

5 USC Ch. 6: THE ANALYSIS OF REGULATORY FUNCTIONS

From Title 5—GOVERNMENT ORGANIZATION AND EMPLOYEES PART I—THE AGENCIES GENERALLY

CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

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§601. Definitions

For purposes of this chapter—

(1) the term "agency" means an agency as defined in section 551(1) of this title;

(2) the term "rule" means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title, or any other law, including any rule of general applicability governing Federal grants to State and local governments for which the agency provides an opportunity for notice and public comment, except that the term "rule" does not include a rule of particular applicability relating to rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services, or allowances therefor or to valuations, costs or accounting, or practices relating to such rates, wages, structures, prices, appliances, services, or allowances;

(3) the term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(4) the term "small organization" means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(5) the term "small governmental jurisdiction" means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the Federal Register;

(6) the term "small entity" shall have the same meaning as the terms "small business", "small organization" and "small governmental jurisdiction" defined in paragraphs (3), (4) and (5) of this section; and

(7) the term "collection of information"—

(A) 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, 10 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; and

(B) shall not include a collection of information described under section 3518(c)(1) of title 44, United States Code.

(8) Recordkeeping requirement.—The term "recordkeeping requirement" means a requirement imposed by an agency on persons to maintain specified records.

(Added Pub. L. 96–354, §3(a), Sept. 19, 1980, 94 Stat. 1165; amended Pub. L. 104–121, title II, §241(a)(2), Mar. 29, 1996, 110 Stat. 864.)

§602. Regulatory agenda

(a) During the months of October and April of each year, each agency shall publish in the Federal Register a regulatory flexibility agenda which shall contain—

(1) a brief description of the subject area of any rule which the agency expects to propose or promulgate which is likely to have a significant economic impact on a substantial number of small entities;

(2) a summary of the nature of any such rule under consideration for each subject area listed in the agenda pursuant to paragraph (1), the objectives and legal basis for the issuance of the rule, and an approximate schedule for completing action on any rule for which the agency has issued a general notice of proposed rulemaking,¹ and

(3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).

(b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.

(c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.

(d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda.

(Added Pub. L. 96–354, §3(a), Sept. 19, 1980, 94 Stat. 1166.)

§603. Initial regulatory flexibility analysis

(a) Whenever an agency is required by section 553 of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretative rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial

regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities. The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule. The agency shall transmit a copy of the initial regulatory flexibility analysis to the Chief Counsel for Advocacy of the Small Business Administration. In the case of an interpretative rule involving the internal revenue laws of the United States, this chapter applies to interpretative rules published in the Federal Register for codification in the Code of Federal Regulations, but only to the extent that such interpretative rules impose on small entities a collection of information requirement.

(b) Each initial regulatory flexibility analysis required under this section shall contain—

- (1) a description of the reasons why action by the agency is being considered;
- (2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
- (3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- (4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- (5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

(c) Each initial regulatory flexibility analysis shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as—

- (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
- (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
- (3) the use of performance rather than design standards; and
- (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

(d)(1) For a covered agency, as defined in section 609(d)(2), each initial regulatory flexibility analysis shall include a description of—

- (A) any projected increase in the cost of credit for small entities;
- (B) any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any increase in the cost of credit for small entities; and
- (C) advice and recommendations of representatives of small entities relating to issues described in subparagraphs (A) and (B) and subsection (b).

(2) A covered agency, as defined in section 609(d)(2), shall, for purposes of complying with paragraph (1)(C)—

- (A) identify representatives of small entities in consultation with the Chief Counsel for Advocacy of the Small Business Administration; and
- (B) collect advice and recommendations from the representatives identified under subparagraph (A) relating to issues described in subparagraphs (A) and (B) of paragraph (1) and subsection (b).

(Added [Pub. L. 96-354, §3\(a\), Sept. 19, 1980, 94 Stat. 1166](#); amended [Pub. L. 104-121, title II, §241\(a\)\(1\), Mar. 29, 1996, 110 Stat. 864](#); [Pub. L. 111-203, title X, §1100G\(b\), July 21, 2010, 124 Stat. 2112](#).)

§604. Final regulatory flexibility analysis

(a) When an agency promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, or promulgates a final interpretative rule involving the internal revenue laws of the United States as described in section 603(a), the agency shall prepare a final regulatory flexibility analysis. Each final regulatory flexibility analysis shall contain—

(1) a statement of the need for, and objectives of, the rule;

(2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;

(4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(5) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(6) ¹ a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected; and

(6) ¹ for a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

(b) The agency shall make copies of the final regulatory flexibility analysis available to members of the public and shall publish in the Federal Register such analysis or a summary thereof.

(Added [Pub. L. 96-354, §3\(a\), Sept. 19, 1980, 94 Stat. 1167](#); amended [Pub. L. 104-121, title II, §241\(b\), Mar. 29, 1996, 110 Stat. 864](#); [Pub. L. 111-203, title X, §1100G\(c\), July 21, 2010, 124 Stat. 2113](#); [Pub. L. 111-240, title I, §1601, Sept. 27, 2010, 124 Stat. 2551](#).)

¹ So in original. Two pars. (6) have been enacted.

§605. Avoidance of duplicative or unnecessary analyses

(a) Any Federal agency may perform the analyses required by sections 602, 603, and 604 of this title in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of such sections.

(b) Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual

basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.

(c) In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.

(Added [Pub. L. 96-354, §3\(a\), Sept. 19, 1980, 94 Stat. 1167](#); amended [Pub. L. 104-121, title II, §243\(a\), Mar. 29, 1996, 110 Stat. 866](#).)

§606. Effect on other law

The requirements of sections 603 and 604 of this title do not alter in any manner standards otherwise applicable by law to agency action.

(Added [Pub. L. 96-354, §3\(a\), Sept. 19, 1980, 94 Stat. 1168](#).)

§607. Preparation of analyses

In complying with the provisions of sections 603 and 604 of this title, an agency may provide either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or more general descriptive statements if quantification is not practicable or reliable.

(Added [Pub. L. 96-354, §3\(a\), Sept. 19, 1980, 94 Stat. 1168](#).)

§608. Procedure for waiver or delay of completion

(a) An agency head may waive or delay the completion of some or all of the requirements of section 603 of this title by publishing in the Federal Register, not later than the date of publication of the final rule, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the provisions of section 603 of this title impracticable.

(b) Except as provided in section 605(b), an agency head may not waive the requirements of section 604 of this title. An agency head may delay the completion of the requirements of section 604 of this title for a period of not more than one hundred and eighty days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 of this title impracticable. If the agency has not prepared a final regulatory analysis pursuant to section 604 of this title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency.

(Added [Pub. L. 96-354, §3\(a\), Sept. 19, 1980, 94 Stat. 1168](#).)

§609. Procedures for gathering comments

(a) When any rule is 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 reasonable use of techniques such as—

(1) the inclusion in an advanced notice of proposed rulemaking, if issued, of a statement that the proposed rule may have a significant economic effect on a substantial number of small entities;

(2) the publication of general notice of proposed rulemaking in publications likely to be obtained by small entities;

(3) the direct notification of interested small entities;

(4) the conduct of open conferences or public hearings concerning the rule for small entities including soliciting and receiving comments over computer networks; and

(5) the adoption or modification of agency procedural rules to reduce the cost or complexity of participation in the rulemaking by small entities.

(b) Prior to publication of an initial regulatory flexibility analysis which a covered agency is required to conduct by this chapter—

(1) a covered agency shall notify the Chief Counsel for Advocacy of the Small Business Administration and provide the Chief Counsel with information on the potential impacts of the proposed rule on small entities and the type of small entities that might be affected;

(2) not later than 15 days after the date of receipt of the materials described in paragraph (1), the Chief Counsel shall identify individuals representative of affected small entities for the purpose of obtaining advice and recommendations from those individuals about the potential impacts of the proposed rule;

(3) the agency shall convene a review panel for such rule consisting wholly of full time Federal employees of the office within the agency responsible for carrying out the proposed rule, the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel;

(4) the panel shall review any material the agency has prepared in connection with this chapter, including any draft proposed rule, collect advice and recommendations of each individual small entity representative identified by the agency after consultation with the Chief Counsel, on issues related to subsections 603(b), paragraphs (3), (4) and (5) and 603(c);

(5) not later than 60 days after the date a covered agency convenes a review panel pursuant to paragraph (3), the review panel shall report on the comments of the small entity representatives and its findings as to issues related to subsections 603(b), paragraphs (3), (4) and (5) and 603(c), provided that such report shall be made public as part of the rulemaking record; and

(6) where appropriate, the agency shall modify the proposed rule, the initial regulatory flexibility analysis or the decision on whether an initial regulatory flexibility analysis is required.

(c) An agency may in its discretion apply subsection (b) to rules that the agency intends to certify under subsection 605(b), but the agency believes may have a greater than de minimis impact on a substantial number of small entities.

(d) For purposes of this section, the term "covered agency" means—

(1) the Environmental Protection Agency;

(2) the Consumer Financial Protection Bureau of the Federal Reserve System; and

(3) the Occupational Safety and Health Administration of the Department of Labor.

(e) The Chief Counsel for Advocacy, in consultation with the individuals identified in subsection (b)(2), and with the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, may waive the requirements of subsections (b)(3), (b)(4), and (b)(5) by including in the rulemaking record a written finding, with reasons therefor, that those requirements would not advance the effective participation of small entities in the rulemaking process. For purposes of this subsection, the factors to be considered in making such a finding are as follows:

(1) In developing a proposed rule, the extent to which the covered agency consulted with individuals representative of affected small entities with respect to the potential impacts of the rule and took such concerns into consideration.

(2) Special circumstances requiring prompt issuance of the rule.

(3) Whether the requirements of subsection (b) would provide the individuals identified in subsection (b)(2) with a competitive advantage relative to other small entities.

(Added [Pub. L. 96–354, §3\(a\), Sept. 19, 1980, 94 Stat. 1168](#); amended [Pub. L. 104–121, title II, §244\(a\), Mar. 29, 1996, 110 Stat. 867](#); [Pub. L. 111–203, title X, §1100G\(a\), July 21, 2010, 124 Stat. 2112](#).)

§610. Periodic review of rules

(a) Within one hundred and eighty days after the effective date of this chapter, each agency shall publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities. Such plan may be amended by the agency at any time by publishing the revision in the Federal Register. The purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities. The plan shall provide for the review of all such agency rules existing on the effective date of this chapter within ten years of that date and for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule. If the head of the agency determines that completion of the review of existing rules is not feasible by the established date, he shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years.

(b) In reviewing rules to minimize any significant economic impact of the rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the agency shall consider the following factors—

- (1) the continued need for the rule;
- (2) the nature of complaints or comments received concerning the rule from the public;
- (3) the complexity of the rule;
- (4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and
- (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

(c) Each year, each agency shall publish in the Federal Register a list of the rules which have a significant economic impact on a substantial number of small entities, which are to be reviewed pursuant to this section during the succeeding twelve months. The list shall include a brief description of each rule and the need for and legal basis of such rule and shall invite public comment upon the rule.

(Added [Pub. L. 96–354, §3\(a\), Sept. 19, 1980, 94 Stat. 1169](#).)

§611. Judicial review

(a)(1) For any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7. Agency compliance with sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of section 604.

(2) Each court having jurisdiction to review such rule for compliance with section 553, or under any other provision of law, shall have jurisdiction to review any claims of noncompliance with sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7. Agency compliance with sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of section 604.

(3)(A) A small entity may seek such review during the period beginning on the date of final agency action and ending one year later, except that where a provision of law requires that an action challenging a final agency action be commenced before the expiration of one year, such lesser period shall apply to an action for judicial review under this section.

(B) In the case where an agency delays the issuance of a final regulatory flexibility analysis pursuant to section 608(b) of this chapter, an action for judicial review under this section shall be filed not later than—

(i) one year after the date the analysis is made available to the public, or

(ii) where a provision of law requires that an action challenging a final agency regulation be commenced before the expiration of the 1-year period, the number of days specified in such provision of law that is after the date the analysis is made available to the public.

(4) In granting any relief in an action under this section, the court shall order the agency to take corrective action consistent with this chapter and chapter 7, including, but not limited to—

(A) remanding the rule to the agency, and

(B) deferring the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

(5) Nothing in this subsection shall be construed to limit the authority of any court to stay the effective date of any rule or provision thereof under any other provision of law or to grant any other relief in addition to the requirements of this section.

(b) In an action for the judicial review of a rule, the regulatory flexibility analysis for such rule, including an analysis prepared or corrected pursuant to paragraph (a)(4), shall constitute part of the entire record of agency action in connection with such review.

(c) Compliance or noncompliance by an agency with the provisions of this chapter shall be subject to judicial review only in accordance with this section.

(d) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise permitted by law.

(Added [Pub. L. 96-354, §3\(a\), Sept. 19, 1980, 94 Stat. 1169](#); amended [Pub. L. 104-121, title II, §242, Mar. 29, 1996, 110 Stat. 865](#).)

§612. Reports and intervention rights

(a) The Chief Counsel for Advocacy of the Small Business Administration shall monitor agency compliance with this chapter and shall report at least annually thereon to the President and to the Committees on the Judiciary and Small Business of the Senate and House of Representatives.

(b) The Chief Counsel for Advocacy of the Small Business Administration is authorized to appear as amicus curiae in any action brought in a court of the United States to review a rule. In any such action, the Chief Counsel is authorized to present his or her views with respect to compliance with this chapter, the adequacy of the rulemaking record with respect to small entities and the effect of the rule on small entities.

(c) A court of the United States shall grant the application of the Chief Counsel for Advocacy of the Small Business Administration to appear in any such action for the purposes described in subsection (b).

(Added Pub. L. 96-354, §3(a), Sept. 19, 1980, 94 Stat. 1170; amended Pub. L. 104-121, title II, §243(b), Mar. 29, 1996, 110 Stat. 866.)