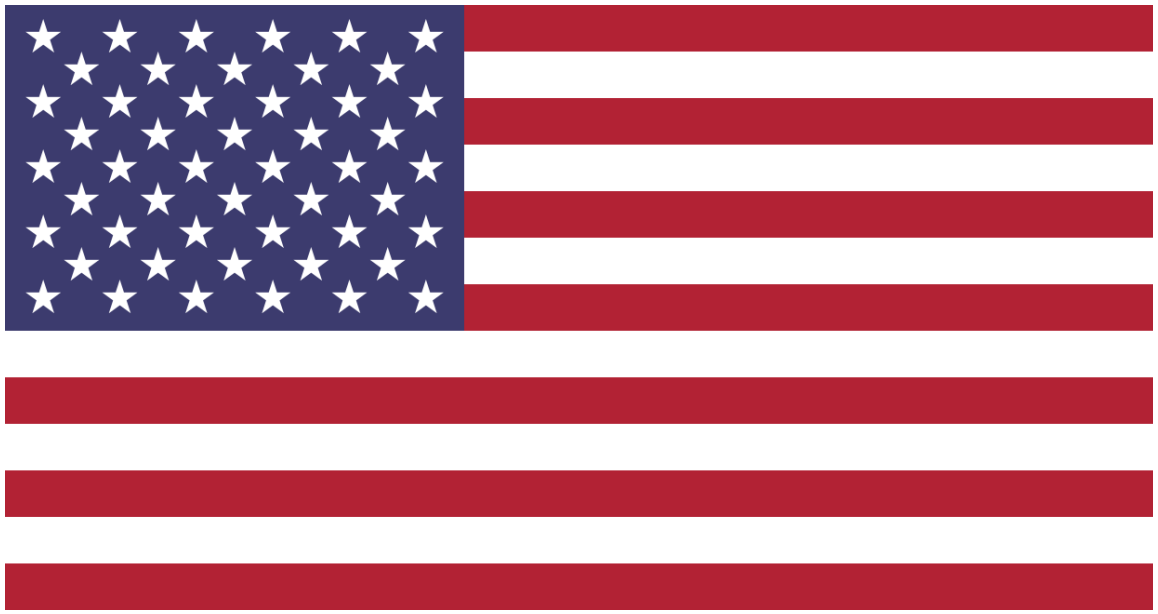
UNITED STATES



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1. Regulatory Forecast	Each regulatory agency, including independent regulatory agencies, must prepare semi-annually a Unified Agenda of Regulatory and Deregulatory Actions that includes all regulations under development or review. Executive Order 12866 (Sept. 30, 1993) at § 4(b). The description of each regulatory action shall contain a regulation identification number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. As part of the Unified Agenda, agencies shall prepare an annual Regulatory Plan (released in conjunction with the fall Agenda) including "the most important significant regulatory actions" that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. Executive Order 12866 (Sept. 30, 1993) at § 4(c). The Plan must include a statement of the agency's regulatory objectives and priorities, a summary of each planned significant regulatory action, a summary of the legal basis for the action, a statement of all need for such action, the agency's schedule for action, and the contact information for a knowledgeable agency official. Executive Order 12866 (Sept. 30, 1993) at § 4(c). A significant regulatory action is defined as any regulatory action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs; or raise novel legal or policy issues. Executive Order 12866 (Sept. 30, 1993) at § 3(f). The Unified Agenda shall be made available to Congress; State, local, and tribal governments; and the public. Executive Order 12866 (Sept. 30, 1993) at § (4)(c)(7). Unless otherwise required by law or unless the OMB Director approves in advance and in writing the issuance of a regulation, no regulation may be issued unless it was included in the Unified Agenda. Executive Order 13771 (Jan. 30, 2017) at § 3(c). The Order, however, indicates that no statements contained in Order 13771 should be construed to impair the OMB Director's functions "relating to budgetary, administrative, or legislative proposals." Executive Order 13771 (Jan. 30, 2017) at § 5(a)(ii).
2. National Regulatory Register	The Federal Register, created by the Federal Register Act, publishes an official publication every working day. 44 U.S.C. § 1504. The Federal Register has four main sections: (1) presidential documents; (2) final rules; (3) proposed rules; and (4) notices, which include documents describing official actions and functions of an agency that provide important information, but do not affect a rulemaking proceeding. Pursuant to the Administrative Procedure Act, a general notice of proposed administrative action, such as a rule, shall be published in the Federal Register and must include a statement of the time, place, and nature of public rule making proceedings, reference to the authority under which the rule is proposed, and either the terms or substance of the proposed rule or a description of the subjects and issues involved. 5 U.S.C. § 553. Certain proposed regulatory actions are exempt from publication in the Federal Register. Specifically, an agency may issue a final rule without publishing a proposed rule in the Federal Register if the agency has "good cause" to find that the notice and comment process would be "impracticable, unnecessary, or contrary to public interest."

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	The agency may designate such a rule as either an "interim final rule" or a "direct final rule." Where the agency designates the rule an "interim final rule," it normally will stipulate that it will alter the interim rule if warranted by public comments. If the agency decides not to make changes to the interim rule, it generally will publish a brief final rule in the Federal Register confirming that decision. *See* A Guide to the Rulemaking Process. An agency may designate a proposed rule a "direct final rule" where it decides that a proposed rule would only relate to routine or uncontroversial matters. In a direct final rule, the agency states that the rule will go into effect on a certain date, unless it gets substantive adverse comments during the comment period. An agency may finalize this process by publishing a notice in the Federal Register confirming it received no adverse comments. If adverse comments are submitted, the agency is required to withdraw the direct final rule before the effective date. The agency may re-start the process by publishing a conventional proposed rule or decide to end the rulemaking process entirely. 49 C.F.R. § 190.339. Moreover, interpretive rules, general statements of policy, or rules of agency organization do not need to be published in the Federal Register. Finally, proposed rules involving military, naval, or foreign affairs are not subject to publication requirements. 5 U.S.C. § 553. Rulemaking materials, including the proposed rule, any Regulatory Impact Analysis, and scientific or technical studies, are also publicly available at www.regulations.gov. A department or agency head must approve publication of any proposed or final regulation in the Federal Register prior to publication. Jan. 20, 2009 Memorandum regarding Regulatory Review. The National Archivist is charged with custody of the Federal Register. 44 U.S.C. § 1502.
3. Advanced Notice of Proposed Rulemaking	An agency in the preliminary stages of rulemaking may publish an "Advance Notice of Proposed Rulemaking" in the Federal Register. The Advance Notice is a formal invitation to participate in shaping the proposed rule and initiates the notice-and-comment process. An agency is not, however, required to issue an Advance Notice of Proposed Rulemaking unless a specific statute or the agency's own rules require it to do so. If an agency chooses to use an Advance Notice of Proposed Rulemaking, it still must issue a Notice of Proposed Rulemaking before issuing a final rule. The Advance Notice of Proposed Rulemaking is typically published in the proposed rule section of the Federal Register. Any party interested may respond to the Advance Notice by submitting comments aimed at developing and improving the draft proposal or by recommending against issuing a rule. *See* A Guide to the Rulemaking Process.
4. Opportunity for Public Comment and Participation	The Administrative Procedure Act requires that an agency afford interested parties an opportunity to participate in the rulemaking process through the submission of written data, views, or arguments. 5 U.S.C. § 553.Each agency is required to provide to the public an opportunity to participate in the regulatory process. Executive Order 12866 (Sept. 30, 1993) at § 6(a); Executive Order 13563 (Jan. 19, 2011) at § 2(b); Executive Order 13579 (July 11, 2011) at § 1(a). Consequently, each agency, to the extent feasible must allow the public a meaningful opportunity to comment through the Internet (www.regulations.gov) on any proposed regulation. In most cases, the comment period should last at least 60 days. Executive Order 12866 (Sept. 30, 1993) at § 6(a); Executive Order 13563 (Jan. 18, 2011) at § 2(b).

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	Agencies also are required to invite, on a regular basis, public comments regarding existing regulations and appropriate modifications thereto. Executive Order 13610 (May 10, 2012) at § 2. The public may mail or fax their comments on a proposed rule directly to an agency, or they may comment through a web portal maintained by the federal government at www.regulations.gov. The public may provide written comments to the Office of Information and Regulatory Affairs (OIRA) regarding any rule that is under review. Outside parties may email OIRA to request a meeting with the OIRA administrator or her designee when a draft proposed or draft final rule is under OIRA review. OIRA Q&As. Pursuant to the Logical Outgrowth Doctrine, an agency cannot publish a final rule that contains requirements that were not included in the Notice of Proposed Rulemaking, unless those changes develop as a "logical outgrowth" of the proposed regulation. If an agency chooses to make significant changes to a regulation after the notice-and-comment period, it will need to submit a Supplemental Notice of Proposed Rulemaking, advising the public of the revised proposal and providing an opportunity for additional comment. *See South Terminal Corp. v. EPA*, 504 F.2d 646, 659 (1st Cir. 1974). Moreover, an agency cannot incorporate a document by reference in a final rule if the reference includes any subsequent versions of the document because doing so would circumvent the Administrative Procedure Act's requirement that an agency afford interested parties the ability to comment. 1 C.F.R. § 51.1(f). As a result, an agency cannot incorporate by reference a specific standard "as it may subsequently be amended;" rather, it will need to update the reference to the standard in the rulemaking each time the standard is revised, which is time and resource intensive. Consequently, there are many outdated standards still incorporated by reference in U.S. regulation. OMB Circular A-119, which was updated in 2015, contains relatively recent guidance for agencies on how to address this issue (see #15).
5. Publication of Evidence/ Regulatory Analysis	To the extent feasible and permitted by law, each agency shall provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov, including relevant scientific and technical findings. Executive Order 13563 (Jan. 18, 2011) at § (2)(b). Participating agencies provide these materials at www.regulations.gov. Independent agencies are not required to publish their relevant scientific and technical findings, but many independent agencies still choose to participate. Executive Order 13563 (Jan. 18, 2011) at § 7. For significant regulatory actions, the agency must provide OIRA with an assessment, including the underlying analysis, and quantification, of: • benefits anticipated from the regulatory action (such as, but not limited to, the promotion of efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias); • costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment); and

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	• costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation for why the planned regulatory action is preferable to the identified potential alternatives. Executive Order 12866 (Sept. 30, 1993) at § 6(c). After a final significant regulatory action is published in the Federal Register, the agency must make available to the public at www.regulations.gov the above-described analysis that the agency sent to OIRA. Executive Order 12866 (Sept. 30, 1993) at § 6(a)(3)(E). The Regulatory Flexibility Act further requires that federal agencies consider the impact of regulations on small entities when developing proposed and final rules. Specifically, when an agency is required to publish a general notice of proposed rulemaking for a proposed rule, the agency must prepare and make available for public comment an initial regulatory flexibility analysis, which should include: (1) the reasons why the agency is considering taking action; (2) the objectives and legal basis for the proposed rule; (3) the kind and number of small entities to which the proposed rule will apply; (4) the projected reporting, recordkeeping and other compliance requirements of the proposed rule; and (5) all federal rules that may duplicate, overlap or conflict with the proposed rule. 5 U.S.C. § 603(a)-(b). The initial regulatory flexibility analysis should also include a description of any significant alternatives to the proposed rule. 5 U.S.C. § 603(c). Moreover, under the Regulatory Flexibility Act, once an agency issues a final rule, it must prepare a final regulatory flexibility analysis or certify that the rule will not have a significant economic impact on a substantial number of small entities. The analysis must include: (1) a statement of objectives of the rule; (2) a statement of significant issues raised by public comments and any response thereto; (3) the response of the agency to any comments filed by the Chief Counsel of the Small Business Administration; (4) a description of, and estimate of, the number of small entities to which the rule will apply; (5) a description of the projected reporting, recordkeeping and other compliance requirements; and (6) a description of the steps the agency took to minimize the significant economic impact on small entities. 5 U.S.C. § 604(a). The final regulatory flexibility analysis, or a summary thereof, must be published in the Federal Register. 5 U.S.C. § 604(b).
6. Respond to Stakeholder Input	An agency should respond in a reasoned manner to comments received, explain how the agency resolved any significant problems raised by such comments, and show how that resolution led the agency to the ultimate rule. *Ohio Valley Environmental Coalition v. Hurst*, 604 F. Supp. 2d 860 (S.D. W. Va. 2009). Agencies, however, must only respond to comments that are material to issues raised in a rulemaking proceeding. *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 393-94 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974). A comment is considered material when, if shown to be true, the comment "would require a change in [the] proposed rule." *Louisiana Federal Land Bank Ass'n, FCLA v. Farm Credit Administration*, 336 F.3d 1075, 1080 (D.C. Cir. 2003). The agency's responses are included in the preamble to the final rule.
7. Reasonable period for entry into force	Publication of a final rule must be made 30 days prior to the effective date. 5 U.S.C. § 553. Circular A-119 provides guidance suggesting that "except in urgent circumstances, and where consistent with law and international obligations, agencies must allow a reasonable interval between the publication of final rules and their effective dates, in order to provide affected stakeholders sufficient time to adapt their products and methods of production to comply with the updated or new standard." Section 5(m). The Circular does not provide additional guidance regarding

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	what length of time would be considered "reasonable." For instance, however, WTO members have agreed that a "reasonable" period of time is normally at least six months.
8. **Opportunity for Judicial Review**	The Administrative Procedure Act contemplates judicial review of agency actions, unless a statute precludes judicial review of the action or the agency action is committed to agency discretion by law. Section 10 of the Administrative Procedure Act. Under the Administrative Procedure Act, the reviewing court will set aside agency action if such action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is deferential to the agency, and requires the court to decide, as a matter of law, whether an agency action is supported by the administrative record. Every agency action made reviewable by statute and every final agency for which there is no other adequate remedy in any court is subject to this judicial review. Preliminary, procedural, or intermediate agency action is not reviewable. Section 10 of the Administrative Procedure Act.
9. **Clearly Written and Understandable Regulations/ Directives**	Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other federal regulations. Executive Order 12866 (Sept. 30, 1993) at § 1(10). Each agency is also required to draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty. Executive Order 12866 (Sept. 30, 1993) at § 1(12); *see also* Executive Order 13563 (Jan. 18, 2011) at § 1(a). OIRA, an office within the Office of Management and Budget is responsible for ensuring that proposed significant agency action is consistent with this principle. Executive Order 12866 (Sept. 30, 1993) at § 2(b). OIRA does not review non-significant regulatory actions.
10. **Use of Valid and Reliable Data & Sound Science**	Executive Order 12866 requires that all agencies base their regulatory decision-making on the best reasonably obtainable scientific information. Executive Order 12866 (Sept. 30, 1993) at § 1(a)(7). Each agency is further required to ensure the objectivity of any scientific information and processes used to support the agency's regulatory actions. Executive Order 13563 (Jan. 18, 2011) at § 5. The Director of the Office of Science and Technology Policy (OSTP) is assigned to ensure the highest level of integrity is applied in all aspects of scientific and technological processes. OSTP scientists participate in the OIRA review process for significant regulatory actions where such issues are implicated in draft proposed and draft final rules under review. And, agencies are directed to ensure that, where permitted by law, all scientific findings and conclusions be made available to the public. Mar. 9. 2009 Memorandum Regarding Scientific Integrity. The Office of Management and Budget's Circular A-4, which applies to all significant regulatory actions, requires agencies to "provide documentation that the[ir] analysis is based on the best reasonably obtainable scientific, technical, and economic information available." Section 4. The Office of Management and Budget also released the Information Quality Bulletin for Peer Review, requiring that important scientific information be peer reviewed by qualified specialists before dissemination. The Bulletin establishes the parameters of acceptable peer review standards.

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11. Risk-Based Approach	In developing regulatory actions, agencies should consider "how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency." Executive Order 12866 (Sept. 30, 1993) at § 4(c)(1)(D). OIRA works in conjunction with the Office of Science and Technology Policy to ensure that an agency has conducted an adequate risk assessment to support its proposed significant regulatory actions. Such risk assessments should be objective, realistic, and scientifically balanced. Sept. 20, 2001 Memorandum. The Office of Management and Budget's September 19, 2007 Memorandum Regarding Updated Principles of Risk Analysis provides additional detail regarding how agencies should conduct risk assessments. Specifically, the Memorandum states that agencies should, among other things, establish and maintain a clear distinction between the identification, quantification, and characterization of risks; assess risk quantitatively and qualitatively; state all assumptions, defaults, and uncertainties explicitly when developing a risk assessment; and utilize peer review of risk assessments.
12. Regulatory Impact Analysis (RIA)	Agencies must prepare a Regulatory Impact Analysis for each proposed regulatory measure that OIRA designates as significant. The analysis shall include an assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions. Executive Order 12866 (Sept. 30, 1993) at § 6(a)(3)(B). An agency's Regulatory Impact Analysis for a proposed regulatory measure that OIRA designates as economically significant must also include: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis. Circular A-4. Specifically, the agency must provide the following information when proposing an economically significant regulatory measure: (i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits; (ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and (iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives. Executive Order 12866 (Sept. 30, 1993) at § (6)(a)(3)(C). An economically significant regulatory action is defined as any regulatory action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments. Executive Order 12866 (Sept. 30, 1993) at § 3(f)(1).

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13. Pro-Competitive Analysis	Agencies are required to include an assessment of a significant proposed regulatory action's effects on competition. Specifically, an agency must provide to OIRA as part of the decision making process: • An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (including the promotion of the efficient functioning of the economy and private markets) together with, to the extent feasible, a quantification of those benefits; and • An assessment, including the underlying analysis, of costs anticipated from the regulatory action (including the direct cost to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness)), together with, to the extent feasible, a quantification of those costs. Executive Order 12866 (Sept. 30, 1993) at § (6)(c). At their discretion, the Department of Justice and Federal Trade Commission provide comments on proposed rules regarding the effects those proposed rules may have on competition. The Department of Justice makes its comments available on its website: https://www.justice.gov/atr/comments-federal-agencies. The Federal Trade Commission also makes its comments available on its website: https://www.ftc.gov/policy/advocacy/advocacy-filings.
14. Assessment of International Impact	A federal agency must identify significant regulatory actions that have "significant international impacts." Executive Order 13609 (May 1, 2012) at § 3. Specifically, to the extent permitted by law, each agency shall ensure that significant regulations that the agency identifies as having significant international impacts are designated as such in the Unified Agenda of Federal Regulatory and Deregulatory Actions, on RegInfo.gov, and on Regulations.gov. The agency also shall consider, to the extent feasible, appropriate, and consistent with law, any regulatory approaches by a foreign government that the United States has agreed to consider under a regulatory cooperation council work plan. Executive Order 13609 (May 1, 2012) at § 3. The United States maintains regulatory cooperation councils with Canada and Mexico. Factors to consider in determining whether a regulatory action could have a significant international impact include: • impacts on international economic activity, including trade flows; • impacts on a specific product, group of products, or products in general; • impacts on a specific service, group of services, or services in general; • impacts on health, safety, labor, security, the environment; • the likely anticipated costs and benefits of the regulation; and • whether the regulation would bring the United States into or out of alignment with a relevant international standard, guide, or recommendation.

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	Regulatory Working Group Guidelines For Executive Order 13609 (June 26, 2015).
15. Leverage Private Sector in the Development of Standards & Conformity Assessment	The National Technology Transfer and Advancement Act ("NTTAA"), and the supporting guidance set forth in OMB Circular A-119, establish policies regarding the federal government's role in the development and use of standards and conformity assessments. The NTTAA requires that the federal government "coordinate the use by Federal agencies of private sector standards, emphasizing where possible the use of standards developed by private, consensus organizations." 15 U.S.C. § 272(b)(3). Section 12(d)(1) of the NTTAA requires all federal agencies to use voluntary standards in lieu of government-unique standards in their regulatory activities. Circular A-119 encourages reliance on the private sector to develop these voluntary standards for use by the federal government. Section 1. In evaluating whether to adopt a standard, a federal agency should consider certain factors directly related to the private sector, including the prevalence of the use of the standard in the national and international marketplace, and the ability of small- and medium-sized enterprises to comply with the standard. Section 5(a). Agencies are also encouraged to engage with private sector voluntary consensus standards bodies to develop voluntary consensus standards. A voluntary consensus standard body is an association, organization, or technical society that plans, develops, establishes, or coordinates voluntary consensus standards using a voluntary consensus standards development process that is open, balanced, and provides due process. Section 2. Moreover, Section 12(b) of the NTTAA requires the National Institute of Standards and Technology to coordinate federal, state, and local standards activities and conformity assessment activities with private sector standards development and conformity assessment activities. The goal of this coordination is to eliminate unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures. Circular A-119, § 7. Agencies are also tasked with coordinating with the private sector to develop conformity assessments. Circular A-119, § 7. OMB Circular A-119 implements the NTTAA and provides additional guidance to agencies on standards and conformity assessment issues. For example, the Circular: • encourages agencies to allow their staff to participate in standards development activities, and provides guidance for such participation; • sets out factors for agencies to consider when evaluating whether to use a standard to meet agency needs, as well as options for how to ensure that references to standards that have been incorporated in regulation are updated on a timely basis: • provides criteria for agencies to consider when assessing the effectiveness of conformity assessment options and determining the types of conformity assessment to employ;

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	• provides guidance on when agencies should consider using or recognizing a standard or conformity assessment procedure used by a trading partner; • strengthens the role of agency Standards Executives, the senior officials in each federal agency in charge of standards and conformity assessment; • lays out relevant international trade obligations with respect to standards and conformity assessment. In particular, the Annex to the Circular contains the Decision of the [WTO TBT] Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the [WTO TBT] Agreement. The Committee Decision sets out six principles that should be observed when developing international standards, guides and recommendations, namely: (1) transparency; (2) openness; (3) impartiality and consensus; (4) effectiveness and relevance; (5) coherence; and (6) development dimension. Because the TBT Agreement did not designate specific bodies as having the exclusive right to develop international standards, the members of the TBT Committee, through the Committee Decision, set out principles that any body could follow in developing international standards. The Circular encourages U.S. agencies to keep these principles in mind when evaluating whether to incorporate a particular standard in regulation.
16. **Ex-Post Assessments of Regulatory Impacts**	Agencies are required to periodically review all existing significant regulatory actions to determine whether any such regulatory actions should be modified or eliminated as inappropriately burdensome or duplicative. Executive Order 12866 (Sept. 30, 1993) at § 5. Such periodic reviews should be made available online to the public. Executive Order 13563 (Jan. 18, 2011) at § 6; *see also* Executive Order 13579 (July 11, 2011) at § 2; Executive Order 13610 (May 10, 2011). The Implementing Guidance for Executive Order 13771, which requires an agency proposing a new rule to also propose two existing regulations for repeal, requires that agencies review existing rules to determine whether they should be considered for deregulation. Specifically, agencies should identify regulations that: • Eliminate jobs or inhibit job creation; • Are outdated, unnecessary, or ineffective; • Impose costs that exceed benefits; • Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies; or • Derive from or implement Executive Orders or other Presidential directives that have been rescinded or substantially modified.

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17. Located Close to Important Government Decision Makers	OIRA is a part of the Office of Management and Budget, which is an agency within the Executive Office of the President. OIRA was established by the 1980 Paperwork Reduction Act. The OIRA Administrator is nominated by the President and confirmed by the Senate. Paperwork Reduction Act of 1995, § 3503. OIRA is tasked with providing guidance to agencies regarding regulatory actions, and coordinating regulatory planning at the federal level. It is also the entity that reviews and approves drafts proposed and draft final significant regulatory actions before they can be published in the Federal Register. Executive Order 12866 (Sept. 30, 1993) at §§ 2(b), 6(b). OIRA is required to provide an annual report to Congress detailing the costs and benefits of federal rules. 31 U.S.C. § 1105. OIRA's authorities with respect to significant regulatory actions, regulatory planning, information collection requests, and federal regulatory and information policy, coupled with OIRA's location within the White House agency that has oversight of agency budgets (OMB), enables it to be effective in carrying out its mission.
18. Given Formal Authority of Regulatory Oversight	See #17 above. OIRA is tasked with providing meaningful guidance and oversight of significant regulatory actions. Specifically, OIRA is given formal authority to: review significant regulatory actions before they are proposed for public comment and again before they are issued in final form; and to maintain a publicly available log listing the status of all regulatory actions, a notation of all written communications forwarded to an agency, and the dates and names of individuals involved in all substantive oral communications between OIRA personnel and any person not employed by the executive branch of the Federal Government, as well as the subject matter discussed in that communication. Executive Order 12866 (Sept. 30, 1993) at § 6(b). A list of all meetings held between OIRA and non-executive branch employees (and the participants in such meetings) to discuss rules that are under OIRA review (otherwise known as "EO 12866 meetings") is log is available at www.reginfo.gov. RegInfo is also available as a mobile application, which includes links to the Unified Agenda, a list of rules currently under OIRA review, a list of recently approved proposed rules, and information collection requests. Independent agencies are exempted from OIRA review of their regulations. Executive Order 12866 (Sept. 30, 1993) at § 3(b). If OIRA believes that a proposed agency rule is not consistent with law or with the principles set forth in Executive Order 12866, it issue a Return Letter to the agency and sends the rule back to the agency for further consideration. The agency must address deficiencies identified in the OIRA review process before OIRA will approve the draft proposed or draft final rule for publication. Sept. 20, 2001 Memorandum. OIRA and agencies generally engage in less formal exchanges when reviewing proposed rules, in which the parties exchange drafts numerous times. OIRA is also tasked with sending prompt letters to agencies to pro-actively suggest issues agencies might address. Sept. 20, 2001 Memorandum.

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	In addition, pursuant to the Paperwork Reduction Act of 1995, OIRA is tasked with overseeing the use of information resources to improve the efficiency and effectiveness of governmental operations. § 3503. The Paperwork Reduction Act also requires agencies to submit information collection requests to OIRA for approval. The Information Collection Request (ICR) Approval process can, in some cases, take up to more than 200 days to complete. The process proceeds as described below: • The agency must publish a 60-Day Federal Register Notice, which includes a description of the proposed information collection; a description of the intended audience; an estimate of how many respondents are expected to participate; an estimate of the time it will take to complete the information collection; and an estimate of the burden hours on the public. • The agency must consider all of the input received and publish a 30-Day Federal Register Notice to provide the public with an opportunity to comment on the text of the information collection. The 30-Day Notice must also contain: a description of the intended audience; an estimate of how many respondents are expected to participate; an estimate of the time it will take to complete the information collection; and an estimate of the burden hours on the public. • The agency must then prepare an ICR package for submission to OMB. The package must include several components, including: a statement of justification explaining the purpose, scope and benefits of the collection; the relevant legal instruments; a privacy impact statement if the ICR involves the collection of personally identifiable information, and a summary of all comments received during the 60-day notice period. • OMB will review and issue a Notice of Action that contains one of three responses: Approval; Disapproval with a process for appeal; or Withdrawal. After OMB approves an ICR, the agency seeking the information collection is approved to work with the Office of Personnel Management to conduct the collection. Paperwork Reduction Act Guide. Where an Information Collection Request is submitted in association with a Notice of Proposed Rulemaking, it appears that the agency is not required to separately publish the Information Collection Request in the Federal Register and may instead publish it as part of the Notice of Proposed Rulemaking. *See* Paperwork Reduction Act Guide.
19. Staffed with Experts and Given Independence	OIRA employs between 40-50 full-time career public servants. Historically, OIRA staff have had graduate training in economics, policy analysis, statistics, and information technology. In recent years, OIRA has sought out employees with expertise in public health, toxicology, epidemiology, engineering, and other technical fields. OIRA Q&As. OIRA is tasked with being the "repository of expertise concerning regulatory issues, including methodologies and procedures . . . ." Executive Order 12866 (Sept. 30, 1993) at § 2(b).

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20. Given the Necessary Scope of Review to be Effective	OIRA only reviews actions identified by OIRA as significant regulatory actions. A significant regulatory action is defined as any regulatory action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs; or raise novel legal or policy issues. Executive Order 12866 (Sept. 30, 1993) at § 3(f). OIRA does not review regulations issued in accordance with the formal rulemaking procedure set forth in 5 U.S.C. §§ 556, 557; regulations or rules that pertain to a military or foreign affairs function; regulations or rules that are limited to agency organization, management, or personnel matters; or any other category of regulations exempted by the OIRA Administrator. Executive Order 12866 (Sept. 30, 1993) at § (3)(d).
21. Establish and Foster Good Regulatory Practices and Principles of Regulation	OIRA is tasked with ensuring that significant regulatory actions are consistent with the principles of good regulatory practices set out in Executive Order 12866 (Sept. 30, 1993) at § 2(b). OIRA reviews all significant regulatory actions to determine whether those actions align with good regulatory practices. Specifically, OIRA determines whether the agency has assessed the costs and benefits of available regulatory alternatives; conducted an adequate risk assessment; and, if applicable, assessed the impact of the regulatory action on state, local, or tribal governments, energy supply, production and consumption, other federal agencies, and small businesses. See Sept. 20, 2001 Memorandum. OIRA also provides guidance to agencies regarding good regulatory practices. For example, OMB Circular A-4 provides guidance on how to conduct regulatory impact analyses for significant regulatory actions.
22. Ensure Forward Planning of Regulatory Activity	Each regulatory agency, including independent regulatory agencies, must prepare and submit semi-annually to OIRA a Unified Agenda of all regulatory and deregulatory actions under development or review. Executive Order 12866 (Sept. 30, 1993) at § 4(b). The description of each regulatory action shall contain a regulation identification number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. No regulation shall be issued if it was not included in a published version of the Unified Agenda, unless the issuance of the regulation was approved in advance in writing by the Director of OMB. Executive Order 13771 (Jan. 30, 2017) at § 3(c). As part of the Unified Agenda, agencies shall prepare a Regulatory Plan including "the most important significant regulatory actions" that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. Executive Order 12866 (Sept. 30, 1993) at § 4(c). The Plan must include a statement of the agency's regulatory objectives and priorities, a summary of each planned significant regulatory action, a summary of the legal basis for the action, a statement of all need for such action, the agency's schedule for action, and the contact information for a knowledgeable agency official. Executive Order 12866 (Sept. 30, 1993) at § 4(c). OIRA shall review all Regulatory Plans to determine whether a planned regulatory action is inconsistent with the President's priorities or the principles set forth in Executive Order 12866 or in conflict with any policy or action taken or planned by another agency. Executive Order 12866 (Sept. 30, 1993) at § 4(c)(5). OIRA also will determine, within 10 days of receipt of the Plan, whether any proposed agency actions are deemed "significant." Executive Order 12866 (Sept. 30, 1993) at § 6(a)(3)(A).

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	Moreover, during the Presidential budget process, the Director of OMB shall identify to agencies a total amount of incremental costs that will be allowed for each agency in issuing new regulations and repealing regulations for the next fiscal year. No regulations exceeding the agency's allowance will be permitted, unless required by law or approved in writing by the Director. Executive Order 13771 (Jan. 30, 2017) at § 3(d).
23. Review Proposed and Final Regulatory Measures before they are Published	OIRA is required to review significant substantive regulatory actions before the agency can propose them for public comment and again before the agency can issue them in final form. The OIRA desk officer with responsibility for a specific agency makes the determination as to whether a draft rule is significant and thus, whether it is subject to OIRA review. A significant regulatory action is defined as any regulatory action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs; or raise novel legal or policy issues. Executive Order 12866 (Sept. 30, 1993) at § 3(f). OIRA also does not review regulations or rules issued in accordance with the formal rulemaking procedure set forth in 5 U.S.C. §§ 556, 557; regulations or rules that pertain to a military or foreign affairs function; regulations or rules that are limited to agency organization, management, or personnel matters; regulations or rules issued by independent regulatory agencies; or any other category of regulations exempted by the OIRA Administrator. Executive Order 12866 (Sept. 30, 1993) at § (3)(d). OIRA reviews all significant regulatory actions to determine whether the agency has assessed the costs and benefits of available regulatory alternatives; conducted an adequate risk assessment; and, if applicable, assessed the impact of the regulatory action on state, local, or tribal governments, energy supply, production and consumption, other federal agencies, and small businesses. See Executive Order 12866 (Sept. 30, 1993) at § 6(c); Sept. 20, 2001 Memorandum. OIRA also forwards drafts to other agencies with equities (e.g., OSTP for science issues, USTR for trade issues) for their review and clearance. The drafts may often undergo more than one round of interagency review before the regulator has addressed all of the comments to the satisfaction of the other agencies. In some cases, final clearance may require that some issues are elevated to the political level for disposition. Pursuant to Executive Order 12866, OIRA must either waive its review or inform the agency of the results of its review within 90 days, with the option to extend one time for 30 additional days. Executive Order 12866 (Sept. 30, 1993) at § 6(b)(2)(B). In practice, however, rules may remain under OIRA review for much longer if, for example, a rule is particularly controversial.
24. Coordinate International Regulatory Cooperation	The Regulatory Working Group established by Executive Order 12866 is responsible for coordinating international regulatory cooperation activities that are reasonably anticipated to lead to significant regulatory actions, as well as efforts across the Federal Government to support significant, cross-cutting international regulatory cooperation activities, such as the work of regulatory cooperation councils. The Regulatory Working Group also promotes good regulatory practices internationally. The Regulatory Working Group is also responsible for examining appropriate strategies for engaging in the development of regulatory approaches

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	through international regulatory cooperation, best practices for international regulatory cooperation with respect to regulatory development, and factors that agencies should take into account when determining whether and how to consider other regulatory approaches. Executive Order 13609 (May 1, 2012) at § 2. The Administrator of OIRA is responsible for convening this Regulatory Working Group and serves as the Chair of the Regulatory Working Group ("RWG"), which consists of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility, Advisors, and the Vice President. Executive Order 12866 (Sept. 30, 1993) at § 4(c)(7). It is rare for the Administrator to convene the RWG; normally RWG meetings are held at the staff level. It is important to note that other federal agencies have authorities for international regulatory cooperation, including USTR, State, and Treasury, that are exempted from Executive Order 13609. Executive Order 13609 (May 1, 2012) at § 6. For instance, USTR has statutory authority to negotiate mutual recognition agreements. Thus, there is no single lead federal agency for international regulatory cooperation. Moreover, federal agencies are required to consider, to the extent feasible, appropriate, and consistent with law, any regulatory approaches by a foreign government that the United States has agreed to consider under a regulatory cooperation council work plan. Executive Order 13609 (May 1, 2012) at § 3. The United States maintains regulatory cooperation councils with Canada and Mexico.