Through Deregulation. Informal consultation is anticipated to ensure mutual understanding and agreement. Please contact your OIRA Desk Officer to update them on the progress of this effort.

Q12: What is a significance determination request?
A: OIRA is responsible for determining which agency regulatory actions are "significant" as defined by Section 3(f) of EO 12866 and are therefore subject to EO 12866 review. In coordination with your OIRA Desk Officer (for more information, see Q. 25), agencies should submit a list of their planned regulatory actions, and indicate which actions the agency believes are significant and non-significant regulatory actions. If the information initially conveyed is enough to make a determination, your Desk Officer will notify you within 10 business days whether a planned regulatory action is a significant regulatory action; otherwise, your agency will receive follow up within that same time period. Section 3(f) of EO 12866 defines "significant regulatory action" as "any regulatory action that may:

1. 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;
2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in EO 12866."

Category 4 will be interpreted in a fashion such that it is supplemented by the legal concerns relevant to the "major questions doctrine." *West Virginia v. EPA*, 597 U.S. 697 (2022). This includes rulemakings that raise significant federalism and separation of powers issues. *See id.* 735-53 (Gorsuch, J., concurring).

Agencies should not assume that actions that appear or have appeared in the *Unified Agenda of Regulatory and Deregulatory Actions* as "Nonsignificant" will be determined the same by OIRA. Any agency anticipated EO 12866 determinations in the *Unified Agenda* are preliminary and non-binding.

Q13: How should agencies coordinate with OIRA?
A: Through the Regulatory Second or delegated point of contact (see answer to Q. 10), agencies should remain in contact with their OIRA Desk Officer (see answer to Q. 25) through the duration of review. There are multiple points before, during, and after EO 12866 review where staff-level coordination with your Desk Officer will be beneficial. For example, it may be helpful to reach out to your Desk Officer before the agency plans to submit a regulatory action for review, when agency regulatory priorities are

developed, and when new policies or external factors affect the regulatory actions under development. Given the regularity with which such developments occur, your Desk Officer may find it useful to establish a recurring check-in to avoid the need for one-off updates.

Importantly, during review of a regulatory action, all interagency communication – including with components with the EOP – regarding the action under review should take place through OIRA. This is critical to ensure version control, ensure visibility on all ongoing discussions, ensure that agencies are coordinating effectively, and helps to streamline EO 12866 review. A good practice is to mark interagency communications as deliberative and pre-decisional.

Q14: **What is the role of the regulatory impact analysis required by Sections 6(a)(3)(B)(ii) and 6(a)(3)(C) of EO 12866?**
A: Regulatory analysis is a tool that is used to anticipate and evaluate the likely consequences of regulatory actions (including both costs and benefits). It provides a formal means of organizing the evidence on the key effects—both intended and unintended—of various alternatives that should be considered in developing regulations. Among its purposes are: (1) to learn if the quantified and non-quantified benefits of an action are likely to justify its costs, (2) to promote accountability to the public; (3) to discover which of various possible alternative policy approaches would produce the highest net benefits; and (4) establish a strong record for the policy choices in the action. Sometimes careful analysis can show that stringency should be adjusted from the level that initially seemed optimal; sometimes a different combination of regulatory provisions is shown to be more appropriate; sometimes a creative policy option will emerge. As one of its regulatory principles, EO 12866 states that agencies developing a regulation "shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."

Q15: How should the problem a regulatory action addresses be identified?
A: EO 12866 states that a regulating agency "shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." Consideration of and modeling of an underlying market failure—e.g., externality, market power, or asymmetric information—is a standard starting point for conducting cost-benefit analysis of a regulatory action or other government intervention. Importantly, analysis should not take as given either that a market failure exists, or that a single policy intervention corrects an identified market failure.[4] However, if careful analysis indicates

[4] Observing the mere potential for market failure is only an initial step in a regulatory analysis. Next, the extent of any relevant market failure should be quantified, with the resulting estimates integrated into subsequent regulatory analysis. As regulatory analysis is developed, there should be a continual assessment of whether the analysis as a whole achieves internal consistency. For example, if a market failure cannot be identified, then an estimate of positive monetized net benefits may be the result of missing cost categories, inappropriate methods or data, or implausible assumptions.

that either or both conditions hold, then an economic analysis or regulatory impact analysis (RIA) can, to a large extent, fulfill the EO 12866 Section 6(a)(3)(B)(i)-(C) requirements for a problem statement. Other portions of a draft action (e.g., preamble (or narrative, such as in a sub-regulatory document)) should state whether an action is required by statute or judicial directive and should explain the specific authority under which the regulatory action is being issued, the extent of agency discretion as granted by statute, and permissible regulatory instruments.

Q16: How should EO 12866 analysis be conducted?

A: OIRA's guidance on how to conduct regulatory impact analysis is set forth in OMB Circular A-4, which includes the following principles[5]:

- The scope of an analysis should incorporate significantly affected entities, and the time horizon should encompass all important effects of the agency action (including, where relevant, new equilibria being reached in affected markets). A regulatory analysis should present undiscounted year-by-year streams of benefit, cost, and transfer estimates for the full analytic time horizon.
- A rule's costs, benefits, and transfer impacts must be assessed relative to a baseline—that is, the predicted future state of the world in the absence of the rule being analyzed.[6] A baseline should be grounded in evidence (including quantitative data, to the extent feasible) and reflect a best assessment of market evolution and other factors that may change independent of the rule. In some instances, an agency may provide analysis using multiple baselines, especially when doing so would highlight areas of uncertainty or (as discussed in more detail in the answer to Q 17, below) of agency policy discretion. This allows OIRA to perform sensitivity analysis of any assumptions made by the agency concerning the baseline chosen or other issues. Regardless of the number of baselines used in an analysis, presentation of effects without transparent characterization of the relevant baseline is generally not appropriate.
- Agencies should assess potential impacts of substantial magnitude, as experienced by any individuals or entities in society. Such effects may include, but are not limited to: private-sector compliance costs and savings; government administrative costs and savings; gains or losses in consumer or producer surplus; discomfort or inconvenience costs and benefits; and gains or losses of time in work, leisure or travel settings. Opportunity cost is the comprehensive cost principle.

[5] https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf

[6] Clarifications of Circular A-4's guidance occasionally appears in peer-reviewed OMB reports. See, for example, the discussion of interactions between analytic baselines, regulatory compliance, and aggregation across analyses on p. 6 in the 2017 Report to Congress on the Benefits and Costs of Federal Regulations (https://trumpwhitehouse.archives.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf).

- Agency analysis should extend beyond the direct effects of agency action and encompass any important ancillary or indirect effects.[7] In summing or otherwise listing effects, care should be taken to avoid either double-counting or undercounting.
- The precise consequences (benefits, costs, or transfers) of a rule may be uncertain, so agencies should analyze and present important uncertainties—for example, by noting the probability of effects' occurrence.
- For a significant rule requiring analysis under EO 12866 Section 6(a)(3)(C), there should be quantification, to the extent feasible, of the effects of alternative regulatory approaches. These alternatives may be characterized by different degrees of stringency, different combinations of provisions, or other such changes from the regulation as proposed or finalized.[8]
- Any technical or scientific information (including economics or other social science) that the agency relies upon for its analysis should comply with the Information Quality Act (IQA), OMB's information quality guidance, and the regulating agency's supplemental IQA guidance.[9] Please see questions 38 and 40, below, for more detail about the Information Quality Act.
- Monetized estimates of benefits, costs and transfers should be: (a) presented as undiscounted year-by-year streams, and (b) summarized as annualized values using 7% and 3% discount rates (and, optionally, other rates, if relevant for a particular regulatory action's analysis).

Generally, the extent of regulatory analysis should be commensurate with the magnitude of the regulation being proposed or finalized, though in conjunction with any statutory analytic requirements, this presumption may not hold. For instance, although the principles of Circular A-4 are relevant to analyses conducted under EO 12866 Section 6(a)(3)(B)(ii), the Circular more formally applies when annual regulatory effects may exceed $100 million (or otherwise meet the criteria of Section 3(f)(1) or the Congressional Review Act's Section 804(2)) and thus trigger the analytic requirements of EO 12866 Section 6(a)(3)(C). As a further example, formal quantitative uncertainty analysis becomes a requirement under Circular A-4 when regulatory effects exceed $1 billion.

Authorities other than EO 12866 may require analysis; examples include the agency's authorizing statute, the Regulatory Flexibility Act (see question 45, below) and the Paperwork Reduction Act (see question 41, below, and pra.digital.gov). Additionally, the

[7] For some regulations, costs can be associated with activity that does not itself yield benefits, but instead may prompt intermediate actions that connect those effects with ultimate beneficial outcomes. For instance, a regulation may require collection and dissemination of information related to safety practices; the information itself does not make anyone safer, but its greater availability may prompt more widespread use of safety practices. An analysis should avoid the inappropriate omission of the costs of these activities (such as more widespread safety practices, in the example above) when indicating — quantitatively or qualitatively – that there will ultimately be beneficial outcomes.

[8] The anticipated state of the world in the absence of agency action restates the analytic baseline, and thus its inclusion in an RIA's alternatives assessment would not serve the goal of increasing the informational content of the overall regulatory impact analysis.

[9] Section 515 of Public Law 106–554; H.R. 5658. OMB's IQA Guidelines: https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information

Congressional Review Act (CRA; see question 44 below) sets forth provisions for which at least some analysis would be an integral aspect of compliance—e.g., analysis of whether any conditions of CRA Section 804(2) have been met. These other analyses have the potential, given agencies' longstanding familiarity with conducting them, to offer an accessible starting point for complying with the analysis requirements of EO 12866 and Circular A-4. For example, quantification of the effects of alternative regulatory approaches, per item 6 above, would use many of the same inputs as an analysis informing a designation under Section 804(2) of the Congressional Review Act (quantifying effects of a regulation as finalized).

OIRA staff are available to lead training sessions on general analytic practices and for consultations as individual analyses are developed. To request training or consultations, please contact your OIRA Desk Officer.

Q17: If a statute gives an agency little or no discretion over the issuance of a regulatory action (including how to craft its provisions or whether to regulate at all), is EO 12866 analysis still required, and if so, are there areas of special emphasis in conducting such an analysis?

A: Yes, EO 12866 analysis is generally required. Even when statute prevents the use of cost-benefit analysis in decision-making, presenting evidence about likely regulatory consequences provides transparency for the public. When assessing the economic effects of the first rule that implements a statutory requirement, agencies should account for the effects of the statute itself—that is, they should use a without-statute baseline.[10] The regulatory analysis should provide clarity about the extent of agency discretion (if any), by presenting clear provision-by-provision estimates, by using a supplementary assessment comparing against a with-statute baseline, or both. Circular A-4 notes that the Regulatory Alternatives portion of a regulatory impact analysis may include assessment of approaches that are not statutorily permissible, when doing so would provide useful transparency.

Q18: If a regulatory action has been determined "significant" by OIRA, when do we submit the item to OIRA for review?

A: If a regulatory action has been designated "significant" by OIRA, agencies should submit the final, complete draft package to OIRA when it is a ready for review, and generally should anticipate up to 90 days for review. A complete package means the regulatory documents have been through your agency's required internal clearance processes and are considered "final" drafts that represent the views of the agency as a whole. The package should also include any required cost benefit analyses, alternative analyses, and other legal and policy requirements associated with rulemaking such as tribal consultations, a federalism analysis, and others. Please let your Desk Officer know when you submit items to OIRA so they can begin the review and centralized

[10] The terms "pre-statute baseline" and "post-statute baseline" are used in Circular A-4. The baseline for a regulatory analysis is the predicted future state of the world in the absence of the policy being assessed, so "without-statute" or "with-statute" are clearer terms, in that they avoid the potentially misleading temporal element of the prefixes "pre" or "post."

coordination process promptly. The more policy coordination on the front end of submission the better chance of moving the rule in less than 90 days.

Q19: If a regulatory action has been determined "significant" by OIRA, when may we publish it?
A: Agencies may publish or otherwise make public a significant regulatory action only after OIRA has concluded its review, as discussed in Q22.

Q20: How do we submit a significant regulatory action to OIRA for review?
A: To facilitate the submission of significant regulatory actions, as well as other aspects of the regulatory review process, GSA's Regulatory Information Service Center (RISC) manages an information system that is used by both agencies and OIRA. This system, called the RISC/OIRA Consolidated Information System (ROCIS), is a secure, web-based platform that provides secure, role-based access for OIRA and federal agencies.[11] If you need assistance with ROCIS, please consult the user manual located on the landing page of rocis.gov, contact the GSA help desk, or ask your OIRA Desk Officer.

Q21: What does OIRA's review process look like for "significant" regulatory actions?
A: Once your agency submits a complete package to ROCIS for OIRA for review and it is accepted, your Desk Officer shares it with the relevant, affected Executive Branch entities. This may include other Executive Branch agencies (inclusive of historically independent regulatory agencies), White House policy councils, and legal review offices. These materials are treated with sensitivity given their deliberative and pre-decisional nature, and neither the materials nor any communications regarding their content are shared with entities outside of the Executive Branch. This includes communication with the legislative branch government. When a regulatory action is under review with OIRA, all interagency communication regarding the action should be coordinated through OIRA, as discussed in Q13. This OIRA-coordinated interagency process is also likely to replace the need for agencies to submit comments on each other's regulatory actions during the public comment period as part of the rulemaking docket, as any interagency concerns should have been raised within the EO 12866 review process.

Executive Branch reviewers review the materials for consistency with the President's priorities, adherence to statutory requirements, and analytic cohesion. EO 12866 generally allows up to 90 calendar days for this review to occur, and agencies should plan accordingly, although OIRA notes that at all times it attempts to complete review as expeditiously as possible, particularly as to rules that are deregulatory in nature. During this review period, you may receive comments or questions from OIRA, and you are encouraged to respond promptly in order to ensure adherence to this rigorous timeline.

[11] In addition to facilitating the EO 12866 review process, ROCIS supports the business processes, needs, and workflows relating to the development of the Unified Agenda of Regulatory and Deregulatory Actions and Regulatory Plan, the review and approval of Information Collection Requests (ICRs) under the Paperwork Reduction Act, and the review of System of Record Notices and Matching Agreements under the Privacy Act.

Additionally, there are sometimes emergency situations in which OIRA must act more quickly than normal procedures would allow, in which case the agency should notify OIRA as soon as possible to schedule the rulemaking proceedings so as to permit sufficient time for OIRA to conduct an adequate review.

Q22: **What happens when OIRA concludes review of a regulation?**
A: After interagency and EOP comments have been addressed and any elevation issues have been resolved, OIRA will initiate the "conclusion of review" process with the agency. This final stage allows the agency and OIRA to confirm the final versions of all documents under review, as they will be submitted to the *Federal Register* for publication. No substantive changes of any kind can take place after EO 12866 review is concluded on a package. However, this does not prevent agencies from making editorial changes in response to edits from the Office of the *Federal Register* between conclusion of review and publication in the *Federal Register*. Nor does this prevent agencies from making changes between the proposed and final rulemaking stages in response to public comments.

At conclusion of review, the following information will be made public via RegInfo.gov:

- the date that the regulatory action was received for review in ROCIS, and the date that review was concluded;
- the Regulatory Identification Number (RIN), issuing agency/subagency, and the title of the rulemaking; and
- the conclusion action.

There are several categories of "conclusion action" when OIRA concludes review on a rule. These include:

- Concluded without Change – The EO Package was reviewed by OIRA, and no substantive changes were necessary.
- Concluded with Change – The EO Package was reviewed by OIRA and responsive changes were made by the agency to the submission.
- Improperly Submitted – OIRA determined that the EO package was not appropriate for OIRA review.
- Returned for Reconsideration – OIRA returns the EO Package for reconsideration by the agency.
- Withdrawn – The submitting agency asked that the EO package be withdrawn from consideration.

Q23: What are "OIRA letters" and when might one be sent?
A: The Administrator of OIRA has the authority to issue several different types of letters pertaining to review.

- Return Letter – During the course of OIRA's review of a draft regulatory action, the Administrator may decide to send a letter to the agency that returns the draft for reconsideration. Such a return may occur if the quality of the

agency's analyses is inadequate, if the regulatory standards adopted are not justified by the analyses, if the action is not consistent with the regulatory principles stated in EO 12866 or with the President's policies and priorities, or if the action is not compatible with other Executive Orders or statutes. Such a return does not necessarily imply that either OIRA is opposed to the draft regulatory action. Rather, the return letter explains why OIRA believes that the action would benefit from further consideration by the agency.

- Prompt Letter – The purpose of the prompt letter is to suggest an issue that OIRA believes is worthy of agency priority. Rather than being sent in response to the agency's submission of a draft regulatory action for OIRA review, a "prompt" letter is sent on OMB's initiative and contains a suggestion for how the agency could improve its regulatory framework.
- Review Letter – The OIRA Administrator issues "review" letters at various stages of the rulemaking process. A "review" letter following the issuance of a proposed rule may urge the agency to perform additional regulatory analysis or consider other alternatives prior to finalizing the rule. A "review" letter following the issuance of a final rule may offer implementation advice or explain OMB's dispute resolution process. These letters are issued in the Administrator's discretion.

These letters are generally made public and, particularly in the case of return or review letters, are typically a last-case resort should internal Executive Branch resolution processes not succeed.

B. OIRA responsibilities

Q24: What are OIRA's core responsibilities within the EO 12866 review process?

A: OIRA is responsible for:

a) making a determination whether a regulatory action is significant and should be subjected to review and the depth of economic analysis that is required;
b) interagency review of the regulatory action that has been accepted;
c) analyzing the draft regulatory action for consistency with the principles of EO 12866; and
d) hosting calls requested by the public to share their views on the regulatory action, among other roles.

Q25: What is an OIRA Desk Officer?

A: Desk Officers, also called Policy Analysts, are the primary staff-level points of contact for each agency within OIRA. Desk Officers coordinate the review of each regulatory action submitted to OIRA and will build review teams in OIRA and across the EOP including experts in economic analysis, statistics, science, technology, privacy, etc. as appropriate. If you do not know who your OIRA Desk Officer is, please reach out to the contact address provided at the end of this guidance document to inquire.

Q26: How does OIRA make a significance determination?
A: As the EO 12866 review process involves a substantial commitment of time both by EOP and agency personnel, OIRA will determine whether conducting such a review is appropriate. This determination is made based on whether the regulatory action implicates one or more of the four conditions set forth in Sec. 3(f) of EO 12866. If the regulatory action meets the Sec. 3(f)(1) threshold that it may have $100 million or more in impacts in any year, it will be deemed "economically significant", including where one or more of the other conditions is met, requiring a more robust regulatory impact analyst that is consistent with the principles of OMB Circular A-4. If a regulatory action meets none of the conditions, OIRA will deem it "not significant" and allow the agency to proceed with publication of the action.

Q27: How does OIRA decide to which agencies or EOP components is a regulatory action distributed?
A: OIRA distributes the regulatory action to EOP components with interest or overlapping jurisdiction over the subject matter. OIRA welcomes any suggestions from the drafting agency regarding the importance of including particular agencies.

Q28: What is the interagency review aspect of the EO 12866 review process?
A: When an agency submits a regulatory action to OIRA for review, it will be distributed for interagency and EOP review. Review iterates between reviewers and the drafting agency until conclusion.

Q29: **How does the EO 12866 process handle overlapping equities between the drafting agency and reviewers?**
A: As noted earlier, review is an iterative process that may involve interagency comment, discussion, and/or policy discussion. Interagency proceedings conducted by OIRA under EO 12866 are deliberative.

Q30: How long is EO 12866 review?
A: EO 12866 presumptively provides up to 90 calendar days for review, and many reviews organically conclude well before that milestone, while some conclude after it. As noted above, EO 12866 review is an iterative process.

V. Accountability and Transparency

Q31: What information relating to regulatory actions submitted to OIRA is available to the public via *Reginfo.gov*?
A: To assure greater openness and accountability in the regulatory review process, EO 12866 requires OIRA to publicly log all agency regulatory actions under review. *Reginfo.gov*, is a publicly facing website that is updated daily with specific information regarding OIRA review. The publicly logged information includes the title of the regulatory action; the stage of rulemaking; the date review started, agency's requested significance and upon conclusion whether the action is "significant" or "economically significant" a brief abstract of the action entered by the agency; and upon conclusion,

conclusion status. When the action is concluded in ROCIS, the conclusion date is also populated on *Reginfo.gov*. The public log does not include the actual text of the draft documents, as those are considered deliberative and pre-decisional until OIRA concludes review.

Q32: What are EO 12866 meetings?
A: EO 12866 meetings occur at the initiative of external parties who request a meeting to present views about a regulatory action under OIRA review. Congressional meeting requests also follow the EO 12866 meeting process when a regulatory action is under review. The requestor may also invite other parties to attend. Per EO 12866, OIRA invites representatives from the drafting agency. Occasionally, other agencies or members of the EOP may also attend.

EO 12866 meetings serve as listening sessions. Members of the public can share their views on a regulatory action, as well as any scientific, technical, social, economic, or information drawn from individual experience that may be helpful to the government while reviewing a regulatory action. Government officials may ask clarifying questions but will not share deliberative or pre-decisional information about the regulation under review. EO 12866 meetings are not a substitute for public comments submitted to the rulemaking agencies, but they offer an additional opportunity to convey information to the government. EO 12866 meetings can provide the government with information that it would not be able to gather during interagency review and bring to light new information about how a regulatory action might positively or negatively impact particular stakeholders or lead to unintended consequences or present unforeseen opportunities.

Q33: What public disclosures are made for the EO 12866 meetings OIRA has with the public on regulatory actions under review?
A: The primary purpose of EO 12866 disclosure requirements in Section 6(b) concerning EO 12866 meetings has always been to make transparent communications between the public and the Executive Office of the President while a regulatory action is under review. EO 12866 also establishes a disclosure process regarding the OIRA Administrator's (or his/her designee's) meetings with outside parties during formal review of a regulatory action, if such meetings occur. In such instances, OIRA discloses the subject, date, and participants of the meeting on the Reginfo.gov website, as well as any materials provided to OIRA at such meetings. Public disclosure about meetings with outside parties is a cornerstone of a fair and transparent regulatory review process. OIRA currently releases information about EO 12866 meetings at: https://www.reginfo.gov/public/do/eom12866Search.

Q34: Are written comments OIRA receives on regulatory actions under review disclosed publicly?
A: OIRA occasionally receives written materials from outside parties concerning regulatory actions under OIRA review. OIRA will forward these materials to the issuing

agency within 10 working days of receipt and disclose them on Reginfo.gov. Issuing agencies will be responsible for putting these written materials in the rulemaking docket.

Q35: Are documents that are exchanged during interagency review disclosed publicly?

A: As a general matter, documents exchanged during the review process are considered deliberative materials that are not subject to public disclosure. Upon external party request, following the conclusion of OIRA review and after a regulation is published in the *Federal Register* or otherwise made public by the issuing agency, OIRA will provide the drafting agency's initially submitted document. OIRA will also provide written correspondence exchanged between senior officials in OIRA and the issuing agency.

Q36: How do the requirements of The Government in the Sunshine Act of 1976 interact with EO 14215?

A: The Government in the Sunshine Act of 1976 (Sunshine Act or Act) requirements apply to any agency "headed by a collegial body composed of two or more individual members, a majority of whom are appointed to such position by the President with the advice and consent of the Senate, and any subdivision thereof authorized to act on behalf of the agency (5 USC 552(e))."

The Sunshine Act requires that every portion of every "meeting" of an agency shall be open to public observation, and any associated documents be made public, unless it falls within one of ten exemptions. A "meeting" is defined as "the deliberations of at least the number of individual agency members required to take action on behalf of the agency where such deliberations determine or result in the joint conduct or disposition of official agency business," 5 U.S.C § 552b(a)(2).

OLC's opinion of October 8, 2019 states that, "[t]he Sunshine Act's requirements would not preclude compliance with EO 12866, because most discussions between a covered agency and OIRA would likely not qualify as a 'meeting.' As the Supreme Court explained in *FCC v. ITT World Communications, Inc.*, 466 U.S. 463 (1984), Congress was cognizant in drafting the Sunshine Act that 'the administrative process cannot be conducted entirely in the public eye.' Id. at 469. The Act is therefore limited to 'meetings' as defined above. See id. at 471 (holding that a 'meeting' must involve deliberations 'sufficiently focused on discrete proposals or issues as to cause or be likely to cause the individual participating members to form reasonably firm positions'). Many of the consultations that occur in the EO 12866 process likely would not meet that standard. As the Court explained, 'informal background discussions that clarify issues and expose varying views' are a necessary part of an agency's work,' and the Act was not intended to 'prevent such discussions.' Id. at 469–70. A 'meeting' also must involve 'at least the number of individual agency members required to take action on behalf of the agency.' 5 U.S.C. § 552b(a)(2). An exchange of views between OIRA and the staff of an agency (or its Chairman) during the EO 12866 process would not qualify. Thus, the Sunshine Act would be consistent with applying EO 12866 to independent agencies."

Per the OLC opinion, the typical EO 12866 interagency review process would not implicate the Sunshine Act because an exchange of views between OIRA and agency staff does not constitute a "meeting" under the Act. However, a meeting and vote may be necessary to adopt any changes to the regulatory action resulting from 12866 review. To avoid unnecessarily revealing confidential information subject to the deliberative process privilege, any such changes should be adopted in a single concluding vote as the culmination of the review process.

Q37: How does the EO 12866 process intersect with the Information Quality Act (IQA)?

A: EO 12866 requires that agency regulatory actions be informed by the best available evidence. The IQA (Section 515 of Public Law 106–554; H.R. 5658), requires OMB to promulgate guidance to agencies ensuring the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies. Under the IQA, agencies shall ensure that the information relied upon when making regulatory decisions is high-quality. Agencies must also ensure that the data underlying all aspects of their regulatory analyses and risk assessments meet the above IQA standards. Both EO 12866 and the IQA work together to provide transparency and quality of information used by agencies in their regulatory actions.

Q38: Who is responsible for ensuring that the evidence used to support regulatory actions meet the IQA standards?

A: Agencies, the public, and OIRA have roles in ensuring the quality, objectivity, utility, and integrity of the information they disseminate through a regulatory action. Agencies are responsible for providing public access to the information they use in their regulatory actions, any peer-review processes used in the regulatory action, and responding to any requests for correction from the public. The public can provide input throughout the EO 12866 process and can make requests for correction to any information disseminated by the agency. OMB is responsible for ensuring that the agencies meet their obligations under the IQA throughout the EO 12866 process. Agencies should identify an official responsible for implementation of the IQA and provide that individual's contact information to their OIRA Desk Officer via email and cc MBX.OMB.InformationQuality@omb.eop.gov.

Q39: What resources are available to support agency compliance with the IQA?

A: The IQA directed OMB to issue government-wide guidelines that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality of information disseminated by Federal agencies, including a process for requesting correction. These guidelines and related initiatives are described below:

- Information Quality Guidelines (2002) – The IQA Guidelines implement the statutory requirements of the IQA, and provide a framework for oversight of the quality of information disseminated by the Federal government. OMB designed the guidelines to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate (meaning to share with, or give access to, the public).

- Peer Review Bulletin (2004) – The Peer Review Bulletin (the Bulletin) establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents. Peer review is an important procedure used by the scientific community to ensure the quality of published information. Peer review can increase the quality and credibility of the scientific information generated across the Federal government.
- OMB M-19-15: Improving Implementation of the Information Quality Act (2019) – OMB M-19-15 builds on, and does not replace, the OMB Information Quality Guidelines. It provided implementation updates in the context of innovations and subsequent policy in the information landscape as well as common questions that have arisen since the OMB Guidelines were issued.
- Improving Implementation of the Information Quality Act: Frequently Asked Questions (2023) – The purpose of these FAQs is to answer questions that Federal agencies have often asked about how to apply OMB Guidelines and OMB M-19-15.

Q40: How does the Paperwork Reduction Act interact with EO 12866?
A: The Paperwork Reduction Act, as implemented in 5 CFR 1320, establishes the process through which agencies receive approval from OMB to collect information from the public. For standard information collections, agencies must publish two sequential *Federal Register* notices that seek comment from the public on any proposed collection of information prior to submitting such a request to OMB for approval.

Some information collections are initiated, amended, or eliminated by an agency rulemaking. In such cases, 5 CFR 1320.11 establishes the process that agencies shall use to seek comment from the public and submit for OMB approval for information collections in proposed and final rules. For information collections associated with significant regulatory actions, supplemental information regarding the information collection may be requested by your Desk Officer during EO 12866 review of the underlying action.

Q41: Do forms, surveys, and other information collections need to be reviewed by OIRA as part of a regulatory action?
A: In general, yes, all information collection requests (ICRs) associated with a regulatory action need to be submitted to OMB for review through ROCIS. Because such ICRs may contain deliberative information about an associated regulatory action, consult with your OIRA Desk Officer regarding the timing of submission.

Q42: How should agencies handle information collections currently under review that are associated with a proposed or final rule?
A: Agencies should consult their OIRA Desk Officer on proposed rule(s) with a related ICR currently under review.

Information collections associated with nonsignificant proposed and final rules should continue to be published for public comment and submitted to OMB for review as specified in OMB's implementing regulations at 5 CFR 1320.11. If OMB filed comments on the collection and deferred review at the proposed rule stage, the agency must resubmit the collection to OMB for review when the agency finalizes the associated rule. Consistent with 5 CFR 1320.11, when the final rule is published in the *Federal Register*, the agency shall explain how any collection of information contained in the final rule responds to any comments received from OMB or the public and any modifications made in the rule. If requested by OMB, the agency shall include OMB's comments in the preamble to the final rule. The collection will then be reviewed by OMB consistent with the requirements of 5 CFR 1320.11.

If OMB "preapproves" the collection and it remains unchanged from when it was preapproved, then the agency can take action in ROCIS to finalize the approval and receive an OMB control number. But if there were substantive changes to the collection, then the agency must resubmit the collection to OMB for review and approval. If there is uncertainty about whether the changes are substantive, the agency should consult its OIRA Desk Officer.

For collections associated with proposed and final rules that have not yet published, and are therefore not yet public, please discuss with your Desk Officer how to submit the rule for prepublication review. To preserve the deliberative nature of the rulemaking process, do not upload the information collection into the ROCIS PRA module until after the rule has published.

Q43: How do the requirements of EO 12866 interact with preexisting agency requirements under the Congressional Review Act (CRA)?

A: An agency's obligations under the CRA, or any other statute, do not change and are not impacted by their compliance with EO 12866. The CRA creates a special category of "major rules" and requires OIRA to determine at the final rule stage whether a rule is major per the criteria listed at 5 U.S.C. § 804(2). The CRA's definition of major rule closely corresponds to the economic standard for "significant regulatory action" in Section 3(f)(1) of EO 12866. The language is not identical (and a rule could potentially be economically significant under EO 12866 but not major under the CRA or vice versa). For final stage regulatory actions submitted for review pursuant to EO 12866, OIRA will incorporate the CRA major determination into its standard EO 12866 review process. Agencies should include both a proposed significance determination and a proposed determination of whether the rule is major under Section 804(2) when submitting a significance determination request to OIRA pursuant to EO 12866, as amended by EO 14215. For rules determined not to be significant under EO 12866, OIRA will make the major determination at the significance determination stage.

Q44: What are the interactions between analyses conducted under EO 12866 and the Regulatory Flexibility Act?

A: As noted under Section 6(a)(3) of EO 12866, agencies are expected to adhere to the Regulatory Flexibility Act, among other applicable requirements, including the Paperwork Reduction Act. The Small Business Administration's Office of Advocacy offers guidance on how to comply with the Regulatory Flexibility Act, which requires analysis of regulatory effects experienced by small entities.[12] By comparison, analysis conducted under EO 12866 should reflect a society-wide perspective, including small and large entities (business and non-profit entities and state, local, territorial, tribal and federal levels of government), as well as consumers and other individuals. Whereas regulatory alternatives assessed in an Initial or Final Regulatory Flexibility Analysis should be focused on approaches that would be feasible under the regulating agency's statutory authority and would reduce adverse impacts on small entities (as compared with effects of the regulation as proposed or finalized), regulatory alternatives assessed in an EO 12866 analysis may be implementable only with statutory revisions (the formal analysis might eventually help inform such revisions) and should be broad enough to include options that are more and less costly to society than the proposed or finalized regulatory action.

Q45: Does EO 14215 interact with the Unfunded Mandates Reform Act?

A: No, the definition of "agency" in the Unfunded Mandates Reform Act of 1995 (UMRA) is not impacted by the issuance of EO 14215 and agency practice under UMRA is not expected to change.

Q46: What is the *Unified Agenda of Federal Regulatory and Deregulatory Actions*?

A: The Unified Agenda of Federal Regulatory and Deregulatory Actions, established in Section 4 of EO 12866, provides uniform reporting of data on regulatory and deregulatory activities under development throughout the Federal Government, covering approximately 60 departments, agencies, and commissions including independent regulatory agencies. Each edition of the Unified Agenda includes regulatory agendas from all Federal entities that currently have regulations under development or review. Agencies of the United States Congress are not included. Fall editions of the Unified Agenda include The Regulatory Plan, which presents agency statements of regulatory priorities and additional information about the most significant regulatory activities planned for the coming year.

[12] https://advocacy.sba.gov/wp-content/uploads/2019/06/How-to-Comply-with-the-RFA.pdf

Q47: What is the historically independent regulatory agency's role in the Unified Agenda of Federal Regulatory and Deregulatory Actions?

A: Such agencies should already be in compliance with the Unified Agenda of Federal Regulatory and Deregulatory Actions process. Please consult with your OIRA Desk Officer if you have questions regarding participation in the Unified Agenda process.

i. Section 4(b) of EO 12866 requires agencies, including independent regulatory agencies, to publish a regulatory and deregulatory agenda.
ii. In Section 4(b) of EO 12866, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in *44 U.S.C. 3502(10)*.[13] Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. See Section 4(b) for more on what should be in the agenda at a minimum.
iii. In Section 4(c) of EO 12866, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in *44 U.S.C. 3502(10)*. (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. See Section 4(c) for more on what should be in the Regulatory Plan at a minimum.

Q48: Why Publish the *Unified Agenda for Federal Regulatory and Deregulatory Actions*?

A: Section 4(b) of EO 12866 requires agencies to publish a regulatory and deregulatory agenda. The *Unified Agenda of Federal Regulatory and Deregulatory Actions* is a compilation of each agency's regulatory agenda, broadly defined. A central goal of the agenda is to promote transparency and open government. In addition, the agenda furthers the purposes of the Regulatory Flexibility Act (5 U.S.C. § 601 et seq.) (RFA); EO 13132, "Federalism," 64 FR 43255 (August 4, 1999); the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1501–04, 1531–38, 1551–56 (UMRA); and the Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. § 601 (SBREFA).

VI. Additional Guidance to Agencies

Q49: How should agencies consider sequencing of internal processes with EO 12866 review?

A: As a general matter, OIRA recognizes that Commissions or Boards may have differing requirements as far as procedural voting to approve sending a draft regulatory action to the *Federal Register* for publication. As part of the implementation of EO 14215, agencies should update their voting procedures to ensure that draft regulatory actions are sent to OIRA for a significance determination under EO 12866 *before* publication. As

[13] Note: this definition of 'agency' in Executive Order 12866 cites to the definition in the Paperwork Reduction Act (PRA) of 1980. The PRA was reauthorized (and definitional sections were reorganized) in 1995. While the current PRA defines 'person' at 3502(10), the reference was originally to the definition of 'independent regulatory agency' now found at 3502(5).

noted earlier, the significance determination process is deliberative. Should a draft regulatory action be found "significant" under EO 12866, Commissions, etc. will need to update their voting procedures to ensure that the OIRA-reviewed version of the draft regulatory action is the one sent to the *Federal Register*. If a substantive change is made to the document following OIRA's conclusion of review, the document must be resubmitted to OIRA for clearance of those changes.

Q50: Where an agency has discretion, can it continue to make draft regulatory actions public before publication in the *Federal Register* for notice and comment?

A: Barring statutory mandates, under no circumstances should agencies disclose to the public any draft regulatory action prior to completion of EO 12866 review, which includes OIRA's significance determination under EO 12866 and the review of any regulatory action found to be "significant" under EO 12866. Section 8 of EO 12866 outlines the process that should occur before an agency publishes a regulatory action in the *Federal Register*.

If your agency believes that you have a statutory mandate of this nature that would impede this sequencing of events, please contact your Desk Officer as soon as possible to discuss, and prior to submitting your first regulatory submission to OIRA for review.

Q51: How should agencies handle public statements following votes to adopt their rules?

A: To ensure the confidentiality of pre-decisional, deliberative materials that are part of the EO 12866 process, public disclosure of regulatory actions subject to EO 12866 review should not occur during the EO 12866 review process. While, in the past, some agencies, and members of the Commissions for those agencies have issued public statements following a vote related to rulemakings, such agencies and Commissioners should now tailor their public statements as appropriate to reflect the specific procedural step voted upon—for example, voting only to send the rulemaking to OIRA for EO 12866 review, and limiting public statements accordingly. Additionally, such public statements should not disclose the substance of the draft sent to OIRA unless it was already made public through a statutory mandate (please contact your OIRA Desk Officer as soon as possible and prior to your first regulatory submission to discuss any statutory mandates of this nature).

Q52: What should historically independent regulatory agencies do if a regulatory action is already published and it is expected that the action will be finalized in the future?

A: Agencies should submit a significance determination request under EO 12866 to OIRA for review before publishing the final regulatory action. Please see Question 12 on submitting a significance determination for more information.

Q53: How does an agency comply with Executive Order 14192, *Unleashing Prosperity Through Deregulation*?
A: Unless expressly exempted or prohibited by statute, EO 14912 applies to historically independent agencies. Please refer to OIRA's Guidance on Implementing Section 3 of EO 14192 (OMB Memorandum M-25-20) for further information.[14]

Q54: What if we have agency specific issues that may necessitate flexibility with the requirements of EO 12866?
A: OIRA understands that some agencies may have statutory or regulatory requirements that may necessitate deviations from how OIRA has historically implemented EO 12866. Prior to the issuance of this guidance, OIRA has reached out to your agencies to work to better understand any of such circumstances and identify solutions. To the extent that there are still unresolved concerns, please notify your OIRA Desk Officer as soon as possible. Such circumstances may include agency-specific requirements related to: disclosure, voting, transparency, risk analysis, or cost-benefit analysis.

VII. For Further Information

Q55: How do I contact OIRA to ask any remaining questions?
A: If you know your OIRA Desk Officer, please feel free to reach out to them directly. Otherwise, please contact the OIRA Independent Agency Working Group at OIRAIndependentAgencyTeam@omb.eop.gov.

[14] https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf