By the authority vested in me as President by the Constitution and laws of the United States of America, it is hereby ordered that Executive Order 12866 of September 30, 1993, as amended, is further amended as follows:

Section 1. Section 1 is amended as follows:

(a) Section 1(b)(1) is amended to read as follows:

“(1) Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted.”

(b) by inserting in section 1(b)(7) after “regulation” the words “or guidance document”.

(c) by inserting in section 1(b)(10) in both places after “regulations” the words “and guidance documents”.

(d) by inserting in section 1(b)(11) after “its regulations” the words “and guidance documents”.

(e) by inserting in section 1(b)(12) after “regulations” the words “and guidance documents”.

Sec. 2. Section 2 is amended as follows:

(a) by inserting in section 2(a) in both places after “regulations” the words “and guidance documents”.

(b) by inserting in section 2(b) in both places after “regulations” the words “and guidance documents”.

Sec. 3. Section 3 is amended as follows:

(a) by striking in section 3(d) “or ‘rule’ ” after “ ‘Regulation’ ”;

(b) by striking in section 3(d)(1) “or rules” after “Regulations”;

(c) by striking in section 3(d)(2) “or rules” after “Regulations”;

(d) by striking in section 3(d)(3) “or rules” after “Regulations”;

(e) by striking in section 3(e) “rule or” from “final rule or regulation”;

(f) by striking in section 3(f) “rule or” from “rule or regulation”;

(g) by inserting after section 3(f) the following:

“(g) ‘Guidance document’ means an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.

(h) ‘Significant guidance document’ —

(1) Means a guidance document disseminated to regulated entities or the general public that, for purposes of this order, may reasonably be anticipated to:
(A) Lead to an annual effect 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; (B) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (C) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or (D) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order; and (2) Does not include: (A) Guidance documents on regulations issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557; (B) Guidance documents 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; (C) Guidance documents on regulations that are limited to agency organization, management, or personnel matters; or (D) Any other category of guidance documents exempted by the Administrator of OIRA.”

Sec. 4. Section 4 is amended as follows:

(a) Section 4(a) is amended to read as follows: “The Director may convene a meeting of agency heads and other government personnel as appropriate to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.”

(b) The last sentence of section 4(c)(1) is amended to read as follows: “Unless specifically authorized by the head of the agency, no rulemaking shall commence nor be included on the Plan without the approval of the agency’s Regulatory Policy Office, and the Plan shall contain at a minimum:”.

(c) Section 4(c)(1)(B) is amended by inserting “of each rule as well as the agency’s best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities” after “of the anticipated costs and benefits”.

(d) Section 4(c)(1)(C) is amended by inserting “, and specific citation to such statute, order, or other legal authority” after “court order”.

Sec. 5. Section 6 is amended as follows:

(a) by inserting in section 6(a)(1) “In consultation with OIRA, each agency may also consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations” after “comment period of not less than 60 days.”

(b) by amending the first sentence of section 6(a)(2) to read as follows: “Within 60 days of the date of this Executive order, each agency head shall designate one of the agency’s Presidential Appointees to be its Regulatory Policy Officer, advise OMB of such designation, and annually update OMB on the status of this designation.”

Sec. 6. Sections 9–11 are redesignated respectively as sections 10–12.

Sec. 7. After section 8, a new section 9 is inserted as follows:

“Sec. 9. Significant Guidance Documents. Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with advance notification of any significant guidance documents. Each agency shall take such steps as are necessary for its Regulatory Policy Officer to ensure the agency’s compliance with the requirements of this section. Upon the request of the Administrator, for each matter identified as, or determined by the Administrator to be, a significant guidance document, the issuing agency shall provide to
OIRA the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need. The OIRA Administrator shall notify the agency when additional consultation will be required before the issuance of the significant guidance document.”

Sec. 8. Newly designated section 10 is amended to read as follows:

“Sec. 10. Preservation of Agency Authority. Nothing in this order shall be construed to impair or otherwise affect the authority vested by law in an agency or the head thereof, including the authority of the Attorney General relating to litigation."

THE WHITE HOUSE,