The Federal Rulemaking Process

Federal agencies are created and empowered by Congress to protect the public from dangerous food and products, ensure ethical and fair market behavior, promote equal educational opportunity and civil rights, and preserve and advance American democracy, prosperity, health, and welfare. Agencies like the Environmental Protection Agency, the Consumer Product Safety Commission, the Occupational Safety and Health Administration, and others achieve these goals in large part by crafting and issuing regulations. This process, called rulemaking, is governed by several statutes and executive orders that require an agency to solicit and consider public comment, perform rigorous analyses of costs and benefits, and work with other government actors such as the Office of Management and Budget (OMB), the Small Business Administration (SBA), and the Congress before issuing a final rule.

Several statutes and executive orders added new requirements to the rulemaking process in the 1990s. The stated purpose of these new rules was to make agencies more responsive to the concerns of businesses. The effect was to add major costs and delays to a process that already operated slowly and carefully. In spite of this, industry groups and their allies perennially call for adding more requirements to the rulemaking process, delaying new rules, and making them more costly to produce. Fair and informed consideration of these proposals requires awareness of the existing rulemaking process. Agencies do not rapidly and unilaterally issue new regulations; instead, the process is full of studies, panels, and opportunities for the public, industry, and other government bodies to provide input.

40 YEARS PUBLIC CITIZEN

Agencies may submit proposals to collect information to OMB.

- 44 U.S.C. § 3502(3) The term "collection of information" means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either—
  - (i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons, other than agencies, instrumentalities, or employees of the United States; or
  - (ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes, related to similar outcomes.
- 5 C.F.R. § 1320.3(c) Collection of information.
  - (1) Forms and collections of information before submission to the OMB Review for review under the subchapter, including—
    - (i) An explanation of the need for the collection of information;
    - (ii) A description of the information to be collected;
    - (iii) A description of the collection of information;
    - (iv) A description of the burden of the collection of information;
    - (v) A total of the collection of information through a joint proposal, if appropriate; and
    - (vi) Any certification that the collection of information is not in violation of the criteria, including necessary resources.
  - (2) Factors that must accompany each collection of information.
    - (i) Minimize the burden of the collection of information on those who are to respond;
    - (ii) Maximize the collection in accordance with the resources requirements of section 3507; and
    - (iii) Minimize the burden of the collection of information on—
      - (A) The persons the information is being collected;
      - (B) The way such information is to be used;
      - (C) The extent to which the information will be shared by the collection;
      - (D) The frequency with which it is collected; and
      - (E) The steps that have been taken to obtain comment, and advice to staff required to respond to, collection of information unless it displays a valid control number.
- 44 U.S.C. § 3506(c)(2)(A) Each agency shall provide 60 day notice in the Federal Register, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information, to solicit comment to—
  - (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
  - (ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;
  - (iii) enhance the quality, utility, and clarity of the information to be collected; and
  - (iv) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.
- 44 U.S.C. § 3506(c)(3) Each agency shall certify (and provide a record supporting such certification, including public comment received by the agency) that each collection of information submitted to the OMB Review for review—
  - (A) is necessary for the proper performance of the functions of the agency, including that the information has practical utility;
  - (B) is not unnecessarily duplicative of information otherwise reasonably accessible to the agency;
  - (C) reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities, as defined under 5 U.S.C. § 601 (d), the use of such techniques as—
    - (i) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond;
    - (ii) the clarification, consolidation, or simplification of compliance and reporting requirements; or
    - (iii) an exemption from coverage of the collection of information, or any part thereof;
  - (D) is written using plain, coherent, and unambiguous terms that are understandable to those who are to respond;
  - (E) is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond;
  - (F) indicates for each recordkeeping requirement the length of time persons are required to maintain the records specified;
  - (G) informs persons who are to respond to the collection of information—
    - (i) why the information is being collected;
    - (ii) how such information will be used;
    - (iii) if applicable, the time during which the person is required to maintain the information specified;
    - (iv) whether responses to the collection of information are voluntary, required to obtain a benefit, or mandatory; and
    - (v) the fact that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a valid control number.
  - (H) was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of the information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public;
  - (I) uses effective and efficient statistical survey methodology appropriate to the purpose for which the information is to be collected; and
  - (J) to the maximum extent practicable, uses information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public.
- 44 U.S.C. § 3507 An agency shall not conduct or sponsor the collection of information unless in advance of the adoption or revision of the collection of information—
  - (1) the agency has—
    - (A) conducted the review established under 44 U.S.C. § 3506 (c)(1);
    - (B) evaluated the public comments received under 44 U.S.C. § 3506(c)(2);
    - (C) submitted to the Director the certification required under 44 U.S.C. § 3506(c)(3), the proposed collection of information, copies of pertinent statutory authority, regulations, and other related materials as the OMB Director may specify; and
    - (D) published a notice in the Federal Register—
      - (i) stating that the agency has made such submission; and
      - (ii) setting forth—
        - I. a title for the collection of information;
        - II. a summary of the collection of information;
        - III. a brief description of the need for the information and the proposed use of the information;
        - IV. a description of the likely respondents and proposed frequency of response to the collection of information;
        - V. an estimate of the burden that shall result from the collection of information; and
        - VI. notice that comments may be submitted to the agency and OMB Director;
  - (2) The Director has approved the proposed collection of information or approval has been inferred, under the provisions of this section; and
  - (3) the agency has obtained from the OMB Director a control number for or displayed upon the collection of information.

Agency revises and resubmits or withdraws the proposed information collection.

OMB reviews the proposed information collection under Paperwork Reduction Act.

- 44 U.S.C. § 3507(h) The OMB Director shall provide at least 30 days for public comment prior to approving a collection of information under 44 U.S.C. § 3507(c), (d), (f), except under 44 U.S.C. § 3507(j).
- 44 U.S.C. § 3507(e) For any proposed collection of information contained in a proposed rule (to be reviewed by OMB under 44 U.S.C. § 3507(d)), the agency shall—
  - (1) consider each comment received under section 553(c) of title 5;
  - (2) include in the explanation given under section 553(c) of title 5, responses to the comments, if any, received under section 553(c) of title 5;
  - (3) in the response to a comment under paragraph (2), explain how any modification of the collection of information addresses the comment; and
  - (4) make compatible any information collection certification with the final action of the agency with respect to the rule with which the collection is associated.
- 44 U.S.C. § 3507(j) Public protection.
  - (1) Notwithstanding any other provision of law, no person shall be subject to penalty for failing to maintain, provide, or disclose to or for, or obtain approval of a collection of information from, any agency if—
    - (A) the collection of information—
      - (i) is conducted or sponsored by the agency in modification of a rule published in the Federal Register to implement a statute adopted before the effective date of this subsection; and
      - (ii) is not substantially consistent with or in addition to that rule; or
    - (B) after the effective date of this subsection, the collection of information is conducted or sponsored by the agency in modification of a rule published in the Federal Register to implement a statute adopted after such effective date, and—
      - (i) the collection of information is not necessary for the proper performance of the functions of the agency, including that the information has practical utility;
      - (ii) the agency fails to demonstrate that it has taken every reasonable step to ensure that the collection of information—
        - (I) is the least burdensome necessary for the proper performance of the agency, including that the information has practical utility; and
        - (II) is not duplicative of information otherwise accessible to the agency; and
      - (iii) the collection of information is the initial collection of information by the agency from the public after such effective date.
  - (2) A person may assert a violation of this subsection as an affirmative defense in a judicial or administrative proceeding, and a court or agency may not impose a penalty on a person who is entitled to assert an affirmative defense under this subsection.
  - (3) An employee of the United States shall not be subject to a penalty for failing to comply with a collection of information that does not display a valid control number.

OMB disapproves the proposed information collection.

- See 44 U.S.C. § 3507(h).

OMB approves the proposed information collection.

- 44 U.S.C. § 3507(a) Not more than 60 days before the beginning of the period during which a collection of information is conducted under this section, the head of each agency shall provide in the agency's budget justification submitted to the Director of the Office of Management and Budget a written certification that—
  - (1) the collection of information—
    - (A) is necessary for the proper performance of the functions of the agency, including that the information has practical utility;
    - (B) is not unnecessarily duplicative of information otherwise reasonably accessible to the agency;
    - (C) reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities, as defined under section 601(6) of title 5, the use of such techniques as—
      - (i) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond;
      - (ii) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
      - (iii) an exemption from coverage of the collection of information, or any part thereof;
    - (D) is written using plain, coherent, and unambiguous terms that are understandable to those who are to respond;
    - (E) is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond;
    - (F) indicates for each recordkeeping requirement the length of time persons are required to maintain the records specified;
    - (G) informs persons who are to respond to the collection of information—
      - (i) why the information is being collected;
      - (ii) how such information will be used;
      - (iii) if applicable, the time during which the person is required to maintain the information specified;
      - (iv) whether responses to the collection of information are voluntary, required to obtain a benefit, or mandatory; and
      - (v) the fact that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a valid control number.
    - (H) was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of the information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public;
    - (I) uses effective and efficient statistical survey methodology appropriate to the purpose for which the information is to be collected; and
    - (J) to the maximum extent practicable, uses information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public.
  - (2) the agency has—
    - (A) conducted the review established under section 3506(c)(1);
    - (B) evaluated the public comments received under section 3506(c)(2);
    - (C) submitted to the Director the certification required under section 3506(c)(3), the proposed collection of information, copies of pertinent statutory authority, regulations, and other related materials as the Director may specify; and
    - (D) published a notice in the Federal Register—
      - (i) stating that the agency has made such submission; and
      - (ii) setting forth—
        - I. a title for the collection of information;
        - II. a summary of the collection of information;
        - III. a brief description of the need for the information and the proposed use of the information;
        - IV. a description of the likely respondents and proposed frequency of response to the collection of information;
        - V. an estimate of the burden that shall result from the collection of information; and
        - VI. notice that comments may be submitted to the agency and OMB Director;
  - (3) the Director has approved the proposed collection of information or approval has been inferred, under the provisions of this section; and
  - (4) the agency has obtained from the OMB Director a control number for or displayed upon the collection of information.

OMB approves the proposed information collection.

OMB approves the proposed information collection consistent with change.

- 44 U.S.C. § 3507(c) Any decision by the OMB Director regarding the approval or disapproval of a proposed collection of information, or any decision to withdraw a previously approved collection of information, shall be publicly available and include an explanation of the reasons for such decision.

OMB may send agency prompt letters.

- Memo from OMB Administrator John Graham to OMB Regulatory Review Managers and Executive Staff, "Implementation of Executive Order 13422 Amendments to Regulatory Review and Planning Executive Order," (Feb. 7, 2007) (directing OMB to "encourage agencies to submit draft regulatory actions that are consistent with Administration policies, particularly those that are likely to have significant benefits, cost-effective alternatives, or significant distributional consequences. For example, the regulation might be final or otherwise sufficiently developed that it could be issued in a relatively short period of time, such as a year or less. Agencies should also submit 'breakthrough' rules, including rules that would significantly reduce the burdens associated with existing regulations.")

Agency may publish an advance notice of proposed rulemaking.

- 5 U.S.C. § 553(b) When an rule is a promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule or the official of the agency with statutory responsibility for the promulgation of the rule shall assure that small entities have been given an opportunity to participate in the rulemaking for the rule through the procedures set forth herein and in section 610 of this title to the fullest extent possible, consistent with the objectives of the statute under which the rule is promulgated, by preparing an initial regulatory flexibility analysis pursuant to section 603 of this title unless the head of the agency certifies that the rule will not have a substantial economic impact on a substantial number of small entities.
- Exemption 552(b)(5) Except that to the publication of any notice of proposed rulemaking, the Federal Trade Commission, the Securities and Exchange Commission, or any successor agency, shall not be required to comply with the provisions of section 553(b) of this title.
- Exemption 552(b)(6) Except that to the publication of any notice of proposed rulemaking, the Federal Trade Commission, the Securities and Exchange Commission, or any successor agency, shall not be required to comply with the provisions of section 553(b) of this title.
- Exemption 552(b)(3) If the Commission finds that the public interest requires that the provisions of section 553(b) of this title are inapplicable to a rule, such finding shall be published with the rule.
- Exemption 552(b)(2) If the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that the provisions of section 553(b) of this title are impracticable, unnecessary, or contrary to the public interest.

Agency may solicit public opinion.

- Department of Labor Memo by Employee Benefits Security Administration Assistant Secretary Ann L. Combs, "Publication of Interpretive Bulletin Relating to the Fiduciary Standards Under ERISA in Connection with the Proxy Voting by Plan Fiduciaries of Securities Held by Plan," (Dec. 21, 2006) (stating that the agency would solicit public comment on a proposed rule to amend a regulation).

Agency may receive petitions for rulemaking.

- 5 U.S.C. § 553(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

Agency may hold public meetings.

- National consultation for agencies to solicit voluntary suggestions, not comments.

Agency may solicit the advice of federal advisory committees.

- Federal Advisory Committee Act, 5 U.S.C. App. 2 § 9(a)(2) Subject to section 552b of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, and other documents which were made available to or prepared for or by each advisory committee shall be kept by the agency establishing such committee.
- Guidance to advisory committees and agencies can be found at http://www.fido.gov/facadb/publications.htm.
- Guidance to agencies on how to use advisory committees can be found at http://www.fido.gov/facadb/publications.htm.
- Guidance to advisory committees on how to conduct their business