

SBA

SOP 70 20 2

**Regulation Development and
Review Program**

Office of General Counsel

U.S. Small Business Administration



**SMALL BUSINESS ADMINISTRATION
STANDARD OPERATING PROCEDURE**

Headquarters

SUBJECT: Regulation Development and Review Program	S.O.P.		REV
	SECTION 70	NO. 20	2

INTRODUCTION

1. Purpose. To establish guidelines and procedures for the SBA Regulation and Review Program.
2. Personnel Concerned. All SBA employees who work on developing or reviewing regulations.
3. Directives Cancelled. SOP 70 20 1.
4. Originator. Office of the General Counsel.

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Chapter 1

General Information

1. What is the Purpose of this SOP?

This SOP describes guidelines and procedures for developing, publishing, and reviewing regulations.

2. What is the Legal Authority for this SOP?

The Small Business Act, 15 U.S.C. 631 et seq.; The Small Business Investment Act of 1958, 15 U.S.C. 661 et seq.; Executive Order (EO) 12866, issued on September 30, 1993, at 58 FR 51735; The Regulatory Flexibility Act, 5 U.S.C. 601 et seq.; and The Administrative Procedure Act, 5 U.S.C. 551-559. 701 et seq.

3. What Rules Does this SOP Cover?

This SOP applies to rules published in or amending Title 13 of the Code of Federal Regulations (CFR), Chapter 1. The procedures in this SOP are in addition to the requirements of SOP 00 03, "Federal Register Documents."

4. Who Implements this SOP?

All Headquarters employees who develop, draft, prepare for publication, and review regulations also implement this SOP. The appropriate program office must prepare proposed and final regulations, with the assistance of the Office of General Counsel (OGC) and other interested offices. The Chief Counsel for Legislation and Regulation (CCLR) and other staff in OGC coordinate the regulatory process and communicate with the Office of Information and Regulatory Affairs (OIRA) at Office of Management and Budget (OMB), the Office of the Federal Register, and SBA's Office of Administrative Services. The Administrator must approve all proposed and final regulations, the regulatory agenda, and the regulatory plan. Thereafter, the CCLR must clear them before they are sent to the Federal Register for publication.

5. Who Enforces the Administration's Regulatory Policy?

OIRA enforces Federal agency compliance with the statutes, Executive orders, and the Administration's regulatory policy. OIRA issues policy guidance on regulatory policy and reviews rules before publication.

6. Who Coordinates SBA's Regulatory Policy with OIRA?

Under E.O. 12866, SBA must designate a Regulatory Policy Officer who reports to the Administrator and represents SBA on OIRA's Regulatory Working Group. The Regulatory Policy Officer helps develop the most effective, innovative, and least burdensome regulations and furthers the principles set forth in E.O. 12866 in the Agency. The Administrator has designated the General Counsel as SBA's Regulatory Policy Officer.

7. What are the Responsibilities of the CCLR and Staff?

The CCLR and staff will:

- a. Assist SBA offices in writing regulations and in training personnel to write regulations;
- b. Make recommendations to SBA offices writing regulations regarding resources, priorities, and coordination of SBA regulations development;
- c. Provide staff support on regulatory matters and coordinate the analysis and review of proposed and final regulations;
- d. Monitor the development of regulations by SBA offices;
- e. Develop the material for and prepare the SBA submission for the semiannual regulatory agenda and annual regulatory plan;
- f. Act as liaison with interested offices and organizations concerning SBA's regulation development and review process; and
- g. Work directly with program offices to prepare for the Administrator's signature on documents that SBA must transmit to OIRA for review under E.O. 12866.

8. What Legal Authorities Must SBA Comply with in Developing, Publishing, and Reviewing its Rules?

- a. Executive Order 12866 (E.O. 12866);
- b. Regulatory Flexibility Act, 5 U.S.C. 601 et seq. (RFA);
- c. Administrative Procedure Act, 5 U.S.C. 551-559, 701 et seq.;
- d. Paperwork Reduction Act, 44 U.S.C. §1320.1, et seq.;

- e. Unfunded Mandates Reform Act, 2 U.S.C. §1501 et seq.;
- f. Executive Order 12612 (E.O. 12612); and
- g. Executive Order 12788 (E.O. 12788).

Chapter 2

Regulatory Requirements to Consider When Drafting a Rule

1. What are the Regulatory Questions that Must Be Answered Before Issuing Regulations?

- a. Is the rule a significant regulatory action under E.O. 12866?
- b. Will the rule have a significant economic impact on a substantial number of small entities under the RFA?
- c. Does the rule have a collection of information requirement under the Paperwork Reduction Act?
- d. Does the rule contain an unfunded mandate under the Unfunded Mandates Act?
- e. Does the rule have a federalism implication under E.O. 12612?
- f. Does the rule unduly burden the Federal court system?
- g. Must SBA submit the final rule to Congress for review under the APA?

2. Is the Rule a “Significant” Regulatory Action Under E.O. 12866?

- a. What is a “significant” regulatory action?

A significant regulatory action is any action or rule which is likely to:

- (1) Have an annual effect on the economy of \$100 million or more;
- (2) Have a material effect on:
 - (a) The economy;
 - (b) Competition;
 - (c) The environment;
 - (d) Safety;
 - (e) Productivity;
 - (f) Jobs;
 - (g) Public Health; and

- (h) State, local, tribal governments.
 - (3) Create a serious inconsistency or interfere with another agency's action;
 - (4) Materially alter budgetary impact of entitlements, grants, etc.; and
 - (5) Raise novel legal or policy issues.
- b. Who determines if a rule is significant?
- SBA submits the proposed rule to OIRA stating whether we believe the rule is significant. OIRA makes the final determination.
- c. What must SBA do if a rule is "significant?"
- (1) If rule is significant, SBA must give OIRA:
 - (a) The draft text of the proposed rule;
 - (b) An explanation of the need for the rule;
 - (c) An assessment of costs and benefits including:
 - (i) Benefits: analysis and quantification;
 - (ii) Costs: analysis and quantification;
 - (iii) Alternatives' costs and benefits; and
 - (iv) Why the proposed rule is preferable to alternatives
 - (2) The proposed rule, as published in the Federal Register, serves as notice to the public about policy changes and solicits public comment. SBA should allow a comment period of at least 60 days.
 - (3) When the final rule is published, include a summary of the changes between the draft submitted to OIRA and the final rule and identify the changes made at the recommendation of OIRA.
- d. If SBA calls the rule "significant," does OIRA accept that or do they review it?
- Yes, OIRA reviews it. OIRA must notify SBA, in writing, of its determination within 90 days, or, if there has been no material change in facts upon which the rule is based, within 45 days. Either SBA or OIRA may extend the time period by 30 days.

e. What must SBA do if the rule is not “significant?”

If the rule is not significant, SBA must certify so and send it to OIRA. OIRA then has 10 days to review non-significant rules and determine if they agree.

f. What if there is an “emergency situation” requiring fast treatment?

If there is an “emergency situation,” SBA should notify OIRA for guidance as soon as possible.

3. Will the Rule Have a Significant Economic Impact on a Substantial Number of Small Entities Under the RFA?

a. What is a significant economic impact?

The RFA does not define “significant economic impact” or “substantial number of small entities.” The Chief Counsel for Advocacy states in the May 1996 “Guide to the Regulatory Flexibility Act” that “any rulemaking that generates the interest of a significant number of small entities warrants the application of the RFA’s analysis tools,” and that “in practice, this requires agencies to prepare an analysis whenever a rule’s impact on small entities cannot be described as *de minimis*.” The impact can be adverse or beneficial.

b. What must SBA do if a rule is likely to have a significant economic impact?

- (1) For any rule SBA believes will have an economic impact under the RFA, SBA must "assure that small entities have been given an opportunity to participate in the rulemaking through techniques such as—"
- (a) Stating in an advanced notice of proposed rulemaking, if issued, that the proposed rule may have a significant economic effect on a substantial number of small entities;
 - (b) Publishing a general notice of proposed rulemaking in publications that small entities are likely to receive;
 - (c) Directly notifying small entities about the rule;
 - (d) Holding "open conferences or public hearings" concerning the rule; and
 - (e) Adopting or modifying SBA procedural rules to reduce the cost or complexity of participation by small entities in the rulemaking process.

- (2) Each program office must review and study additional steps to notify interested organizations and individuals that a regulation is being developed and seek their advice and reaction. The Chief Counsel for Advocacy will assist in such review and study and will have general responsibility for recommending procedures SBA can adopt to encourage more public participation in the development of SBA regulations.
- (3) If the rule is likely to have a significant economic impact, SBA must complete an Initial Regulatory Flexibility Analysis (IRFA) and publish it with the proposed rule. The IRFA must include the:
 - (a) Reasons for the action;
 - (b) Objectives and legal basis of the proposed rule;
 - (c) Kind and number of small entities to which the proposed rule will apply;
 - (d) Projected reporting, recordkeeping, and other compliance requirements;
 - (e) Federal rules that may duplicate, overlap, or conflict with the proposed rule; and
 - (f) Description of significant alternatives which minimize any significant economic impact, such as:
 - (i) Differing compliance or reporting requirements or timetables;
 - (ii) Clarification, consolidation, or simplification of compliance and reporting requirements;
 - (iii) Use of performance measures; and
 - (iv) Exemption from coverage.
- (4) When the final rule is published, SBA must include a final regulatory flexibility analysis (FRFA). The FRFA must:
 - (a) Include a short statement of the need and objectives of the rule;
 - (b) Describe significant issues raised by public comments in response to IFRA, summary of the assessment of the comments, and the resulting changes;

- (c) Describe the small entities to which the rule will apply;
 - (d) Describe reporting, recordkeeping, and other compliance requirements of the rule, classes of small entities that will be subject to the rule, and type of professional skills necessary for preparing reports or records;
 - (e) Describe steps taken to minimize significant economic impact on small entities, factual, policy and legal reasons for selecting the alternative adopted in the final rule, and why each significant alternative was rejected; and
 - (f) Be summarized and published in the Federal Register.
- c. What must SBA do if the rule will not have a significant economic impact?

If the rule will not have a significant economic impact on a substantial number of small entities, the Administrator must so certify and publish the certification in the Federal Register with the proposed or final rule, along with statement of factual basis for certification. SBA must also send a copy of it to the Chief Counsel for Advocacy of the SBA.

- d. What if there is an “emergency” situation requiring fast treatment?

If there is an “emergency” situation:

- (1) With regard to an IFRA: By the date of publication of final rule, SBA must publish a written finding stating the reasons that SBA is issuing the final rule as a response to an emergency that makes timely compliance impracticable.
 - (2) With regard to a FRFA: SBA can only delay for 180 days after the date of publication of the final rule by publishing a written finding that the final rule is being promulgated in response to an emergency. If the Agency has not prepared a FRFA within this time period, the rule shall lapse and have no effect. Such rule cannot be reissued until a FRFA has been done.
- e. Can the IFRA and FRFA be done in conjunction with other analyses?

Yes. The IFRA and FRFA can be done in conjunction with any other analyses required by law.

4. Does the Rule Have a “Collection of Information” Requirement Under the Paperwork Reduction Act?

a. What is a “collection of information?”

A collection of information (COI) means obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties, or the public of information by or for an agency by means of identical questions posed to or identical reporting, recordkeeping, or disclosure requirements imposed on 10 or more persons, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit.

b. What must SBA do if the rule has a COI requirement?

If there is a COI requirement, you should refer to SOP 00 30 and consult with the SBA’s Administrative Information Branch of the Office of Administration.

5. Does the Rule Contain an “Unfunded Mandate?”

a. What is an “unfunded mandate?”

An unfunded mandate is any provision of a proposed rule which would impose a Federal mandate on State, local, and/or tribal governments without adequate Federal funding in a manner that may displace other essential small government priorities.

b. What must SBA do if the rule contains an unfunded mandate?

(1) If the rule contains an unfunded mandate that results in an annual expenditure by State, local, and tribal governments or by the private sector of \$100 million or more (adjusted annually for inflation), SBA must prepare a budgetary impact statement and include it in the preamble to the proposed rule and send it to OIRA. SBA must prepare this statement in connection with any other analysis, as long as it contains:

- (a) Authority (provision of Federal law for proposed rule);
- (b) Costs and benefits, including qualitative and quantitative assessments of:
 - (i) The extent to which costs can be paid for through Federal financial assistance; and
 - (ii) The extent to which there are other available Federal resources;
- (c) Future compliance costs and disproportionate budgetary effects on particular regions;

- (d) The effect on the national economy (productivity, economic growth, full employment, creation of productive jobs, international competitiveness); and
- (e) The extent of SBA's prior consultation with elected representatives of affected State, local, and tribal governments, summary of comments and concerns that were presented by them, and summary of SBA's evaluation of comments.

(2) In the final rule, SBA must include a summary of the elements listed above.

c. What is OMB's responsibility regarding rules containing "unfunded mandates?"

OMB collects these statements from agencies and forwards them to the Congressional Budget Office (CBO) and notifies Congress annually about agency compliance.

6. Does the Rule Have Federalism Implications Under E.O. 12612?

a. What are federalism implications?

Policies that have federalism implications are those that have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

b. What must SBA do if a rule has federalism implications?

If SBA determines that the rule has federalism implications, SBA must prepare and submit a Federalism Assessment to OIRA. Under E.O. 12612 the Assessment must identify:

- (1) Provisions of the policy inconsistent with Federalism;
- (2) How the policy imposes additional costs/burdens on States;
- (3) The likely source of funding for the States;
- (4) Ability of the States to comply with the policy; and
- (5) How the policy would affect States' governmental functions.

7. What Must SBA Do to Ensure that its Rules Do Not Unduly Burden the Federal Court System Under E.O. 12778?

- a. SBA has the general duty when issuing new regulations and reviewing existing regulations to:
- (1) Review the rule to eliminate drafting errors and needless ambiguity;
 - (2) Write the rule to minimize needless litigation;
 - (3) Provide a clear and certain legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction; and
 - (4) Certify that:
 - (a) It has reviewed the draft rule in light of the standards of E.O. 12778; and
 - (b) The draft rule meets the standards of E.O. 12778 or states why it is unreasonable to require the rule to meet one or more of those standards.

8. What Must SBA Do Under the APA to Submit Rules to Congress for Review?**a. What must SBA submit to Congress?**

SBA must submit to each House of Congress and to the Comptroller General a copy of each final rule that it issues. In addition to a copy of the rule, SBA must submit a concise general statement relating to the rule, including whether it is a "major rule" as defined in section 804 of the APA, and the proposed effective date of the rule.

b. Where does SBA submit the rule and accompanying information?

Agency rules and the accompanying report must be separately addressed and transmitted to the Speaker of the House (the Capitol, Room H209), Washington, DC 20515; the President of the Senate (the Capitol, Room S-212), Washington, DC 20510; and the Comptroller General (GAO Building, 441 G Street, NW, Room 1139), Washington, DC 20548.

c. What is a "major rule" for purposes of congressional review?

The APA defines "major rule" for purposes of its congressional review chapter as any rule that the Administrator of OIRA finds "has resulted or is likely to result in:

- (1) An annual effect on the economy of \$100 million or more;
- (2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- (3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets."

d. When does a non-major rule take effect?

Non-major rules can take effect at any time after they are submitted to Congress and the Comptroller General.

e. When does a major rule take effect?

A major rule does not take effect until at least 60 calendar days after the later of the date on which the rule is submitted to Congress or the date on which the rule is published in the Federal Register. If Congress passes a joint resolution of disapproval and the President vetoes such resolution, the major rule is not effective until the earlier date on which either House of Congress votes and fails to override the veto or 30 session days after the date on which the Congress receives the veto and objections from the President.

Chapter 3

Unified Regulatory Agenda and Regulatory Plan and the Role of the Public

1. What is the Purpose of the Regulatory Agenda and the Regulatory Plan?

SBA publishes a semiannual regulatory agenda and an annual regulatory plan to notify the public and solicit input about future regulations.

a. What is the Unified Regulatory Agenda (Agenda)?

- (1) Under E.O. 12866 and the RFA, each agency must prepare an agenda that is published in the Federal Register every April and October. To complete the Agenda, the CCLR and staff will contact each program office to get a description of the rulemaking activities each office plans to undertake in the next 6 months. The program offices must provide:
 - (a) A description of each proposed or final rule under development by the SBA;
 - (b) The need for and legal basis for each rulemaking action it intends to take;
 - (c) Target dates for completion of steps in the development of those rules; and
 - (d) The status of regulations previously listed in the agenda.
- (2) The CCLR and staff will compile the information provided by the program offices and will prepare a Unified Regulatory Agenda of all regulations under development or review. For each rulemaking activity the Agenda must include: a regulatory identification number (provided by the Regulatory Information Service), a brief summary, the legal authority for the action, any legal deadline, and the name and telephone number of a knowledgeable SBA person. E.O. 12866 permits agencies to incorporate the information required under section 602 of the RFA into their regulatory agendas.
- (3) SBA must note which rules are likely to have a significant economic impact on a substantial number of small entities.

b. What is the Regulatory Plan?

As part of the Unified Regulatory Agenda, under E.O. 12866, SBA must submit annually a Regulatory Plan of the most important regulatory actions that SBA expects to issue in proposed or final form in that fiscal year or later. The Plan will be published annually in the October publication of the Unified Regulatory Agenda. The Plan must contain at a minimum:

- (1) A statement of the Agency's regulatory objectives and priorities and how they relate to the President's priorities;
- (2) A summary of each planned significant regulatory action, including alternatives to be considered and preliminary estimates of the anticipated costs and benefits;
- (3) A summary of the legal basis for each such action, including whether a statute or court order require any aspect of the action;
- (4) A statement of the need for each such action;
- (5) The Agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and
- (6) The name, address, and telephone number of an SBA employee the public may contact for additional information about the action.

2. What is the Role of the Public Before a Rule is Published?

Under E.O. 12866, SBA must provide the public with "meaningful participation in the regulatory process." Therefore, before issuing a proposed rule, SBA must involve those who will be affected by the regulation. SBA must give the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of at least 60 days. SBA should explore the use of consensual mechanisms for developing regulations.

Chapter 4

Periodic Review of Existing Regulations

1. When Must SBA Review its Rules Under E.O. 12866?

Under E.O. 12866, SBA must review periodically its existing significant regulations to determine whether any such regulations should be modified or eliminated. Any significant regulations SBA selects for review must be included in SBA's annual regulatory plan. SBA must also identify any legislative mandates that require it to issue or continue to impose regulations that SBA believes are unnecessary or outdated because of changed circumstances.

2. When Must SBA Review its Rules Under the RFA?

- a. Under the RFA, SBA must periodically review any of its rules that have a significant economic impact on a substantial number of small entities.
- b. SBA must determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable law, to minimize the economic impact on small entities.
- c. SBA must review any such rules within 10 years of their publication as a final rule. If the Administrator determines that such a review is not feasible within that time period, he/she must so certify in a statement published in the Federal Register. The Administrator may extend the completion date by one year at a time for a total of not more than 5 years. In reviewing such rules, SBA must consider:
 - (1) The continued need for the rule;
 - (2) The nature of complaints or comments received from the public concerning the rule;
 - (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;
 - (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; and

- (6) SBA compliance with this review requirement under section 610 of the RFA is subject to judicial review under RFA section 611.