POLICY ECONOMICS INNOVATION

OPEI Regulatory Development Series

EPA's Action Development Process

Final Guidance for EPA Rulewriters: Regulatory Flexibility Act

as amended by the Small Business Regulatory Enforcement Fairness Act

NOTICE

The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on its analysis of the specific facts presented. This guidance may be revised without public notice to reflect changes in EPA's approach to implementing the Regulatory Flexibility Act or to clarify and update text. In fact, such changes have been made to this guidance since the November 30, 2006 signature of the SBAC and are reflected in this version of the guidance.

November 2006

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UNITED STATES ENVIRONMENT PROTECTION AGENCY
Washington D. C. 20460

Nov. 30, 2006

Office of Policy,
Economic and Innovation

MEMORANDUM

SUBJECT: Transmittal of *Final Guidance EPA Rulewriters: Regulatory Flexibility Act as Amended by the Small Business and Regulatory Enforcement Fairness Act*

FROM: Alexander Cristofaro
Small Business Advocacy Chair

TO: Assistant Administrators
Regional Administrators
General Counsel

I am pleased to provide you with the document referenced above. This revised guidance reflects the Agency's accumulated experience with the RFA, as amended by SBREFA, since we issued the previous guidance on March 29, 1999. This new edition retains much of the substance of the 1999 edition, while significantly expanding chapters on screening analysis and adding a new chapter on preparing the initial and final regulatory flexibility analyses.

As we did earlier, we have prepared this revised guidance for EPA managers and staff to use flexibly and with considerable judgment. We have discovered no single "magic formula" that applies equally to all situations. Even so, we are confident EPA employees will find this document even more helpful than its predecessor in sorting through the variety of issues we can expect to encounter considering the unique needs of small entities subject to environmental rules.

Attachment

cc: Steering Committee Representatives
Regional Regulatory Contacts

Send comments on the guidance to me c/o Joan Rogers

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- Telephone: 202-564-6568
- U.S. mail: mail code 1803A @ 1200 Pennsylvania Avenue, NW, Washington, DC 20460
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How to Use This Guidance

A Quick Glimpse at this Guidance and the RFA Process

The purpose of this Guidance is to help you, the rulewriter, understand how the requirements of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) fit into the Agency's Action Development Process.[1] The Agency refers to the RFA as amended by SBREFA simply as the RFA.

When EPA initiates a regulatory development action, RFA compliance should be near the top of the list of issues you address in your project plan or Analytic Blueprint.[2] This guidance outlines the analytical and sequential process that will apply to most rules subject to the RFA. **Figure 1** illustrates the RFA process for proposed rules and **Figure 2** illustrates the RFA process for final rules.

Assessing a Rule's Economic Impact on Small Entities. Once you have determined that your rule is subject to the RFA (i.e., you are required to publish a notice of proposed rulemaking under the APA or any other statute), the first thing you need to do for RFA compliance is to determine what, if any, impact your rule may have on small entities. To do this, you need to perform a screening analysis on your proposed and final rules. Screening analyses are discussed in detail in **Chapter 2** of this guidance.

Preparing the Initial and Final Regulatory Flexibility Analyses. These are analyses of economic impacts on small entities that you must prepare if you do not certify that your rule does not have a significant economic impact on a substantial number of small entities (SISNOSE). These analyses are discussed in detail in **Chapter 3**.

Implementing Small Entity Outreach. If the screening analysis indicates that your rule may have

[1] See *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions,* June 30, 2004. EPA's Action Development guidance can be found at EPA's Action Development Process Library site http://intranet.epa.gov/adplibray.

[2] See Guidelines for Preparing Analytic Blueprints, June 28, 2004, (available at http://intranet.epa.gov/adplibrary or contact OPEI

some impact on some small entities, or you find that you need more information to make that determination, **Chapter 4** will provide you with guidance for identifying and engaging in a dialogue with representatives of small entities that may be subject to the rule under development.

Small Business Advocacy Review Panels. If the screening analysis of your rule indicates that the rule is likely to have a SISNOSE, you should plan to prepare for a Small Business Advocacy Review Panel. In **Chapter 5** you will find detailed information about how you should go about complying with the requirement that the Agency convene a Small Business Advocacy Review Panel for proposed rules which are likely to have a SISNOSE.

Small Entity Compliance Guides. If you must prepare a final regulatory flexibility analysis for your **final rule** (i.e., you do not certify the rule as not having a significant economic impact on a substantial number of small entities), the RFA also requires you to prepare a small entity compliance guide. **Chapter 6** answers questions regarding what constitutes such a guide and gives guidance for designing a small entity compliance guide.

Ongoing Informal Small Entity Guidance. When planning for the post-promulgation stage of your rule, refer to the discussion in **Chapter 7** regarding the RFA provision on giving informal advice to small entities in response to inquiries.

Periodic Review of Rules. RFA section 610 requires a periodic review of promulgated rules which have or will have a significant economic impact on a substantial number of small entities. **Chapter 8** explains the Agency's strategy for continued compliance with this requirement.

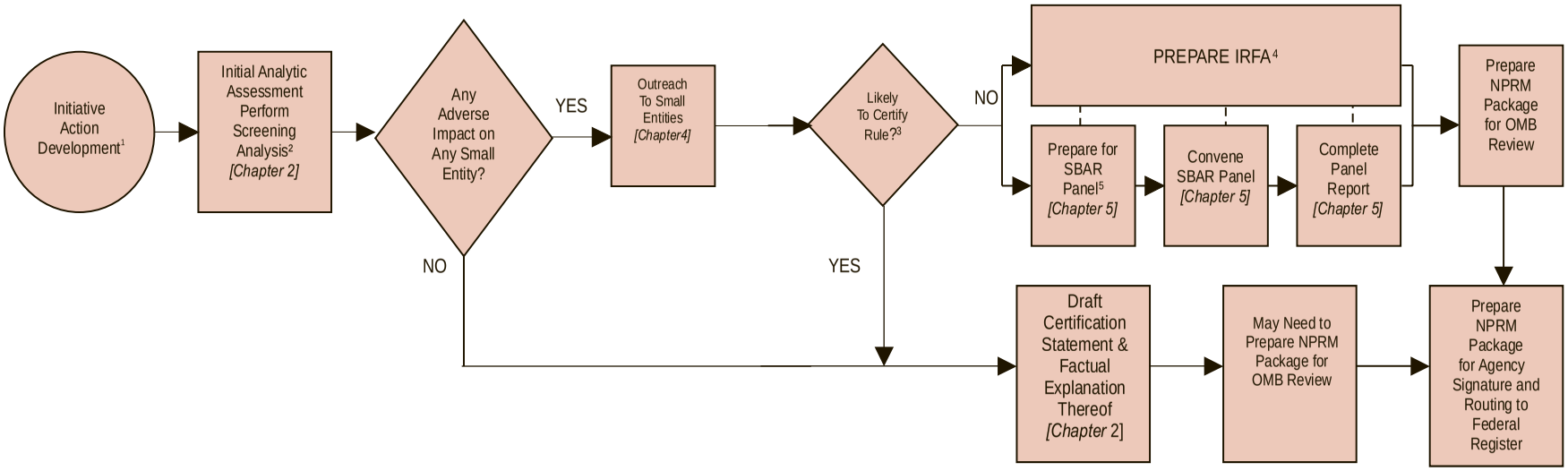
Please note: This guidance is not a binding Agency procedural rule. In determining and mitigating impacts on small entities, we anticipate that there will be many situations in which Agency staff and management must exercise considerable judgment. Nevertheless, we intend this guidance to provide you with an analytic and sequential structure that should be sufficient for most covered rulemakings. Should you come across a situation that does not appear to be discussed in this guidance, or a situation where an approach other than that suggested by this guidance makes sense, you need to consult with your Regulatory Steering Committee representative, the Small Business Advocacy Chair in the Office of Policy, Economics and Innovation (OPEI), and attorneys from the Office of General Counsel (OGC).

This guidance was developed for practical use. Occasionally, it repeats information already introduced in order to increase its accessibility and utility to a rulewriter working under pressure and looking to find adequate guidance on a particular point quickly. Some readers might find the narrative occasionally redundant for this reason. Even so, we strongly urge all users of the guidance to review it in its entirety before embarking on a rulemaking likely to directly regulate small entities.

This document supersedes and revokes all prior Agency guidance on the Regulatory Flexibility Act. This guidance incorporates the information on preparing initial and final regulatory flexibility analyses that was contained in the EPA Guidelines for Implementing the Regulatory Flexibility Act, April 1992. That information is contained in a new Chapter 3 in this guidance. In addition, a revised Chapter 2 based on the Agency's continuing implementation of the RFA is included. A few minor editorial changes have been made to other chapters such as deleting outdated contact information and updating footnote references to other documents.

Please direct any questions to the Small Business Advocacy Chair's staff in the Office of Regulatory Policy and Management of OPEI.

RFA PROCESS OVERVIEW FOR PROPOSED RULES
Figure 1



Notes:

General: References to "Chapters" in the flowchart refer to the chapters in this guidance document. See Table of Contents.

[1] Only rules subject to notice-and-comment requirements are subject to the regulatory flexibility analysis requirements of the RFA. See Chapter 1 and 2 for more details.

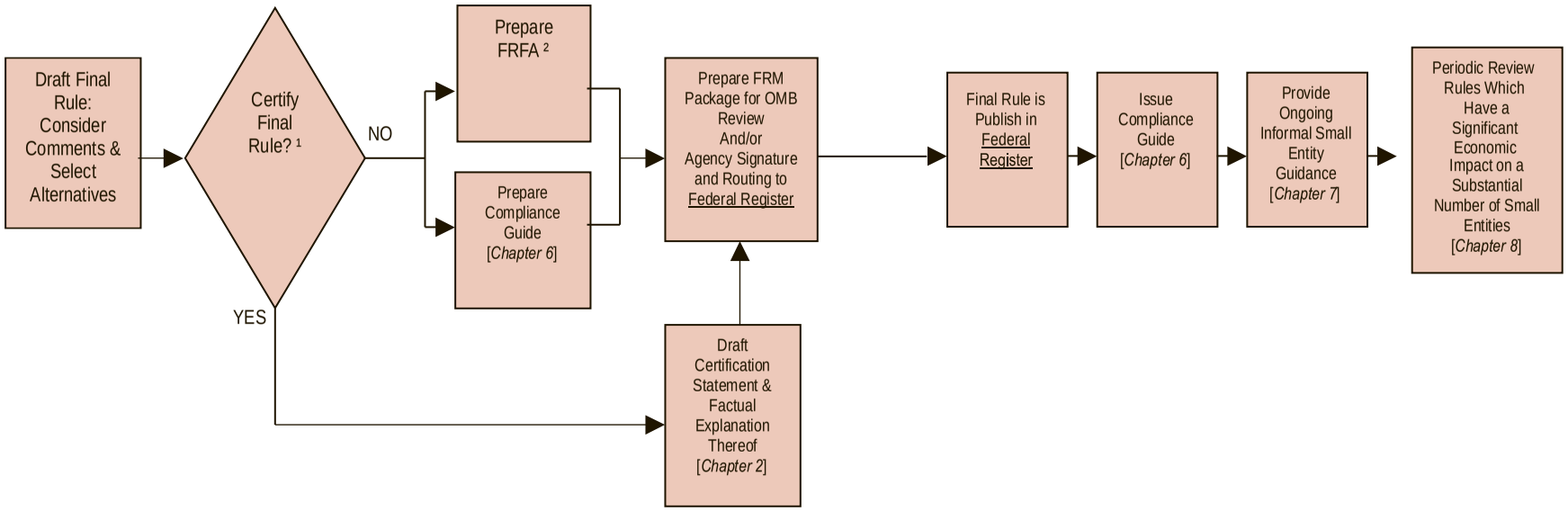
[2] It may be appropriate to start outreach to small entities before or concurrent with performing a screening analysis. See Chapter 2 for more details.

[3] It is EPA's policy to assess impacts on small entities and minimize impacts to the extent feasible. If you do not have enough information to determine with confidence that the Agency can certify (no SISNOSE), proceed with "NO."

[4] Under the RFA, you must prepare an IRFA and meet other requirements for your rule proposal, unless the Administrator certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities." See Chapter 1 for general information and Chapter 3 for more detailed information on preparation of an IRFA. A decision to convene a Panel is not a commitment to prepare an IRFA (or a FRFA for rule promulgation), nor does it prevent EPA from certifying your proposed or final rule if its substance so warrants.

[5] Although the preparation of the IRFA and the term of the Panel are represented here as concurrent activities, in reality, there is no firm linkage in timing for the two tasks. However, the two tasks may inform each other and the IRFA should not be completed until the panel report is signed.

RFA Process Overview for Final Rules
Figure 2



Notes:
General: References to "Chapters" in the flowchart refer to the chapters in this guidance document. See Table of Contents.

[1] If you have not gone through the SBAR Panel process for rule proposal, but think that you may not be able to certify your final rule, consult with your OGC attorney.

[2] Under the RFA, you must prepare a FRFA and meet other requirements for your rule, unless the Administrator certifies that the rule will not have a significant economic impact on a substantial number of small entities. See Chapter 1 for general information and Chapter 3 for more detailed information on preparation of a FRFA.

List of Acronyms

APA	Administrative Procedure Act
CFR	Code of Federal Regulations
FRFA	Final Regulatory Flexibility Analysis
IRFA	Initial Regulatory Flexibility Analysis
NPRM	Notice of Proposed Rulemaking
OPA	Office of Public Affairs (EPA)
OCIR	Office of Congressional and Intergovernmental Relations (EPA)
OECA	Office of Enforcement and Compliance Assurance (EPA)
OGC	Office of General Counsel (EPA)
OIRA	Office of Information and Regulatory Affairs (OMB)
OMB	Office of Management and Budget
OPEI	Office of Policy, Economics and Innovation (EPA)
ORPM	Office of Regulatory Policy and Management (EPA)
RFA	Regulatory Flexibility Act
RMD	Regulatory Management Division (EPA)
SBA	Small Business Administration
SBAC	Small Business Advocacy Chair (EPA)
SBAR	Small Business Advocacy Review
SBO	Small Business Ombudsman (EPA)
SBREFA	Small Business Regulatory Enforcement Fairness Act
SER	Small Entity Representative
SISNOSE	Significant economic Impact on a Substantial Number Of Small Entities

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Chapter 1
Introduction to the Regulatory Flexibility Act

1.1 What is the RFA?

President Carter signed the Regulatory Flexibility Act (RFA) into law on September 19, 1980. In enacting the law, the Congress found that "uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands ... upon small [entities]. . . [T]he practice of treating all regulated [entities] as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation."[3]

The RFA imposes both analytical and procedural requirements on EPA and other federal agencies. The analytical requirements call for EPA to carefully consider the economic impacts our rules will have on small entities. The procedural requirements are intended to ensure that small entities have a voice when EPA makes policy determinations in shaping its rules. Together, these requirements ensure that EPA carefully considers the effect our regulations may have on small entities. However, the RFA's analytical and procedural requirements do not require EPA to reach any particular result regarding small entities.

1.2 What is SBREFA?

SBREFA is the Small Business Regulatory Enforcement Fairness Act, a regulatory reform statute passed by the 104th Congress and signed into law by President Clinton on March 29, 1996. SBREFA (Pub Law No. 104-121) enacted a variety of provisions, including several amendments to the Regulatory Flexibility Act, 5 U.S.C. section 601 et seq, of particular importance to EPA rulemakings. The Agency refers to the RFA as amended by SBREFA simply as the RFA, but there are other SBREFA provisions as well.

1.3 What Do I Need to Know about the RFA and SBREFA?

In short, with respect to the Regulatory Flexibility Act (RFA), SBREFA established certain formal procedural and analytical requirements (detailed below) for the limited number of rules

[3] Regulatory Flexibility Act, Pub. L. No. 96-354, Sec. 2(a) (5 USC § 601 note).

developed by EPA with the potential to impose a significant economic impact on a substantial number of small entities.[4] More specifically, as a rulewriter, if your rule may impose a significant economic impact on a substantial number of small entities (see Chapter 2) you most likely will be required to prepare a formal analysis of the potential adverse economic impacts on small entities, participate in a Small Business Advocacy Review Panel (proposed rule stage), and prepare a Small Entity Compliance Guide (final rule stage).

SBREFA also made other changes to Agency regulatory practice as it affects small entities. Many Agency actions under the RFA are now judicially reviewable, including decisions to certify a rule as not having a significant economic impact on a substantial number of small entities, the preparation of a regulatory flexibility analysis and periodic review of final rules. SBREFA's other provisions include Subtitles A through C, relating to enforcement of federal laws and regulations with respect to small entities, and Subtitle E, wholly unrelated to the small entity provisions of the rest of SBREFA, which provides for Congressional review of virtually all final rules.[5]

The Regulatory Flexibility Act (RFA) was amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) in 1996. The Agency refers to the RFA as amended by SBREFA simply as the RFA.

The purpose of the RFA is "to fit regulatory and informational requirements to the scale of the businesses, organizations and governmental jurisdictions subject to the regulation."[6] To achieve this principle, agencies are required to "solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration."[7] The RFA does not require an agency to necessarily minimize a rule's impact on small entities if there are legal, policy, factual or other reasons for not doing so. The RFA requires only that agencies determine, to the extent feasible, the rule's economic impact on small entities, explore regulatory options for reducing any significant economic impact on a substantial number of such entities, and explain their ultimate choice of regulatory approach.

1.4 What is EPA's Policy for Implementing the RFA?

Since its enactment in 1980, the RFA has required every federal agency to prepare regulatory flexibility analyses for any rule for which the agency is required to issue a notice of proposed rulemaking under the Administrative Procedure Act or any other statute unless the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a

[4] The Regulatory Flexibility Act definition of small entities includes small businesses, small governments and small organizations. The RFA references the definition on small business found in the Small Business Act, which authorizes the Small Business Administration (SBA) to further define small business by regulation. The SBA's small business definitions are codified at 13 CFR section 121.201. More information on the definition of "small" can be found in Chapter 2.

[5] For more information, see the document entitled *Congressional Review Act, Guidance for Rule Writers,* June 1998, available from OPEI or on EPA's Action Development Process Library intranet site: http://intranet.epa.gov/adplibrary

[6] Regulatory Flexibility Act, Pub. L. No. 96-354, Sec. 2(a) (5 USC § 601 note)

[7] Id.

substantial number of small entities." One important function of this guidance is to establish workable guidelines for determining if a particular rule will have a "significant economic impact" on a "substantial number" of small entities. Prior to the enactment of SBREFA, EPA exceeded the requirements of the RFA by preparing regulatory flexibility analyses for every rule that would have any impact on any number of small entities, regardless of the size of impact or the number of small entities affected. That policy was embodied in the *EPA Guidelines for Implementing the Regulatory Flexibility Act* guidance document dated April 1992 (1992 RFA Guidance).[8]

When SBREFA became law in 1996, we developed additional procedures for full compliance with SBREFA's multiple and various provisions. To ensure the Agency gave top priority to this effort, a cross-Agency Task Force was established to develop comprehensive procedures for our implementation of SBREFA. The efforts of the Task Force were reflected in the *EPA Interim Guidance for Implementing the Small Business Regulatory Enforcement Fairness Act and Related Provisions of the Regulatory Flexibility Act* guidance document dated February 5, 1997 (1997 Interim SBREFA Guidance) and the subsequent *"Revised Interim Guidance for EPA Rulewriters: Regulatory Flexibility Act as Amended by the Small Business Regulatory Enforcement Fairness Act* dated March 29, 1999.

It remains EPA policy that program offices should assess the direct adverse impact of every rule on small entities and minimize any adverse impact to the extent feasible, regardless of the magnitude of the impact or number of small entities affected. In view of the changes made by SBREFA, however, the Agency decided to implement the RFA as written; that is, a regulatory flexibility analysis as specified by the RFA will **not** be required simply because the rule has some impact on some number of small entities. Instead, such analyses will be required only in cases where we will not certify that the rule will not have a **significant** economic impact on a **substantial** number of small entities. This approach allows us to manage our resources such that we can consider the potential small entity impacts of all rules while preparing full regulatory flexibility analyses for those rules warranting such analyses under the RFA.

The SBREFA amendments also directed agencies to name a Small Business Advocacy Chairperson (SBAC) to act as permanent chair of their review Panels. EPA's Small Business Advocacy Chair is responsible for convening Small Business Advocacy Review (SBAR) Panels and, among other things, overseeing policy decisions regarding certification that a rule will not have a significant economic impact on a substantial number of small entities. Chapter 5 provides detailed information on the SBAR Panel process.

1.5 What Rules Are Subject to the RFA?

As a threshold matter, the RFA requirement to prepare a regulatory flexibility analysis or a

[8] This 2006 Guidance document supersedes and revokes all prior Agency guidance on the Regulatory Flexibility Act.

certification of no significant economic impact on a substantial number of small entities applies only to:

- **proposed rules subject to notice-and-comment rulemaking requirements** under the Administrative Procedure Act (APA) or any other statute, and

- **final rules promulgated under the notice-and-comment rulemaking requirements** of the APA.

Exempt from the RFA requirement to prepare either a regulatory flexibility analysis or a certification are:

- Agency actions that are **not** rules (e.g., orders or adjudications), and

- rules that the Agency is **not required** by statute to propose before promulgating.

Most EPA rulemakings are subject to section 553 of the APA, which generally requires that an agency issue a notice of proposed rulemaking and take comment on a rule before issuing it. The APA, however, exempts from notice-and-comment requirements:

- rules of agency organization, procedure or practice that do not substantially affect the rights of non-agency parties;

- rules for which the agency finds "for good cause" that notice and an opportunity to comment are "impracticable, unnecessary, or contrary to the public interest;" and

- rules relating to agency management or personnel or to public property, loans, grants, benefits or contracts.

It should be noted that "direct final rules" (i.e., rules that the Agency issues without first proposing them, that are withdrawn if anyone files an adverse comment) are generally subject to notice-and-comment requirements and are therefore subject to the RFA requirements in this guidance. For more information on direct final rulemaking see, *Direct Final Rulemaking: Guidance for EPA Rule Writers,* available on EPA's Action Development Process Library intranet site: http://intranet.epa.gov/adplibrary.

The procedures for some EPA rulemakings are governed by other statutes. For example, many Clean Air Act (CAA) rulemakings are subject to the procedural requirements of section 307(d) of the CAA instead of the APA. In such cases, you should consult those statutes and your OGC attorney.

1.6 What Part of RFA Compliance is Judicially Reviewable?

Judicial review is the process whereby an adversely affected person can challenge an EPA final regulatory action in Federal court if the statute so allows and ask the court either to vacate

or stay enforcement of the rule. During review of a rule, EPA must demonstrate that we complied with not only the substantive statutory requirements of the implementing statute (e.g., the Clean Air Act), but also with requirements contained in procedural statutes, such as the APA and RFA. During judicial review, EPA also must demonstrate that our interpretation of the law is reasonable in areas that we had discretion and that we had a rational basis for our regulatory decision.

The SBREFA Amendments to the RFA added provisions that now allow a *small entity* that is *adversely affected* by a final rule to seek review in court of an agency's compliance with the following RFA requirements:

- Section 601 - Establishing an alternative definition for small businesses, small governmental jurisdictions, and/or small non-profit organizations;
- Section 604 - Final regulatory flexibility analysis (FRFA);
- Section 605(b) - Certification of the proposed or final rule and the factual basis for the certification;
- Section 608(b) - Delaying the completion of a FRFA for up to 180 days due to an emergency; and
- Section 610 - Periodic review of final rules that were not certified within ten years of promulgation.

The RFA gives a reviewing court broad discretion in deciding what the appropriate remedy should be if the court finds an agency has not complied with the RFA's requirements (e.g., consulting with the Small Business Administration and providing notice and an opportunity for comment before establishing an alternative small business definition or preparing a meaningful FRFA). Such remedies may include vacating and/or remanding the rule to the agency for further action or deferring enforcement of the rule against small entities.

Thus, even if you have fulfilled the requirements of your implementing statute, have reasonably interpreted those statutory requirements in areas in which the agency has discretion to do so, have explained on the record your rationale for selecting the option you did, but you fail to comply with one or more RFA requirements or fail to adequately explain your conclusions, a reviewing court *could* decide to vacate, remand, or stay the rule on that basis. Indeed, one agency previously had a rule vacated for basing its RFA analysis on an alternative small entity definition it did not establish properly.

In addition, a rule may be challenged if the agency fails to adequately respond to adverse comments challenging any aspect of the rule. This applies to an agency's failure to respond to comments on the agency's certification, the factual basis for the certification, or the initial regulatory flexibility analysis.

1.7 What is in this Guidance?

The purpose of this Guidance is to help you, the rulewriter, to understand how the requirements of the RFA fit into the Agency's Action Development Process.[9]

When EPA initiates a regulatory development action, RFA compliance should be near the top of the list of issues you address in your project plan or Analytic Blueprint.[10] This guidance outlines the analytical and sequential process that will apply to most rules subject to the RFA. Figure 1 illustrates the RFA process for proposed rules and Figure 2 illustrates the RFA process for final rules.

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[9] *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions,* June 30, 2004. EPA's Action Development guidance can be found at EPA's Action Development Process Library intranet site: http://intranet.epa.gov/adplibrary.

[10] See *Guidelines for Preparing Analytic Blueprints,* June 28, 2004, (available at http://intranet.epa.gov/adplibrary) or contact OPEI.

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Please note: This guidance is not a binding Agency procedural rule. In determining and mitigating impacts on small entities, we anticipate that there will be many situations in which Agency staff and management must exercise considerable judgment. Nevertheless, we intend this guidance to provide you with an analytic and sequential structure that should be sufficient for most covered rulemakings. Should you come across a situation that does not appear to be discussed in this guidance, or a situation where an approach other than that suggested by this guidance makes sense, you need to consult with your Regulatory Steering Committee representative, the Small Business Advocacy Chair in the Office of Policy, Economics and Innovation (OPEI) and attorneys from the Office of General Counsel (OGC).

1.8 What are the RFA Procedural Requirements for Rule Proposal?

If the RFA APPLIES to your rule and your screening analysis indicates your rule most likely WILL NOT have a significant economic impact on a substantial number of small entities:

Certification statement and statement of factual basis. You must prepare a certification statement and a statement of factual basis supporting the certification that your rule will not have a significant economic impact on a substantial number of small entities. The RFA section 605(b) requires you to publish in the Federal Register "a statement providing the factual basis for such certification." That certification and the factual basis for the certification are subject to judicial review. Accordingly, it is important that you provide sufficient detail in your factual basis to explain why the Agency is certifying the rule.

~OR~

If the RFA APPLIES to your rule and your rule most likely WILL have a significant economic impact on a substantial number of small entities:

Initial Regulatory Flexibility Analysis. Generally, the RFA requires EPA to **prepare** an Initial Regulatory Flexibility Analysis (IRFA) for each proposal, **unless** the Administrator **certifies** that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities (see Figure 1).

~AND~

Small Business Advocacy Review Panels. Under the RFA, EPA **must convene** a Small Business Advocacy Review Panel for a rule under development, **unless** the Agency **certifies** that the rule will not impose a significant economic impact on a substantial number of small entities. Each

Panel includes representatives from the Small Business Administration, the Office of Management and Budget, and EPA. The Panels conduct outreach to individuals representative of small entities likely to be subject to the rule and prepare a report to the EPA Administrator for each rulemaking on the potential small entity impacts of the rule and on potential ways to reduce those impacts (see Figure 1). More detailed information on the Small Business Advocacy Review Panel process is contained in Chapter 5.

1.9 What are the RFA Procedural Requirements for Final Rule Promulgation?

If the RFA APPLIES to your rule and your analysis along with any information or analysis developed since the proposal indicates your rule WILL NOT have a significant economic impact on a substantial number of small entities:

Certification statement and statement of factual basis. You must prepare a certification statement and a statement of factual basis to support the certification that your rule will not impose a significant economic impact on a substantial number of small entities. The RFA section 605(b) requires you to publish in the Federal Register "a statement providing the factual basis for such certification." Under SBREFA, that certification and the factual basis for the certification are subject to judicial review. Accordingly, it is important that you provide sufficient detail in your factual basis to explain why the Agency is certifying the rule.

~OR~

If based on your analysis, you are not certifying that your rule WILL NOT have a significant economic impact on a substantial number of small entities:

Final Regulatory Flexibility Analysis. For each rule that EPA promulgates and does not certify as not having a significant economic impact on a substantial number of small entities, the Agency must prepare a Final Regulatory Flexibility Analysis (FRFA; see Figure 2). Importantly, RFA requires that each FRFA summarize the significant issues raised by public comments on the IRFA, assess these issues, and describe any changes made in response to the public comments.

~AND~

Small Entity Compliance Guide. For each final rule where RFA requires preparation of a FRFA, the Agency must also issue a small entity compliance guide providing a Plain Language explanation of how to comply with the regulation (see Figure 2). More guidance on developing a small entity compliance guide can be found in Chapter 6.

1.10 How Does this Guidance Differ from the 1999 Revised Interim Guidance?

This guidance incorporates the information on preparing initial and final regulatory flexibility analyses that was contained in the *EPA Guidelines for Implementing the Regulatory Flexibility Act,* April 1992. That information is contained in a new Chapter 3 in this guidance. In addition, a revised Chapter 2 based on the Agency's continuing implementation of the RFA is included. A few minor editorial changes have been made to other chapters such as deleting outdated contact information and updating footnote references to other documents.

Chapter 2
RFA/SBREFA Screening Analysis: Assessing Impacts on Small Entities

This chapter describes the screening process for determining whether a regulatory flexibility analysis or a certification of no significant economic impact on a substantial number of small entities (SISNOSE) should be prepared for a proposed or final rule.

2.1 RFA: The Basics

The purpose of the Regulatory Flexibility Act (RFA) is to ensure that, in developing rules, agencies identify and consider ways of tailoring regulations to the size of the regulated entities. The RFA does not require an agency to minimize a rule's impact on small entities if there are legal, policy, factual or other reasons for not doing so. The RFA generally requires that for certain rules, you:

- **determine,** to the extent feasible, the **economic impact** on small entities subject to the rule,
- **explore regulatory options** for reducing any significant economic impact on a substantial number of such entities, and
- **explain** your ultimate choice of regulatory approach.

SISNOSE
Significant economic Impact on a Substantial Number Of Small Entities

This chapter, and Chapter 3, provide you with guidance on how to comply with the analytical requirements of the RFA and EPA's policy for implementing those requirements. In many respects, the advice and direction provided here go beyond what the law requires, and instead reflect Agency policy about how best to ensure that small entity concerns are considered in the rulemaking process.

Unless the Agency certifies that a rule subject to the RFA will not have a SISNOSE, sections 603 and 604 of the RFA require that you prepare a regulatory flexibility analysis meeting the applicable statutory requirements. More information on preparation of regulatory flexibility analyses can be found in Chapter 3. It bears repeating, however, that **even where the Agency**

certifies that a rule will not have a SISNOSE, EPA's policy is to make an assessment of the rule's direct adverse impact on any small entities, to engage the potentially regulated entities in a dialog regarding the rule, and to minimize the impact of the rule on small entities to the extent feasible while remaining consistent with applicable statutory requirements. As always, program managers should determine what level of outreach is appropriate given the expected level of impact.

2.2 What is a Screening Analysis and Why Should I Do One?

Once you have determined that your rule is subject to the RFA (see Chapter 1 and Section 2.3 of this Chapter), it is most important for you to determine if your rule may have a SISNOSE. Generally, this determination is made by conducting a "screening analysis." For purposes of the RFA, a screening analysis is an assessment of the potential economic impacts of a rule on small entities and generally indicates whether you can certify the rule as not having a SISNOSE. Under the RFA and SBREFA, you must either:

Certify that the rule will **not** have a SISNOSE (5 U.S.C. section 605(b)); or

Undertake the following activities:

- prepare a regulatory flexibility analysis (5 U.S.C. sections 603-604), see Chapter 3;
- convene a Small Business Advocacy Review Panel (5 U.S.C. section 609), see Chapter 5; and
- prepare a Small Entity Compliance Guide (SBREFA section 212, PL 104-121 as amended by Pub. L. Number 110-28), see Chapter 6.

The RFA does not analytically define the terms **significant** or **substantial** with regard to extent of economic impact and number of small entities affected. In this chapter we suggest guidelines for determining if a particular rule may have a SISNOSE. We recognize that there can be no one-size-fits-all methodology for making this determination. Therefore, we recommend specific approaches but leave you the flexibility to use alternative methods or reach different conclusions where appropriate in the context of a particular rule. However, remember that the rationale underlying your ultimate conclusions should be included in the rulemaking record and is judicially reviewable.

2.2.1 Is a Screening Analysis the Same as a Regulatory Flexibility Analysis?

It is important to note that a screening analysis is not the same as an initial or final regulatory flexibility analysis (IRFA/FRFA). IRFA/FRFAs analyze a rule's economic impact on small entities, including alternative regulatory or policy options that would minimize significant economic impacts. Chapter 3 describes the requirements related to IRFAs and FRFAs. The Agency must prepare an IRFA/FRFA for rules that are subject to the RFA unless the Agency certifies that the rule will not have a SISNOSE (5 U.S.C. sections 603-605). A screening analysis, therefore, serves as a means by which EPA determines and documents its decision to either certify that a rule will not have a SISNOSE or prepare the IRFA/FRFA, convene a Small Business Advocacy Review Panel, and prepare a Small Entity Compliance Guide. It may also be used to

provide the required factual basis for a certification of no SISNOSE.

2.2.2 How is a Screening Analysis Different from the Economic Analysis Described in Executive Order 12866?

The difference between a screening analysis and the broader economic analysis described in Executive Order (E.O.) 12866[11] is that a screening analysis focuses exclusively on economic impacts to small entities, while a broader economic analysis focuses on costs and benefits to society as a whole.

When a general economic analysis is conducted for a rule (e.g., it is a "significant regulatory action" under E.O. 12866), the screening analysis can be conducted as part of the larger economic analysis, provided that the information on small entity impacts is set out clearly. Each economic analysis performed for a given rule should strive to make consistent assumptions and interpretations of results. However, in cases where different approaches call for alternative assumptions, those differing assumptions should be highlighted and the reasons for using them should be clearly explained.[12]

2.3 Is a Screening Analysis Needed for My Rule?

Only rules that are required to undergo notice and comment under the Administrative Procedure Act (APA), or other applicable statutes, are subject to the requirements of the RFA (5 U.S.C. sections 603-604). Therefore, if your rule is **not** required by statute to undergo notice and comment, it is **not** subject to the RFA and you do not need to prepare a regulatory flexibility analysis or a certification of no SISNOSE. See Section 1.5 for a more complete discussion of which rules require notice and comment.

However, as a matter of Agency policy, even if your rule is not subject to the RFA, **to the extent that you foresee that your rule will have an adverse economic impact on small entities, you should assess those impacts and make efforts to minimize them through consultation with the small entities likely to be regulated, while remaining consistent with applicable statutory requirements.** In addition, even if your rule is not subject to the RFA, the preambles to the proposed and final rules should include a "Regulatory Flexibility" section that explains why the rule is not subject to the RFA.

2.4 What Basic Steps Make up a Screening Analysis?

If you have determined that your rule is subject to the RFA, you should conduct a

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[11] For more information on Executive Order 12866's economic analysis - see EPA's Action Development Process Library intranet site: http://intranet.epa.gov/adplibrary/statutes.htm#ombreview

[12] For example, the simple screening methods outlined in this Chapter assume that affected entities absorb the full cost of the regulation, while the broader economic analysis may assume some cost pass-through. An analyst choosing to examine cost pass-through to inform the SISNOSE determination should adopt assumptions that are consistent with relevant assumptions made in other economic analyses conducted for the rule.

screening analysis to determine if you can certify the rule as not having a SISNOSE. This section provides an overview of the four basic steps that make up a screening analysis. This approach is also illustrated in **Figure 3**. More details on specific components of the approach are provided in Sections 2.5 through 2.8. Generally, this screening analysis process is applicable to both the proposed and final versions of your rule, since the RFA requires that a regulatory flexibility analysis or a certification be prepared for each version (5 U.S.C. sections 603-604).[13] The four steps in the screening analysis process are:

Step 1 Determine which small entities are subject to the rule's requirements (see Section 2.5);

Step 2 Select appropriate measures for determining economic impacts on these small entities and estimate those impacts (see Section 2.6);

Step 3 Determine whether the rule may be certified as not having a SISNOSE (see Section 2.7); and

Step 4 Document the screening analysis and include the appropriate RFA statements in the preamble (see Section 2.8).

2.5 Step 1: Determining Which Small Entities are Subject to the Rule's Requirements

The first step in the screening analysis process is determining which, if any, small entities are subject to the rule's requirements. This step involves three activities:

- Identify the entities or types of entities (regardless of size) subject to the rule's requirements (Section 2.5.1);
- Define "small" for each type of entity (Section 2.5.2); and
- Determine whether it is likely that any of the entities subject to the rule's requirements are small (Section 2.5.3).

2.5.1 Identify the Types of Entities Subject to the Rule's Requirements

It is likely that the types of entities regulated by the rule were identified during the development of the rule and preparation of the primary economic analysis. For a screening analysis, you should re-examine these entities to identify those small entities that are subject to

[13] If a program is not planning to certify that a proposed or final rule does not have a SISNOSE, then a screening analysis is not required because a regulatory flexibility analysis will be prepared. Frequently, however, the screening analysis is a necessary step in determining whether to certify a rule as not having a SISNOSE.

the rule's requirements.

The determinative question is "who is subject to the requirements of the rule?" If a small entity will have obligations imposed on them directly by the rule, then the small entity is subject to the requirements of the rule and it should be included in the RFA screening analysis. If a small entity does not have an obligation imposed on them directly by the rule, it should not be included in the analysis. This is true even if the entities are included in the rule's broader economic analysis, either for purposes of complying with Executive Order 12866 or the Unfunded Mandates Reform Act. **Given that the SISNOSE determination is subject to judicial review, it is important to limit the screening analysis to what is needed to make the SISNOSE determination.**[14]

Further, you should analyze who is subject to the requirements of the rule even if the rule is either not immediately enforceable or does not impose immediately applicable requirements on those subject to the rule. You should perform this analysis as long as you know: (1) who will be regulated; and (2) what requirements will be imposed. For example, the promulgation of effluent limitations guidelines in the water program does not result in imposition of requirements on direct dischargers until the limitations are included as conditions in the discharger's NPDES permit. Either EPA or States must take some action before a specific discharger must comply with the requirements. We can, however, generally develop this screening assessment (and a Regulatory Flexibility Analysis if needed) because EPA must include conditions implementing guidelines in any permits it issues and State laws generally must be at least as stringent as EPA's. Moreover, EPA knows who will be regulated (we define that in each effluent limitation guideline). We can perform a screening analysis premised on a reasonably clear prediction as to who will be regulated and with what economic impact.

2.5.2 Define "Small" for Each Type of Entity

The RFA provides separate definitions for what constitutes "small" for three types of entities:

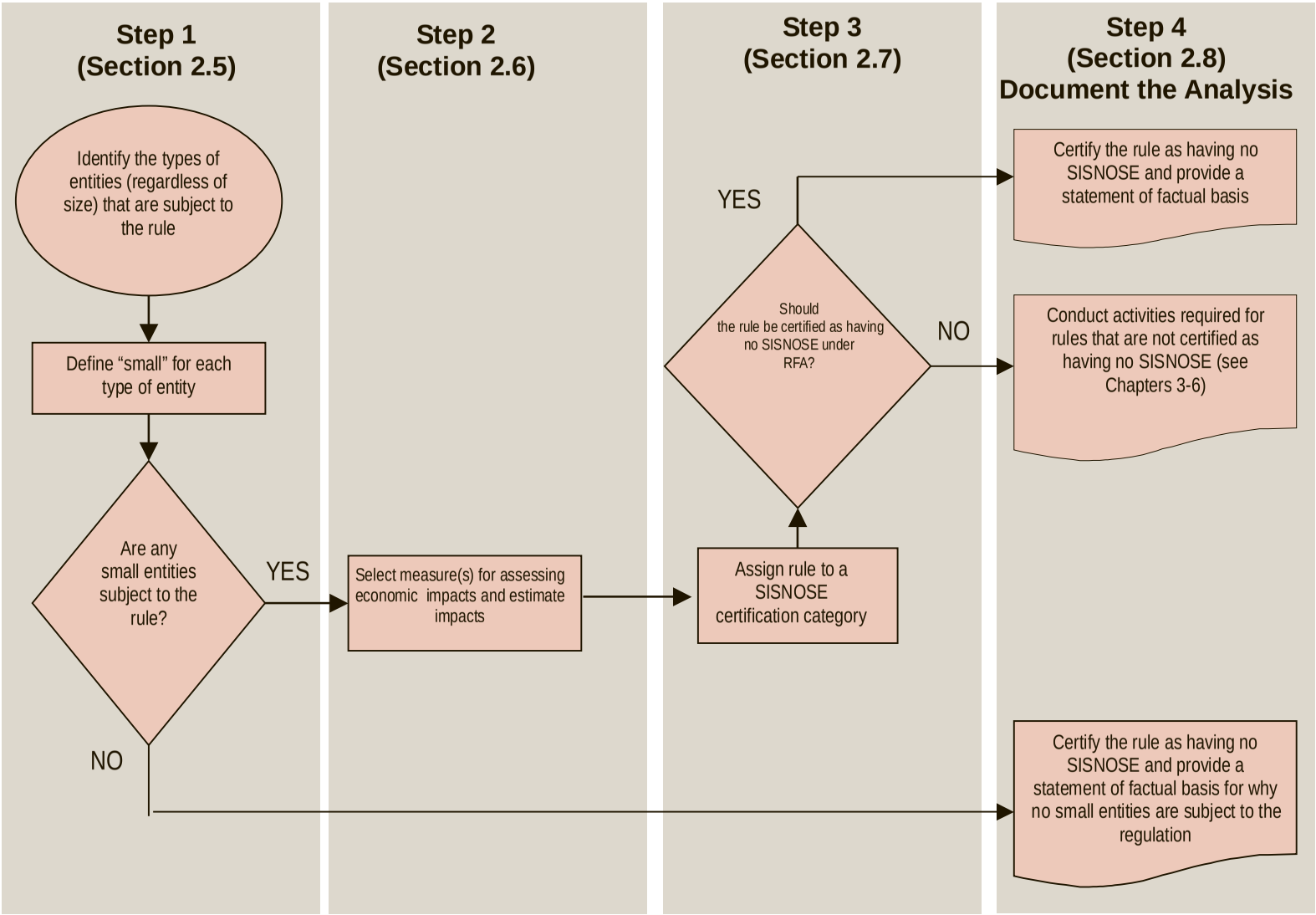
small businesses

small governmental jurisdictions, and

small organizations.

[14] EPA believes that only rules that will have a **direct** significant **adverse** economic impact on a substantial number of small entities that are subject to the rule require an IRFA or FRFA, since the purpose of both analyses is to identify adverse impacts on small entities and discuss regulatory alternatives that **minimize** significant economic impacts on small entities (see 5 U.S.C. section 603-604). Thus, rules that **relieve** regulatory burden, or otherwise have a positive net economic effect on the small entities subject to the rule, do not require an IRFA or FRFA.

Screening Analysis Overview
Figure 3



Under the RFA the Agency can adopt alternative definitions for small business, small organization and small governmental jurisdiction provided that the agency follows procedures set out in the statute (5 U.S.C. section 601). Section 2.5.5 discusses when it may be appropriate to apply an alternative definition and the procedures to follow when establishing an alternative definition.

What is a "small business"?

The RFA incorporates and uses the definition of "small business" found in the Small Business Act (5 U.S.C. section 601(3)). The Small Business Act authorizes the Small Business Administration (SBA) to define "small business" by issuing regulations. The SBA periodically reviews and reissues these definitions. SBA has established size standards for various types of economic activities, or industries, under the North American Industry Classification System (NAICS). These size standards generally define small businesses based on the number of employees or annual receipts. The current version of SBA's size standards can be found at http://www.sba.gov/size. **Note** that the SBA definition of a small business applies to a firm's parent company and all affiliates as a single entity.

What is a "small governmental jurisdiction"?

The RFA defines "small governmental jurisdiction" as the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000 (5 U.S.C. section 601(5)). For the purposes of the RFA, States and tribal governments are not considered small governments.

What is a "small organization"?

The RFA defines "small organization" as any "not-for-profit enterprise which is independently owned and operated and is not dominant in its field" (5 U.S.C. section 601(4)).

2.5.3 Determine Whether Any of the Entities Subject to the Rule are Small

In determining whether any small entities are subject to your rule's requirements, you should first group the entities subject to the rule by type (i.e., business, government, nonprofit entity). Next, for each type of entity, apply the definition of "small," or an appropriate alternative definition that the Agency has adopted or intends to adopt in accordance with the procedures established by the RFA (see Section 2.5.5).

2.5.4 What is the Relationship Between the Definition of "Small" Used in the Analysis and the Definition (if any) Used in the Rule?

Some rules may include special provisions to minimize economic impacts on certain classes or categories of entities otherwise subject to the particular rule. These classes or categories may, in some cases, include or be limited to small entities or subsets of small entities. In cases where the universe of entities to which such provisions apply is not limited to "small entities" as

defined in the RFA, the provisions of such rules may employ a definition of small entity for those entities subject to the special provisions that is different from the definition used for the RFA analysis. This is acceptable since the definitions are used for different purposes. The RFA does not require regulatory relief to be granted to small entities. For example, it may be the case that only a subset of the small entities captured in the screening analysis' definition faces significant economic impacts. In such a case, the rule might provide relief to only the subset of small entities most in need of special treatment. You do not need to propose an alternative size standard under the RFA to provide regulatory flexibility to a subgroup of the small entities most affected by the rule.

It may also make sense to define "small" for environmental regulatory purposes in terms other than revenue or number of employees--the common SBA size measures for characterizing business entities. For example, the regulations for permitting concentrated animal feeding operations (CAFOs) require only that animal feeding operations designated as "small CAFOs" must obtain permits. EPA's regulations define "small CAFOs" in terms of, among other things, the numbers of animals they confine, rather than revenues or employees, because the number of animals relates to the degree of environmental impact. While such an environmentally relevant definition may not correlate exactly with the definition used in the regulatory flexibility analysis, it may nonetheless offer an environmentally appropriate way to provide relief to most "small entities" as defined by the RFA. In the case of the CAFO rules, while a few small entities are regulated as large CAFOs because they happen to confine large numbers of animals, the regulatory definition of small CAFO nonetheless excludes from coverage hundreds of thousands of animal feeding operations that are "small" both in terms of the degree of their environmental impact and in terms of the SBA size standards.

2.5.5 Alternative Small Entity Definitions

Section 601 of the RFA allows you to establish an alternative definition of small for the entities subject to your rule when the definition is "appropriate to the activities of the agency." An alternative definition of small governmental jurisdiction must also be based on "such factors as location in rural or sparsely populated areas or limited revenues due to population of such jurisdiction" (5 U.S.C. section 601(5)).

2.5.5.1 In What Situations Should I Consider Establishing an Alternative Small Entity Definition? [15]

In general, there are several situations in which an alternative definition may be appropriate:

SBA's size standards are not most appropriate for considering impacts on small entities subject to the rule. Section 601(3) of the RFA adopts the SBA size standards established under

[15] When developing and applying alternative definitions of small business, small government and small nonprofit organization, you should be careful to develop alternative definitions that do not confuse small entities with entities of any size that emit a small volume of pollution. It may be appropriate for the Agency to provide regulatory flexibility or relief to small-volume polluters on general policy grounds, but the focus of the RFA is on entities whose size or resources are small in comparison to other entities of their type.

section 3 of the Small Business Act (15 U.S.C. 632) which are primarily intended to determine whether a business entity is eligible for government programs and preferences reserved for small businesses (13 CFR 121.101), i.e., the SBA size standards are primarily intended to "seek to ensure that a concern that meets a specific size standard is not dominant in its field of operation" (13 CFR 121.102(b)). See also section 632(a)(l) of the Small Business Act. You may determine that the SBA size standard for some industrial sectors are not generally the best standards to use in assessing the potential impacts on small businesses. For example, in some industrial sectors, businesses that are considered large multi-national companies in other contexts (such as when regulated under the Federal Insecticide, Fungicide and Rodenticide Act or Toxic Substances Control Act) may qualify as small businesses when applying SBA size standards that are based on number of employees.

The Act's definitions are difficult to implement given methodological or data limitations of the analysis. You may be limited in the precision with which you can apply a size definition because of data or methodology used for the analysis. For example, a rule may cover businesses in many different industries encompassing many different SBA size categories. Using the SBA size definition specific to each industry may be methodologically difficult.

The applicable environmental statute already employs a suitable alternative definition. In these instances, the program may prefer to use the definition contained in the applicable environmental statute not only in the rule itself, but also in the RFA analysis. For example, the Safe Drinking Water Act has numerous provisions for separate requirements for "small systems," which are defined in terms of the number of customers served, not employees or revenue of businesses, or the population of the governmental jurisdiction. Another example of a statutory-specific definition of "small business" is the one found in the Pesticide Registration Improvement Act of 2003 (PRIA). Under PRIA, a small business is defined in terms of both its number of employees and its annual global gross revenues from pesticides.

2.5.5.2 What Procedures Should I Follow to Establish an Alternative Small Entity Size Standard?

The RFA specifies procedures for adopting an alternative definition. For all alternative definitions you must publish the alternative definition in the *Federal Register* and provide an opportunity for public comment (5 U.S.C. section 601). For alternative definitions of "small business" you must also consult with the Chief Counsel for Advocacy of the SBA (5 U.S.C. section 601(3)). Your consultation may include a letter to SBA's Chief Counsel for Advocacy. Document any consultation with SBA to establish an alternative small business size standard (e.g., letters, email, phone conversations) and place the documentation in the rulemaking docket.

To Establish an Alternative Definition of "Small":

- Provide an opportunity for public comment;
- Publish the alternative definition in the *Federal Register,* and
- Consult with the Chief Counsel for Advocacy of the SBA (for alternative definitions of "small business").

If you plan to adopt an alternative definition, it is

extremely important to comply with these specific procedures. At least one federal agency has had a rule vacated for basing its RFA analysis on an alternative small entity definition it did not properly establish. In addition, remain cognizant of the timing of the establishment of an alternative definition in relation to a Panel (if required), so as not to exclude any small entities from the Panel process by prematurely employing an alternative definition. In light of these potential pitfalls, **it is imperative that you consult with your Regulatory Steering Committee representative and the Small Business Advocacy Chair staff before you proceed with the adoption or use of an alternative definition.** If you decide not to adopt a proposed alternative definition, you should use the SBA size standards or other previously established alternative small entity definition for your rulemaking.

You should specify clearly in the rulemaking notice in which an alternative definition is proposed whether you are proposing to use the alternative definition for:

that particular rulemaking only,
that rulemaking and any subsequent amendments, or
that rulemaking as well as all subsequent rulemakings regulating the same small entities under the same authority.

If you fail to clearly state the applicability of the alternative definition to later rulemakings in your original notice or proposed rule, you may have to repeat the process of adopting the alternative definition for subsequent rules (i.e., give notice, take comment and, for an alternative definition of "small business," consult with SBA). Once an alternative definition is established for a particular set of rules, be sure to use that definition for all of those rules unless you adopt a different definition. Adopting a new alternative definition will involve the same process described above. Re-establishing a previous definition also requires notice and opportunity for public comment and may require consultation with SBA if re-establishing a definition for "small business."

2.6 Step 2: Determining Appropriate Measures of Economic Impacts

The analytic objective of your screening analysis is to allow you to determine whether or not you may certify your rule as not having a SISNOSE. The RFA does not establish a formula for estimating the economic impact of a rule on small entities. Nor does it define the terms **significant** or **substantial** as they pertain to the extent of economic impact and the number of small entities affected. Based on past experience, we've identified several methods or quantitative measures that may be used to assess economic impact on small entities. You have the flexibility to select the most appropriate method for your rulemaking. [16]

For purposes of the screening analysis, the question for the rulewriter is: can we properly certify that the rule, if promulgated, will **not** impose a SISNOSE. To answer this question, you

[16] Regardless of the analytic methods you use, you should explain your reasons for selecting the methods in the documentation of the analysis.

should address two subquestions:

1) What is the best way to measure a rule's economic impacts on affected entities?

2) What level of economic impact (i.e., threshold), on what number of small entities is sufficient to establish that there may be a SISNOSE and the rule should thus not be certified?

This section discusses what you should do to answer the first subquestion. Section 2.7 addresses the second sub-question.

In addition to this guidance document, the Agency has published a comprehensive manual on conducting economic analysis, *Guidelines for Preparing Economic Analyses* (September 2000), which is available at http://www.epa.gov/economics . Chapters 8 and 9 of the *Guidelines* provide a comprehensive discussion of methods for estimating costs and economic impacts of proposed regulations. The *Guidelines* also discuss methods for considering equity and distributional concerns as part of the economic analysis of the rule. The economic impacts on small entities are discussed as a specific subset of total impacts. You should refer to the *Guidelines* for an in-depth discussion of these methods.

2.6.1 The Role of Qualitative Analysis

Before beginning a quantitative analysis of the economic impact of the rule on small entities, you should qualitatively think through the actions a small entity will have to take to comply with the rule and how those actions might differ from those taken by large companies. For example, will small entities incur the same initial compliance costs - such as for buying and installing equipment, establishing new procedures, and/or record keeping - as large entities, or are initial costs likely to be proportionate to the size of the company? Will initial compliance costs be high enough that entities will need to obtain financing and, if so, do small entities have the same access to financing as large entities? Will small entities have to obtain access to professional or administrative services that large entities might maintain "in-house?"

Although the broader economic analysis for a rule may identify and include some separate cost elements for small entities, the economic analysis may not identify every meaningful aspect of costs to small entities (see Section 2.2.2 for more information on the relationship between the broader economic analysis and the screening analysis). A comprehensive qualitative assessment provides a good foundation for quantitative analysis of the regulation. A thorough understanding of the compliance procedures will help you develop meaningful quantitative analyses of the rule, such as selecting appropriate methods for estimating economic impacts, collecting relevant data, and using professional judgement to compensate for missing data. A thorough, qualitative analysis of small entities' compliance actions, and associated costs, provides the foundation for the SISNOSE determination.

If a qualitative assessment indicates that you may not be able to certify your rule, you may choose to prepare an IRFA (and, later, FRFA) on that basis and avoid the need for a detailed,

quantitative screening analysis, although the IRFA (or FRFA) itself will require some quantitative information. IRFAs and FRFAs are discussed in Chapter 3. Where a qualitative assessment indicates that a rule will **not** have a SISNOSE, you may be able to certify the rule on that basis or you may need to conduct a quantitative analysis to confirm the results of the qualitative assessment. For example, where the information necessary to conduct a quantitative analysis is not reasonably available, it may be appropriate to certify the rule based on the qualitative assessment alone. Because the decision to certify a rule may be judicially reviewable, you should prepare a quantitative analysis whenever possible to support a decision to certify. **You should consult your Regulatory Steering Committee representative and the Small Business Advocacy Chair when you anticipate relying solely on a qualitative analysis to certify a rule.**

2.6.2 Quantitative Analysis

Assessment of economic impacts on small entities can include many different factors, such as the cost of compliance relative to the entities' income or assets, the ability of the entities to pass compliance costs through to customers or suppliers, and the relative economic impacts on small entities compared to those on large entities.[17] The most appropriate method for a particular screening analysis will usually depend on the data available and on the methodology used for the economic analysis of the rule. In general, more detailed analysis requires more data and resources. Therefore, it is preferable to start with a relatively simple methodology and add more complexity as needed to reach an acceptable level of confidence in the determination of whether the rule may have a SISNOSE.

The simplest method of screening for economic impacts on small entities is the direct compliance cost method. This method may be used as an initial screening analysis. More sophisticated analyses can be conducted later to refine the estimate if a determination about SISNOSE is not clear from the initial analysis (see Section 2.7.4 for more information on additional analysis).

Under the direct compliance cost method, the compliance costs faced by small entities[18] (estimated as the capital, operating, maintenance, administrative, and other direct compliance costs associated with the rule) are compared to one or more financial statistics (e.g., sales, profits, operating expenditures) of the regulated small entities. Annualizing the compliance costs is appropriate when a stream of cash flows or a large capital expenditure is involved with compliance. There are several variations of this method that differ by the financial statistic used as the basis of comparison. Selection of the appropriate financial statistics depends on the type of small entity being regulated and the availability of financial data on those small entities.

Conceptually, we believe that a profits test represents the most accurate screening analysis

[17] Note that an analysis of relative impacts should not be used as the sole basis for certifying a rule as not having a SISNOSE. The phrase "significant economic impact on a substantial number of small entities" describes an absolute measure of economic impacts on small entities, not one that is relative to economic impact on large entities. Nevertheless, an analysis of relative economic impacts can be useful to characterize the distribution of effects.

[18] Chapter 9 of EPA's *Guidelines for Preparing Economic Analyses* provides more information on estimating compliance costs.

for determining whether a regulation will pose a significant economic burden on small businesses. However, because of procedural and operational issues associated with the implementation of a profits test, a sales test remains our preferred quantitative guideline at this time. Because data on profits are limited, especially for small businesses, routine use of a profits test would require us to estimate profits for small businesses where there are currently insufficient data. A summary of preferred and alternative metrics for estimating the economic impacts on each type of small entity (businesses, governments, nonprofit organizations) is presented in **Table 1.**

TABLE 1: Recommended Quantitative Metrics for Economic Impact Screening Analyses[a] (→ indicates preferred measures)	
SMALL BUSINESSES	
→ Sales Test	Annualized compliance costs as a percentage of sales
Cash Flow Test	Debt-financed capital compliance costs relative to current cash flow
Profit Test	Annualized compliance costs as a percentage of profits
SMALL GOVERNMENTAL JURISDICTION	
→ Revenue Test	Annualized compliance costs as a percentage of annual government revenues
Income Test	Annualized compliance costs to household (per capita) as a percentage of median household (per capita) income
SMALL NONPROFIT ORGANIZATIONS	
→ Expenditure Test	Annualized compliance costs as a percentage of annual operating expenditures
Asset Test	Annualized compliance costs as a percentage of total assets
[a] The selection of threshold values for determining whether a given level of economic impact constitutes a "significant economic impact" is discussed in Section 2.7.1.	

While you may choose to apply any of the suggested measures based on the type of information available, the table indicates a preferred guideline for each type of small entity:

→ For small businesses - annualized compliance cost as a percentage of sales;[19]

→ For small governments - annualized compliance cost as a percentage of annual government revenues; and

→ For small nonprofit organizations - annualized compliance cost as a percentage of annual operating expenditures.

[19] When sales data are unavailable, revenue or receipts (though technically different than sales) can usually serve as a reasonable proxy for sales.

2.7 Step 3: How Should I Use the Screening Analysis to Determine If a Rule May Be Certified under the RFA?

Each of the measures shown in Table 1 will yield quantitative estimates of the economic impact on the small entities subject to the rule. The question addressed in this section is how to interpret those values in the context of determining whether your rule may be certified as "no SISNOSE". Since there can be no single formula to produce a consistently appropriate answer, the Agency encourages program offices to consider the unique factors associated with a particular rulemaking in order to reach a conclusion appropriate to the case at hand. To assist you with this process, EPA has developed general guidelines for determining when a rule can be certified as not having a SISNOSE.

Under the Agency's general guidelines, rules are assigned to one of three SISNOSE certification categories based on a comparison of the economic impacts (e.g., one or more measures such as those listed in Table 1) to specific thresholds established based on the circumstances of your rule and the number of entities with impacts above the threshold(s). The thresholds you define for the circumstances of your rule define what level of impact is considered *significant* and the number of small entities that is considered *substantial*. Sections 2.7.1 and 2.7.2 discuss how you may define the significant impact and substantial number thresholds. Comparing the magnitude of the impacts, and the number of small entities facing the impacts, to the thresholds will determine which SISNOSE certification category you assign to your rule. The SISNOSE certification categories are as follows:

Presumed No SISNOSE:	The rule is **presumed not to have a significant economic impact on a substantial number of small entities.** However, your Assistant Administrator may exercise discretion to prepare an analysis of the economic impacts of the rule on small entities.[20]
Uncertain - No Presumption:	**No presumption applies.** You may consult with the Small Business Advocacy Chair (SBAC) if you believe that your rule should be certified as **not** having a SINOSE.
Presumed Ineligible for Certification:	The rule is **presumed to be ineligible for certification.** Unless you can demonstrate, through further analysis, that the rule nonetheless should be certified as not having a SISNOSE, you should contact the SBAC through your Regulatory Steering Committee representative, prepare a regulatory flexibility analysis, and participate in a Small Business Advocacy Review Panel.

Table 2 represents an **example** of a decision process you may use to determine whether your rule may have a SISNOSE (i.e., which category to assign to your rule). The thresholds displayed in Table 2 are 1% and 3% for determining the *significance* of the economic impact on

[20] The terms IRFA and FRFA are used only for rules that are not certified. If a rule is certified as not having a SISNOSE and you perform an analysis that contains some or all of the required elements of and IRFA or FRFA, the documentation of your analysis should be titled "Small Entity Flexibility Analysis" and not IRFA or FRFA.

small entities, and 100 and 1000 and/or 20% for determining if the number of small entities impacted is *substantial.* **These thresholds are only examples.** No bright line exists for determining whether a given set of economic impacts constitutes a SISNOSE. The RFA does not define the terms *significant* or *substantial* as they pertain to the extent of economic impact and the number of small entities affected. EPA has not established fixed definitions for the terms, reflecting the practical difficulty of stipulating what would uniformly represent a significant economic impact or a substantial number in every regulatory circumstance. Even when EPA issues a rule adhering to the full procedural and analytic requirements of the RFA (i.e., without certification), the Agency does not state the rule positively will impose a SISNOSE, since it may or it may not. In such cases, we simply refrain from certifying it.

As in the example decision process in Table 2, you determine the numerical thresholds that are appropriate to the circumstances of your rule. The thresholds represent three factors that may be considered in making your SISNOSE determination. The three factors are:

(1) magnitude of economic impact that may be experienced by regulated small entities;

(2) total number of regulated small entities that may experience the economic impact; and

(3) percentage of regulated small entities that may experience the economic impact.

The first factor relates to defining a numerical threshold for the significance of the economic impact and is discussed in Section 2.7.1. The second and third factors relate to the numerical thresholds for substantial number of small entities and are discussed in Section 2.7.2.

TABLE 2: Example SISNOSE Certification Decision Process[a]

Economic Impact	Number of Small Entities Subject to the Rule and Experiencing Given Economic Impact	Percent of All Small Entities Subject to the Rule That are Experiencing Given Economic Impact	Certification Category[b]
Less than 1% for all affected small entities	Any number	Any percent	Presumed No SISNOSE
1% or greater for one or more affected small entities[c]	Fewer than 100	Less than 20%	Presumed No SISNOSE
	Fewer than 100	20% or more	Uncertain - No Presumption
	100-999[d]	Less than 20%	Presumed No SISNOSE
	100-999	20% or more	Uncertain - No Presumption
	1000 or more	Any percent	Uncertain - No Presumption
3% or greater for one or more affected small entities	Fewer than 100	Less than 20%	Presumed No SISNOSE
	Fewer than 100	20% or more	Uncertain - No Presumption
	100-999[d]	Less than 20%	Uncertain - No Presumption
	100-999	20% or more	Presumed Ineligible for Certification
	1000 or more	Any percent	Presumed Ineligible for Certification

[a] This table and the numbers in it are given only as examples of the decision process and thresholds that may be chosen for a particular rule. The certification decision should not be solely based upon the application of this table nor should this table be referenced in your preamble. Additional information and other factors may be relevant in deciding whether to prepare a regulatory flexibility analysis or certify under the RFA.

[b] There may be cases in which the extent of the impact on small entities (measured in quantitative or qualitative terms) is particularly severe, even though the total number of small entities experiencing that impact is small (i.e., fewer than 100 or 20%). In such cases, the lead office should consider placing the rule in a category more applicable to the situation.

[c] For purposes of applying this portion of the table, the number of small entities that will experience an impact of 1% to 3% should be aggregated with the number of small entities that will experience an impact of 3% or greater. The total number of small entities that will experience an impact of 1% or greater should be used here in order to determine whether the number of small entities so impacted is large enough to warrant preparation of a regulatory flexibility analysis.

[d] As the number of small entities that will be affected by a rule by more than 1% or 3% of sales or revenues approaches 1000 in number, the substantial number guidelines of 20% of affected small entities may become less relevant in determining whether a regulatory flexibility analysis or a certification should be prepared.

2.7.1 Is the Level of Economic Impact on Small Entities Significant?

In the suggested decision process in Table 2, the first step in assigning a rule to a category, is defining a lower and upper threshold for each of the economic impact measures that have been estimated. The thresholds you define should establish whether the level of economic impacts faced by the small entities can be presumed as not significant. The variations of economic impact measures, regulatory requirements, and characteristics of potentially affected small entities is too great to allow EPA to establish threshold values for each measure that could be employed in Table 1. This section, therefore, discusses factors you should consider when establishing threshold values for your screening analysis.

The lower economic impact threshold is particularly important because it is used to screen out rules that generally will **not** have a significant economic impact and, therefore, can be presumed not to require an IRFA/FRFA (i.e., if all small entities subject to a rule face economic impacts less than the lower threshold, then the rule may be assigned to the Presumed No SISNOSE Category). For this reason the lower economic impact threshold should be set conservatively, at a level that precludes any reasonable possibility that a rule placed in the Presumed No SISNOSE Category might later be found to impose a "significant economic impact on a substantial number of small entities." The upper threshold defines a level of economic impact that would be unquestionably significant for a small entity.

In analyzing previous rules, EPA has often defined the lower threshold as compliance costs of 1% of sales and the higher threshold as compliance costs of 3% of sales as shown in the example in Table 2. **The example thresholds provided in Table 2 are for illustrative purposes only and are not meant to imply a uniform standard. It is the responsibility of each program to identify appropriate thresholds for a particular rule and set of regulated small entities.**

There are several types of information that can help you identify the appropriate threshold values. For example, profits can be a better indicator of ability to pay than sales. Moreover, variation in profit-to-revenue ratios exists across industries. Therefore, the magnitude of impacts defined as the lower and upper threshold for a particular rulemaking may take into consideration the average profit margins of the affected small entities and the ability of the entities to pass compliance costs to either customers or suppliers. To the extent that these types of information are available, you may wish to use them to inform your selection of appropriate thresholds.

2.7.2 Are a Substantial Number of Entities Facing a Significant Economic Impact?

Consideration of the number of small entities facing regulatory costs is dependent on the characteristics of the affected industry or group of small entities being regulated. One hundred small businesses may represent a small fraction of the total number of small businesses in some sectors, such as gasoline service stations, while the total number of small businesses in some niche markets may be less than a dozen. For this reason, analysts should examine both the total

number and percentage of regulated small entities experiencing significant economic impacts when determining whether a "substantial number" of small entities may be significantly impacted.

While the number thresholds provided in Table 2 are typical of those used in many past screening analyses, circumstances of a particular rule may cause an analyst to define thresholds differently. For example, there may be cases where the extent of economic impact (measured in quantitative or qualitative terms) is particularly severe, even though the number of affected small entities totals considerably fewer than 100 - or 20% - of all regulated small entities. In such cases, the lead office should consider not certifying the rule, but rather placing it in the Uncertain - No Presumption or Presumed Ineligible for Certification categories. Indeed, in the past the Agency has employed such discretion by choosing not to certify a proposed rule that directly regulated only a small number of small businesses, but with compliance costs considerably greater than 3% of sales. Likewise, the relative importance of the two measures of the number of small entities impacted can vary with the situation. For example, as the total number of small entities bearing "significant" costs approaches a number like 1000, the relevance of the 20% threshold becomes far less significant.

It is important to remember that **these numbers and the process outlined in Table 2 are only guidelines for assessing whether a rule may have a SISNOSE.** They suggest categories that support presumptions. Agency management should exercise its own judgment in deciding whether to certify a particular rule.

2.7.3 What If My Rule Affects a Variety of Different Entities?

While a decision on whether to certify the rule is made based on consideration of the impacts on all small entities subject to the rule, your analysis should consider economic impacts on each of the **three types** of small entities that may be affected: small businesses, small governmental jurisdictions, and small nonprofit organizations. While many rules affect only a single type of small entity (e.g., small businesses), they might affect a variety of entities within the type (e.g., businesses in different industries). Other rules may affect more than one type of small entity (e.g., small businesses and small nonprofit organizations). This section describes how your analysis should account for situations in which a variety of different entities are affected. Section 2.7.3.1 addresses situations for which the variety is contained within a single type of small entity (e.g., only small businesses). Section 2.7.3.2 addresses situations in which affected small entities are of different types (e.g., small businesses and small governmental jurisdictions).

2.7.3.1 Economic Impacts on Entities Within a Type Should Be Aggregated

A rule may apply to more than one kind of business, government, or nonprofit organization. For example, a rule may apply the same requirements to dry cleaners and auto body shops. In assessing the economic impact of such a rule on "small business," it may be appropriate to analyze the rule's impact on each kind of business separately, particularly where the rule may impose significantly higher costs on some kinds of businesses than on others.

However, for the purposes of deciding whether to prepare a regulatory flexibility analysis or to certify no SISNOSE, the impacts of the rule on the two types of business should be aggregated and the decision based on the aggregated impact.

When both a decrease and increase in burden will occur to exactly the same entities, it is appropriate to consider the net impact on those small entities. However, when a rule will reduce burdens on some small entities and create or increase burden on others, these should not be netted (even if all the affected entities fall within the same industry). In this case, only the adverse impacts are relevant to the SISNOSE determination.

2.7.3.2 Economic Impacts on Entities of Different Types Should Be Assessed Both Separately and Aggregated

Where the rule will apply to more than one type of small entity (i.e., small businesses, small governments, and small nonprofit organizations), you should analyze the economic impact separately for each type of entity subject to the rule. For example, for a rule that will impose the same (or substantially similar) requirements on small businesses and small governments, you should analyze the rule's impact on small businesses using an economic measure appropriate to small businesses, and analyze the impact on small governments using an economic measure appropriate to small governments. You should then determine categories separately for each type of entity. The rule will thus be categorized twice - once for its impact on small businesses and a second time for its impact on small governments.

Where a rule applies to more than one type of small entity, and impacts have been analyzed for each type of small entity separately, one further analytic step is required to categorize the rule. This involves applying the total number and percentage thresholds to the aggregate number of small entities affected by the rule. These steps are necessary because the screening process uses total numbers as well as percentages to assess whether the rule is eligible for certification. The total numbers provide a suggested floor and ceiling for considering numbers of small entities that may be impacted above or below the suggested thresholds. For example, a rule imposing "significant" economic impacts on over 1000 small entities is presumed to meet the substantial number threshold, even if that number represents less than 20% of affected small entities.

The total number threshold should be chosen as indicative of a substantial number not only with respect to any one type of small entity, but with respect to **all** small entities taken together. Thus, for the example thresholds displayed in Table 2, a rule with an impact of 2% of sales, revenues or assets with respect to 334 small businesses, 334 small governments and 334 small organizations, where 334 is less than 20% of each type of small entity, would be categorized as Presumed No SISNOSE if each type of entity were examined separately. However, the rule would actually fall into the Uncertain - No Presumption category since more than 1000 small entities may be significantly affected by the rule.

For some rules, the issue of applying the matrix to each type of small entity may be a two step process - that is, **you should apply the matrix separately to different kinds of small**

businesses, small governments, or small nonprofits. A rule may, for example, apply the same requirements to dry cleaners and auto-body shops, but the rule's economic impact may be much greater on one than on the other kind of business. As indicated above, it would be appropriate in such a case to analyze the impact of the rule separately for the two kinds of business. For purposes of deciding whether to prepare a regulatory flexibility analysis or a certification, however, the impacts of the rule, once assessed for the two kinds of business, should be aggregated and the aggregate fed into the matrix. Please note that if your rule is certified, the Agency is assuring the public that the rule will not impose a significant economic impact on a substantial number of small entities of all types taken together. **It is not appropriate to prepare separate certifications for small businesses, small governments, and small non-profit organizations.**

2.7.4 What Additional Information Can I Provide to Decision-makers When the Rule Falls into the "Uncertain - No Presumption" SISNOSE Category?

When the simple direct compliance cost screening method produces an uncertain answer to the question of whether your rule can be certified as not having a SISNOSE, you may wish to consider doing additional analysis in order to provide a better picture of whether the economic impact on small entities is significant or substantial. The decision to conduct more analysis, and what type and level of analysis, will depend on many factors including: qualitative information that points to the rule being certified or not, data availability, and resource or time constraints.

Some analyses that may be helpful in refining an "Uncertain - No Presumption" SISNOSE category are an analysis of cost pass-through, use of or examination of profits or profit margins, measurement of the financial health of entities, or comparing the relative impacts on small entities versus large entities. While the simple initial screen for economic impacts typically assumes that entities are not able to shift some of the burden of higher costs onto consumers, an estimate of cost pass-through can reveal if entities are facing the full burden of the direct compliance costs. When data on profits is available, that information may be used directly, by applying a profit test (see Table 1), or indirectly, by using information on profit margins to inform your selection of appropriate thresholds (see Section 2.6.1) for use with other measures (e.g., cost as a percentage of sales). The financial literature contains many methods of predicting firm (or other entity) health and or closures. Finally, a comparison of a rule's impact on small entities versus large entities may reveal whether the impacts are disproportionately burdensome to the small entities.[21] More information on these analyses and others can be found in Chapter 9 of the *Guidelines for Preparing Economic Analyses.*

2.7.5 What Other Issues Should I Consider?

2.7.5.1 Data Issues

If you are unable to obtain adequate information regarding the entities affected by your

[21] Note that this type of analysis should not be used as the sole basis for certifying a rule as not having a SISNOSE. The phrase "significant economic impact on a substantial number of small entities" describes an absolute measure of economic impacts on small entities, not one that is relative to economic impact on large entities. Nevertheless, an analysis of relative economic impacts can be useful to characterize the distribution of effects.

rule, one option is to model such information based on other available data or on reasonable proxies. For example, you may choose to use quantitative information on another type of small entity whose behavior and financial characteristics are similar to those subject to the rule. Another example might entail the creation of baseline financial characteristics for a set of small entities drawing upon and adjusting quantitative information available for larger entities in the same industrial or governmental sector. In general, where quantitative information is sought, the goal is to obtain the type of data that allow for the most reliable form of quantitative analysis to be used. But where data limitations persist, you should identify and consider other reliable alternatives.

2.7.5.2 Baseline Compliance with Existing Regulations

In calculating the costs the rule will impose on small entities, you should presume full compliance with all existing applicable statutory or regulatory requirements. For example, if the new rule is designed to address widespread non-compliance with an existing rule, you should not assume full compliance with the existing rule, as this could undermine the basis for the new rule. Generally, in the case of a rule revising an existing rule, you should assess only the incremental cost of the rule revision. In such cases, you should consult with your Regulatory Steering Committee representative, the SBAC, and the OGC attorney for your rule before conducting the analysis. This issue is discussed more fully in Chapter 5 of the *Guidelines for Preparing Economic Analysis.*

2.7.5.3 Evaluating Multiple Regulatory Approaches or Options

When you plan to propose multiple regulatory alternatives (i.e., two or more approaches from among which one will be selected for promulgation in the final rule), you preferably should conduct a screening analysis on each of the proposed alternatives, but, at a minimum, you should analyze the alternative that most likely would have the greatest economic impact on small entities.

Similarly, if you plan to propose a single regulatory approach but seek comment on variations of that approach or on different approaches altogether, you should analyze not only the proposed approach but also the most potentially burdensome variation or approach that has a significant chance of being promulgated. You should contact your Regulatory Steering Committee representative and your OGC attorney if you are uncertain about the appropriate scope of the alternatives or approaches to include in the screening analysis for your proposed rule.

2.8 Step 4: What Should I Do after Assigning My Rule to a Category?

2.8.1 Document the Screening Analysis

For many rules, full documentation of the screening analysis will be contained within the larger economic analysis prepared for the rule. If this is not the case, the screening analysis should be documented in the same manner as any good economic analysis by fully describing the data and methods used, assumptions made, uncertainties and limitations involved, and

conclusions reached. If you are certifying a rule as not having a SISNOSE, you must describe the factual basis for the certification within the preamble for the rule.[22] (See 5 U.S.C. section 605(b)) The text included in the preamble does not have to contain the complete documentation of the screening analysis (see 5 U.S.C. section 605(a)), but should at least present a summary of the findings and cite the document where the full documentation can be found.[23] The certification and statement of factual basis you include in the preamble to a final rule are subject to judicial review.

2.8.2 What Other Steps are a Part of the RFA Process?

For rules that can be certified as not having a SISNOSE, a certification statement and justification must be prepared (see 5 U.S.C. section 605(b)) and included in the preamble for the rule (see Section 2.7.1 above). When a rule will not be certified, you should consult with both your SB AC staff and Regulatory Steering Committee representative (see http://intranet.epa.gov/adplibrary/ for contact information). These representatives will help guide you and your rule through the RFA process, including:

preparing the screening analysis (this Chapter);
preparing an IRFA or FRFA (see Chapter 3);
conducting outreach (see Chapter 4);
convening a Panel (see Chapter 5); and
preparing a small entity compliance guide (see Chapter 6).

[22] Please see the *Rulewriter's Guide: Preamble Templates for the Regulatory Flexibility Act (RFA),* (Office of Policy, Economics and Innovation, Regulatory Management Division, December 2004) for more guidance on writing the RFA section of a preamble.

[23] The terms "IRFA" and "FRFA" are included only in rules that are not certified. If a rule is certified as not having a SISNOSE and you perform an analysis that contains some or all of the required elements of an IRFA or FRFA , the documentation of your analysis should be titled "Small Entity Flexibility Analysis" and not IRFA or FRFA.

Chapter 3
Preparing the Initial and Final Regulatory Flexibility Analyses

3.1 What are IRFAs and FRFAs?

An Initial Regulatory Flexibility Analysis (IRFA) and a Final Regulatory Flexibility Analysis (FRFA) are the analyses of economic impacts on small entities that you must prepare unless your rule is certified as not having a significant economic impact on a substantial number of small entities (SISNOSE). See 5 U.S.C. sections 603 and 604. This chapter explains these analyses, how they are performed and information that the RFA requires each to contain.

What is an IRFA?

Section 603 of the Regulatory Flexibility Act (RFA) requires agencies to prepare an initial regulatory flexibility analysis (IRFA) for proposed rules that are subject to the RFA unless the agency certifies that the rule will not have a SISNOSE.[24] As noted in Section 1.5, only proposed rules subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute are subject to the requirements of the RFA. An IRFA describes the economic impact of the proposed rule on small entities and any significant alternatives to the proposed rule that would accomplish the objectives of the rule while minimizing significant economic impacts on small entities.

An IRFA ensures that the agency has explicitly considered small entities **before** the requirements of the rule are finalized. It is not simply a stand-alone paperwork exercise. In most cases, IRFAs must be made available for public comment along with the proposed rule.[25] Although an IRFA is not subject to judicial review, it is important that you carefully prepare each required component of the analysis.

[24] Chapter 2 describes the process for determining if a rule can be certified as not having a SISNOSE.

[25] Section 608(a) of the RFA authorizes agencies to waive or delay the completion of an IRFA if the agency publishes a finding that the rule is being promulgated in response to an emergency that makes compliance or timely compliance with the IRFA requirement impracticable. The finding must be supported by reasons and published in the Federal Register by the time the final rule is published.

What is a FRFA?

Section 604 of the RFA requires agencies to prepare a final regulatory flexibility analysis (FRFA) for final rules that are promulgated under the notice-and-comment rulemaking requirements of the Administrative Procedure Act (APA) after a notice of proposed rulemaking required by the APA or any other law, unless the agency certifies that the rule will not have a SISNOSE. A FRFA is similar, but not identical, to an IRFA. While both types of analysis contain some similar elements, there are several requirements specific to a FRFA. One such requirement is that the FRFA must summarize and respond to comments received on the IRFA.

A FRFA documents the Agency's consideration of alternatives to minimize economic impacts on small entities. In most cases, the FRFA must be prepared in time for it to be available to the public when the final rule is published (see 5 U.S.C. section 604)[26] The FRFA is subject to judicial review so it is crucial that you carefully complete each required component of the analysis.

Are the IRFA and FRFA Solely Quantitative Analyses?

No. The IRFA and FRFA contain both quantitative and qualitative information and describe several factors in addition to the potential economic impacts of a proposed or final rule on small entities. The central focus of the IRFA is to present the opportunities for, and outcomes of, alternative regulatory or policy options that could minimize the rule's potentially significant economic impacts on small entities subject to the rule. The purpose of the IRFA is to provide the decision maker with an analytic framework to inform the ultimate decision on the final rule and provide the public with information on the alternatives considered by the agency. The central focus of the FRFA is to describe the considerations particularly those related to small entity impacts underlying the ultimate decision on the final rule. The IRFA and FRFA include discussions of program design and scope issues, as well as quantitative economic analysis (see Sections 3.4.1 and 3.5.1 for the specific required elements of an IRFA and FRFA).

Both the IRFA and FRFA usually contain quantitative information about the potential economic impacts of the rule on small entities. Section 607 of the RFA indicates that as an agency complies with the requirement to prepare an IRFA or FRFA, it "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." The Agency's approach should be based on factors such as the quality and quantity of available information and the anticipated economic impact on small entities that are subject to the rule. The quantitative information estimated by the screening analysis may be included as part of the IRFA or FRFA (see Chapter 2 for information on screening analyses).

[26] Section 608(b) of the RFA allows the agency head to delay completion of the FRFA for up to 180 days after publication of the final rule in the Federal Register if the agency publishes a finding that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the FRFA requirement impracticable. The finding must be supported by reasons and published in the Federal Register by the time the final rule is published. If the FRFA has not been prepared within 180 days, the rule lapses and cannot be repromulgated until the FRFA has been completed.

3.2 What is the Relationship Between the IRFA/FRFA and a Rule's Broader Economic Analysis?

While the RFA may require an IRFA or FRFA for a rule, Executive Order (E.O.) 12866 may call for a broader economic analysis of a rule.[27] The focus of the IRFA and FRFA is the impact of the rule's requirements on the small entities that are subject to the rule, while the focus of an E.O. 12866 economic analysis, on the other hand, is social costs and benefits aggregated across all entities and individuals, not just those directly subject to the rule.[28] This broader focus provides a picture of the rule's impact on society as a whole.[29] This difference in focus derives from the different objectives of the mandates for the two types of analyses. Please note, however, that an E.O. 12866 economic analysis may contain a small entity impact section that may be written to satisfy the IRFA/FRFA requirements of the RFA.

Another difference in the analyses is that the RFA requires EPA to identify and consider (but not necessarily adopt) alternatives that minimize a rule's significant economic impacts on small entities subject to the rule.[30] The RFA, however, does not require the agency to adopt the alternative that has the least impact on small entities. E.O. 12866, on the other hand, encourages agencies, when legally permissible, to adopt the regulatory alternative that maximizes the net benefit to society. An E.O. 12866 analysis can encompass all economic impacts attributable to the rule, whether experienced by large or small entities, whether imposed directly or experienced indirectly downstream from the compliance activity, or whether borne by parties subject to the rule or other parties not bound by enforceable requirements.[31] Although these requirements differ, they are generally consistent. Indeed, the alternative that achieves statutory and regulatory objectives while minimizing economic impacts under the RFA may be identical to the alternative that imposes the least burden on society. In some cases, however, the lead office may find that the E.O. 12866 broader economic analysis and the IRFA/FRFA analysis point to different options. Such issues should be resolved on a case-by-case basis, in consultation with the Office of General Counsel (OGC) and the Small Business Advocacy Chair (SBAC).

Another difference between IRF A/FRFAs and E.O. 12866 economic analyses is the rules to which they apply. E.O. 12866 requires agencies to prepare economic analyses for all rules deemed to be "significant regulatory actions," which are defined as any regulatory action likely to result in a rule that may:

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[27] Other statutes also may require the analysis of economic impacts. For example, the Safe Drinking Water Act and Clean Water Act both require EPA to consider the economic achievability or affordability of regulatory options when developing limitations and standards.

[28] Note that section 605(a) of RFA allows agencies to prepare IRFA/FRFAs "in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the IRFA/FRFA provisions."

[29] See EPA's *Guidelines for Preparing Economic Analysis* (September 2000) for methods of estimating a rule's benefits and costs. The Guidelines can be accessed on the internet at http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/Guidelines.html.

[30] Section 603(c) requires an IRFA to describe the alternatives while section 604(a)(5) requires a FRFA to state why any significant alternatives which affect the impact on small entities were rejected.

[31] Note that E.O. 12866 also requires consideration of "any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness)..." This may also entail impact analysis.

(1) Have an annual effect on the economy 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;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this E.O.

The RFA, on the other hand, requires preparation of IRFAs and FRFAs only for notice-and-comment rules that are subject to the RFA and are not certified as having no SISNOSE.[32] It is possible, therefore, that a rule may be subject to the RFA's analytic requirements while not being a "significant regulatory action" or vice versa.

3.3 What is the Relationship of the IRFA/FRFA to the SBAR Panel Process?

A Small Business Advocacy Review Panel (SBAR Panel or Panel) is required for all proposed rules for which EPA is required to prepare an IRFA (5 U.S.C. section 609(b)).[33] The IRFA and the Panel share a common objective: to consider opportunities for minimizing a rule's significant economic impacts on small entities. The Panel provides an additional means for small entities to provide input into certain EPA rulemakings and to ensure that the unique concerns of small entities are carefully considered during the rulemaking process. The FRFA documents how the input received through the Panel and IRFA processes were used to arrive at a final rule.

The RFA requires the Agency to consider the Panel Report and, where appropriate, to modify the proposed rule, the IRFA, or the decision on whether an IRFA is required (5 U.S.C. section 609(b)). While you are not required to provide the Panel with a copy of the draft IRFA - indeed, the Panel typically convenes before the IRFA has yet been assembled in draft - the Panel process can be enhanced through the review of preliminary estimates or qualitative descriptions, where available, of the universe of small entities to which the proposed rule will be applicable; requirements of the proposed rule; Federal rules which may duplicate, overlap or conflict with the proposed rule; and information on significant alternatives that still accomplish the statutory objective of the proposed rule.

The IRFA should document the results of the Panel process and its role in the Agency's deliberations. You should also summarize the substantive Panel recommendations, and the

[32] The terms "IRFA" and "FRFA" are used only in rules that are not certified as having no SISNOSE. If a rule is certified as not having a SISNOSE, the documentation of your analysis should be titled "Small Entity Flexibility Analysis" and not IRFA or FRFA even if the documentation contains all the elements required of an IRFA or FRFA.

[33] Guidance on the Small Business Advocacy Review Panel is provided in Chapter 5.

Agency's actions in response to them, in the RFA section of the preamble of your proposed rule.

3.4 How Do I Prepare an IRFA?

This section discusses the components of an IRFA and considerations in preparing an IRFA. Section 3.4.1 outlines the elements of an IRFA required by section 603 of the RFA. Section 3.4.2 discusses different types of analyses that program offices may consider doing in order to enhance the information provided in an IRFA. Guidance on how to assemble the IRFA and proposed rule preamble appear in Section 3.4.3.

3.4.1 Required Elements of an IRFA

The RFA states that an IRFA "shall describe the impact of the proposed rule on small entities" (5 U.S.C. section 603(a)) and lists several elements that each IRFA shall contain. The statutory language for each required element of an IRFA, as codified by 5 U.S.C. section 603, is presented below. Remember that if the information is contained in the preamble to the proposed rule or another rulemaking document, you do not need to repeat it in the IRFA, rather you can reference the discussion in the other document (see 5 U.S.C. section 605).

Element 1: Description of the reasons why action by the agency is being considered (5 U.S.C. section 603(b)(l))

Element 2: Succinct statement of the objectives of, and legal basis for, the proposed rule (5 U.S.C. section 603(b)(2))

Element 3: Description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply (5 U.S.C. section 603(b)(3))

The IRFA should at a minimum identify, by North American Industry Classification System (NAICS) code, the small entities subject to the rule and the size standard for each type of small entity.[34] See Section 3.4.2 for a discussion of supplemental analysis that may enhance your description of small entities subject to the rule.

Most of the information required for Element 3 may be available from the RFA screening analysis (see Chapter 2), if one was conducted. Other sources of information may include the E.O. 12866 economic analysis, impact analyses prepared pursuant to other statutes, technical background documents, and risk analysis, if any of these were prepared for the rule. Whatever the source of information used, it should be well documented within the IRFA. If you are not able to provide an estimate of the number of small entities, you should provide an explanation of the reasons for this omission.

Element 4: Description of the projected reporting, record keeping 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

[34] See Section 2.5.2 on defining "small" for each type of small entity. If applicable, a description of the steps taken to develop an alternative definition of small for the small entities should be included in the IRFA (see Section 2.5.5).

professional skills necessary for preparation of the report or record (5 U.S.C. section 603(b)(4))

This element of your IRFA, a description of the proposed rule's requirements, should provide details of the impacts on the small entities that will be subject to the proposed rule, as set forth in section 603(a) of the RFA. Analysts have generally provided estimates of the proposed rule's costs on the small entities subject to the rule to describe the small entity impacts of the proposed rule. To address this element, you may refer to the costs estimated for your rule's RFA screening analysis (see Chapter 2), or other analyses prepared for the proposed rule (see 5 U.S.C. section 605(a)). For example, if an Information Collection Request is prepared for a rule, estimates of the costs and administrative burdens associated with reporting and record keeping and the professional skills needed to prepare required reports or records may be obtained from the paperwork burden analysis prepared under the Paperwork Reduction Act. Section 3.4.2 discusses supplemental analyses you may choose to consider for enhancing your description of the proposed rule's impacts on small entities.

If you plan to propose multiple regulatory alternatives (i.e., two or more approaches, one of which will be selected for promulgation in the final rule), you should describe the impacts to small entities of each of the proposed alternatives or, at a minimum, of the alternative that would likely have the greatest economic impact on small entities. Similarly, if you plan to propose a single regulatory approach, but also seek comment on variations of that approach or on different approaches altogether, you should ordinarily describe not only the proposed approach, but also the potentially most burdensome variation.

Element 5: Identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap or conflict with the proposed rule (5 U.S.C. section 603(b)(5))

Many EPA rules complement requirements imposed by other EPA rules or rules promulgated by other Federal Agencies. EPA's authority and responsibility intersect with those of many other Federal Agencies and Departments (e.g., OSHA, Transportation, Energy, Interior). In principle, these controls should all work together to create a comprehensive system of environmental management. Each agency should, therefore, coordinate its regulatory requirements with those already in place. The lead OGC attorney for your rulemaking can assist in identifying duplicate, overlapping, or conflicting rules. These may also be identified through the Panel process (see Section 5.2).

Element 6: 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:

- the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
- the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

- the use of performance rather than design standards; and
- an exemption from coverage of the rule, or any part thereof, for such small entities. (5 U.S.C. section 603(c)).

Element 6 requires the IRFA to describe significant alternatives to the rule which accomplish the stated objectives of applicable statutes and which minimize significant impacts of the proposed rule on small entities. Discussion of regulatory options included in the rule (see Element 4 above) may already include one or more "significant alternatives."

How Many Significant Alternatives Do I Need to Consider?

By law, an IRFA need only explore significant regulatory alternatives "which accomplish the stated objectives of applicable statutes and which minimize **any significant economic impact** of the proposed rule on small entities" (section 603(c) (emphasis added)). At a minimum the IRFA should describe any significant alternatives that meet this criteria. The internal rulemaking process or the RFA Panel process may identify other regulatory mechanisms that could minimize the significant economic impact on small entities.

What if the Statute Is Very Prescriptive in the Type of Regulatory Option to Be Used for Achieving its Environmental Goal?

The lead office, working with OGC, should determine whether the objectives of the statute may be achieved in more than one manner. In many cases even when a statute appears to be prescriptive, there still may be ways to minimize economic impacts on small entities.

If it is determined that the statute does not allow the Agency to consider regulatory alternatives at all, the RFA still requires the Agency to prepare an IRFA. In such cases, the lead office should prepare an explanation as to why the Agency is precluded from considering regulatory options. This IRFA, although shorter and simpler than an analysis designed to consider alternatives, would contain all of the sections required by the RFA.

If the statute does not preclude the agency from pursuing regulatory options designed to minimize adverse economic impacts, the lead office should prepare an IRFA as described in this section.

How Much Analysis Do I Need to Conduct on Each Regulatory Option?

The primary purpose of the analysis is to provide the decision maker with information that will facilitate the choice of a sound regulatory option. As with the rest of the required elements of an IRFA, qualitative descriptions will suffice when quantitative information is not practically available (5 U.S.C. section 607). A qualitative analysis might include: a description of the alternative requirements, the small entities to which they would apply and a qualitative discussion of the change in the number of small entities that would experience significant economic impacts. As data, time, and resources allow, programs may wish to pursue some of the quantitative analysis described in the next section (3.4.2).

3.4.2 Supplemental Analysis

In some instances, a supplemental analysis may provide a more detailed picture of the

economic impacts on small entities than is required by the RFA. Preparing such supplemental analyses may take significant additional time and resources. However, in some instances the information obtained through supplemental analysis may be useful. The decision to undertake such analyses depends on the quality and quantity of available data, the severity of a rule's anticipated economic impact on small entities subject to the rule, and the potential consequences of additional delay in the regulatory schedule. This section summarizes some different types of small entity impact analyses that go beyond what is required by the RFA, and may provide information helpful to understanding the impacts on small entities in a broader context.

In addition to the description required by Element 3, the lead office may wish to consider segmenting the affected entities along lines that are useful for distinguishing among those that are more and less susceptible to the economic impacts of the proposed regulation. For example, if an industrial category consists of a collection of firms having disparate financial characteristics (e.g., annual sales) or operating characteristics (e.g., processes used or pollution generated), it would be preferable to examine the economic impacts in a framework that accounts for this variability. The goal is to provide as detailed a picture as possible of the small entities that will be affected by the proposed regulation. Failure to distinguish properly among small entities may lead to an overstatement or understatement of the anticipated economic impacts of the regulation or to missed opportunities to minimize the economic impacts on small entities.

An evaluation of the pollution contributed by small entities relative to other entities being regulated is another example of a supplemental analysis. This information may highlight how reducing the burden on small entities is compatible with the environmental goals of the rule (e.g., when small entities make a relatively small contribution to the environmental problem being addressed) or why regulatory accommodations for small entities should not be granted in a particular instance (e.g., when an environmental problem is arising from the actions of an industry or sector that is made up primarily of small entities).

A supplemental analysis related to Element 4 may include a comparison of the costs of compliance for small and large entities to determine if small entities are affected disproportionately. Other estimated impacts that may be presented are the ability of small entities to pass on these costs in the form of price increases or user fees; the effects on profitability or the ability to provide services; or effects (if any) on closures, production, and employment in each class. While the RFA does not require an IRFA to discuss these impacts, providing this information may provide a more detailed picture of how small entities are affected by the proposed rule.

The descriptions of significant alternatives described under Element 6 may be expanded by providing estimates for each alternative of the change in costs of the requirements on small entities; the change in pollution contribution of the small entities subject to the rule relative to other entities being regulated; and the changes in other measures of economic impact such as closures, production levels, employment or profit. As previously mentioned, the provision of this type of detailed analysis for alternatives will depend on data, time and resource constraints as well as on the anticipated impact on small entities of the proposed rule and alternatives described.

3.4.3 Assembling the IRFA and Preamble

What Should Be the Format of the IRFA?

The IRFA may be prepared as a stand-alone document or a chapter in the E.O. 12866 economic analysis, if one has been prepared. In either case, it should include distinct sections for each of the requirements specified in the RFA, as discussed above. If you do not include text for one or more sections in the IRFA because it is included in another document supporting the rule (such as the preamble or a broader economic analysis), you should explicitly reference and summarize the other text.

Do I Have to Repeat Text Included in Other Regulatory Support Documents?

No. The statute allows agencies to avoid duplicating effort by performing the required analyses in conjunction with, or as part of, any other analyses, if the other analyses satisfy the requirements of the RFA (5 U.S.C. section 605(a)). Several of the IRFA requirements will generally be met by other analyses or documents prepared for the proposed rulemaking, such as the RFA screening analysis, the E.O. 12866 economic analysis, or the preamble. In lieu of repeating text from these documents, you may cross-reference the relevant portions of the documents and summarize their conclusions in the relevant sections of the IRFA.

Should the IRFA Be Discussed in the Preamble to the Proposed Rule?

Yes. The IRFA should be summarized in the Statutory and Executive Order Reviews section of the proposed rule's preamble. The summary of the IRFA should note, in particular, the ways in which the Agency designed the proposed rule to reduce burdens on small entities. The full IRFA should be placed in the rulemaking docket and the preamble summary should indicate where the IRFA can be found.

What Else Should Be in the Preamble with Respect to Small Entities?

Besides summarizing the IRFA when a rule is not certified as not having a SISNOSE, the Statutory and Executive Order Reviews section of the preamble should also describe or summarize the actions the Agency took to involve small entities in the rule's development, including outreach to small entity stakeholders (see Chapter 4) and convening of a SBAR Panel (see Chapter 5).

3.5 How Do I Prepare a FRFA?

This section discusses the components of a FRFA and considerations in preparing a FRFA. As FRFAs are judicially reviewable, each section must be completed carefully. Section 3.5.1 outlines the elements of an FRFA required by section 604 of the RFA. Guidance on how to assemble the FRFA and final rule preamble appear in Section 3.5.2.

To the extent that the final rule does not differ from the proposed rule and the Agency obtained little or no additional information relevant to the analysis of the rule, the FRFA can repeat or cross-reference applicable sections of the IRFA.

3.5.1 Required Elements of a FRFA

The statutory language for each required element of a FRFA, as codified by 5 U.S.C. section 604, is presented below. Remember that if the information is contained in the preamble to the proposed rule or another rulemaking document, you do not need to repeat it in the FRFA, rather you can reference the discussion in the other document (see 5 U.S.C. section 605(a)).

Element 1: Succinct statement of the need for, and objectives of, the rule (5 U.S.C. section 604(a)(l))

Element 2: Summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary 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 (5 U.S.C. section 604(a)(2))

The RFA requires that a FRFA summarize the significant issues raised by public comments on the IRFA, summarize the agency's assessment of such issues, and describe any changes the agency made in response to the comments. To the extent that the program office prepares a single response-to-comments document for the whole rule that accomplishes these objectives, the FRFA may rely on and cross-reference that document.

Element 3: 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 U.S.C. section 604(a)(3))

This description is likely to be an updated version of the corresponding section of the IRFA. If you are not able to provide an estimate of the number of small entities, you must provide an explanation of the reasons why not.

Element 4: Description of the projected reporting, record keeping 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 (5 U.S.C. section 604(a)(4))

This section of the FRFA should discuss the option selected for the final rule. Other options considered may be discussed in the last section (see Element 5 below). Completion of this section should involve only updating the description in the IRFA to incorporate any changes to the requirements of the final rule relative to those of the proposed rule.

Element 5: 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 (5 U.S.C. section 604(a)(2))

The most critical component of the FRFA is the requirement that an agency explain the "factual, policy and legal reasons" for selecting the regulatory approach promulgated in the final rule and for rejecting "each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities."

While the RFA does not require that an agency necessarily minimize regulatory burdens on small entities, it does require that the agency describe the "steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes." It is, therefore, important to thoroughly document all considerations of alternatives to reduce significant economic impacts on small entities, as well as any small entity

outreach conducted (see Chapter 4) and the SBAR Panel process (see Chapter 5). To the extent this requirement is met by the main body of the preamble of the final rule, the FRFA may cross-reference that text.

3.5.2 Assembling the FRFA and Preamble

What Should Be the Format of the FRFA?

The FRFA may be prepared as a stand-alone document or as a chapter in the E.O. 12866 economic analysis, if one has been prepared. If you do not include text for one or more sections in the FRFA because it is included in another rule support document (such as the preamble or broader economic analysis), you should explicitly reference and summarize the other text. In either case, it should include distinct sections for each of the requirements specified in the RFA, as discussed above.

Do I Have to Repeat Text Included in Other Regulatory Support Documents?

No. The statute allows agencies to avoid duplicating effort by performing the required analyses in conjunction with or as part of any other analyses, if the other analyses satisfy the requirements of the RFA. Several of the FRFA requirements will generally be met by other analyses or documents prepared for the proposed rulemaking, such as the RFA screening analysis, broader economic analysis, or the preamble. In lieu of repeating text from these documents, you may cross-reference the relevant portions of the documents and summarize the conclusions of the analysis in the FRFA (5 U.S.C. section 605(a)).

Should the FRFA Be Discussed in the Preamble?

Yes. The FRFA should be summarized in the Statutory and Executive Order Reviews section of the final rule's preamble. The summary of the FRFA should note, in particular, the ways in which the Agency reduced the economic impact of the final rule on small entities. The full FRFA must be placed in the rulemaking docket and the preamble summary should indicate where the FRFA can be found (5 U.S.C. section 604(b)).

What Else Should Be in the Preamble with Respect to Small Entities?

Besides summarizing the FRFA, the Statutory and Executive Order Reviews section of the final rule's preamble should describe the actions the Agency took to ensure that small entities had a meaningful opportunity to comment on the rule. That section should also reference the sections of the proposed rule's preamble describing the SBAR Panel convened for the rule, if applicable (see Chapter 5). This information regarding the Agency's outreach efforts helps the Agency prepare the report used when it submits the rule to Congress and the Government Accountability Office under the congressional review provisions of the Congressional Review Act (CRA) 5 U.S.C. sections 8O1-8O8.[35]

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[35] The CRA was enacted by Subtitle E of the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. sections 801-808). All final rules must be assessed to determine if the Congressional review requirements apply whether or not the final rule has any effect on small entities. EPA guidance on the CRA, "Congressional Review Act: Guidance for Rulewriters" (July 1998) can be accessed at EPA's intranet website, "Action Development Process Library," http://intranet.epa.gov/adplibrary.

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Chapter 4
Implementing Small Entity Outreach: Informing, Listening, Responding

4.1 Small Entity Outreach: The Basics

The Small Business Regulatory Enforcement Fairness Act (SBREFA) amended the Regulatory Flexibility Act (RFA) to bolster the RFA's requirements that agencies provide small entities with a meaningful opportunity to participate in the development of rules that may significantly affect them. EPA's success in carrying out our obligations under the RFA requires early and continuing interaction with small entities throughout the regulatory development process. The RFA process, and your interactions with small entities in general, should be a genuine dialogue with meaningful engagement and exchange of ideas and information. The goal of small entity outreach is to ensure promulgation of a rule that is tailored to achieve a specific environmental goal while taking into account the particular concerns of small entities.[36]

It is important that outreach to small entities occur as early as possible in regulation development. Indeed, it will often be appropriate to start outreach before or concurrently with performance of a preliminary screening analysis (see Figure 1). Early outreach and accommodation of small entity issues has proven to have a substantial positive impact on the quality of our regulations. First, small entities can often fill gaps in our knowledge and experience to provide alternate, less burdensome regulatory options that can accomplish a stated environmental goal. Second, you can gain support for the regulatory option ultimately selected by bringing small entities into the process early on, listening and responding to their concerns, and having that input influence the direction of your rule. When you believe that is unlikely that you will be able to certify that your rule, if promulgated, will not have a significant economic impact on a substantial number of small entities (SISNOSE), this early involvement should also include OGC and staff to the Agency's Small Business Advocacy Chair (SBAC). At a later point it will be

Early outreach and accommodation of small entity issues has proven to have a substantial positive impact on the quality of regulations.

[36] As a practical matter, most of the outreach we describe in this chapter will take place in the pre-proposal phase of the rule development process. While further outreach may be appropriate in the post-proposal stage, any contact with small entities at that time is subject to the same ex-parte restrictions that govern all external contacts once the public comment period closes.

appropriate to involve the Small Business Administration's (SBA) Office of Advocacy and the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs.

Detailed below is a strategy outlining how you can identify and engage in dialogue with representatives of small entities that may be subject to your rule.

4.2 What Does "Outreach" Mean?

According to the *EPA Manual on Consultative Processes,*[37]

> Outreach is a means by which the Agency keeps its constituencies - those who are interested in or affected by its action - informed about what it is doing, what it is planning, and what its needs are. Outreach is basic communication. In addition to informing those affected of the Agency's activities, outreach also encourages and provides the means by which members of the public can communicate their needs and desires to the Agency so they may be taken into account when making decisions.

In sum, outreach includes informing potentially regulated parties about EPA's regulatory plans, listening to their concerns and suggestions about how the rule may affect them, and responding through appropriate action to meet environmental objectives while minimizing unnecessary burden.

There are many forms and styles available for providing information to small entities potentially subject to a rule, including:

- public announcements
- interviews
- informal and formal meetings
- web sites and list serves·
- magazine and journal articles
- speeches
- dockets, and
- press releases.

While each of these methods of communication can be used to transmit necessary information to members of the public, simply providing notice of EPA's intent is not enough. Adequate outreach also requires that we seek opportunities for genuine engagement that places the Agency in a position to hear from and respond to small entities.

4.3 Is Small Entity Outreach Subject to FACA?

Some forms of outreach are regulated by statute. Specifically, the Federal Advisory Committee Act (FACA) establishes requirements for the convening and operating of an official advisory committee. However, many groups are exempt from FACA coverage including: fact-finding and information exchange groups, meetings with persons providing individual advice or recommendations (as opposed to collective advice or recommendations); and meetings with groups of people to interactively discuss and debate individual opinions or recommendations.[38]

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[37] *EPA Manual on Consultative Processes: Better Decisions Through Consultation and Collaboration,* Draft - October 1998.

[38] For more information on FACA and other public involvement, see http://www.epa.gov/publicinvolvement.

Outreach in compliance with the RFA has commonly occurred in the form of information exchanges. According to the *EPA Manual on Consultative Processes*, information exchanges primarily seek to enhance the parties' understanding of the situation. During information exchanges, at least one side will be providing information or advice to the other and oftentimes there will be an exchange of views or concerns. Importantly, the participants involved in information exchanges are not expected to reach agreement. Sections 4.4 and 4.6 (below) provide more specific information on where to get assistance with your outreach efforts and steps to take to reach small entities.

4.4 Should I Coordinate My Stakeholder Involvement Activities?

You are strongly encouraged to coordinate your stakeholder activities and allow these distinct processes -- e.g., internal workgroup, peer review, FACA committee, SBAR Panel -- to inform each other. Although each group has its own policies and procedures, they do not take place in isolation; indeed, they may have overlapping membership. Moreover, every stakeholder activity is based on relationships, and the relationships you develop rely on trust. Consequently, you are likely to have greater success if you demonstrate a willingness to share information not only with your stakeholders but also between your stakeholder groups to nurture that trust. Beyond the importance of these considerations, you should make the most of your time and resources. As you invest time at the outset of your rulemaking to develop an Analytic Blueprint or other planning document for your rule, you should be able to recognize some efficiencies in coordinating some of your stakeholder activities. For example, if you engage a contractor to assist you in identifying participants for a FACA committee, as part of the same effort, the contractor may be able to identify a group of potential small entities for a SBAR Panel. Similarly, outreach documents prepared for one group may be appropriate for your other stakeholders.

> A stakeholder involvement process is not an end in itself; it is a means to a better, more widely accepted decision.
>
> - EPA Manual on Consultative Processes

4.5 What Kind of Outreach Does the RFA Require?

The RFA requires an agency to "assure that small entities have been given an opportunity to participate in the rulemaking" process for any rule that "will have a significant economic impact on a substantial number of small entities." 5 U.S.C. section 609(a). The RFA also directs us to ensure small entity participation through the reasonable use of techniques such as those listed in section 609(a), as follows:

- use of computer networks to solicit and receive comments;
- publication of general notice of proposed rulemaking in publications likely to be obtained by small entities;
- direct notification of interested small entities;

- conduct of open conferences or public hearings concerning the rule for small entities;
- inclusion in an advance 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, and
- the adoption or modification of agency procedural rules to reduce the cost and complexity of participation in the rulemaking for small entities.

SBREFA strengthened the RFA's outreach provisions in two principal ways. First, the RFA now requires EPA to convene a Small Business Advocacy Review Panel (SBAR Panel or Panel) prior to proposing a rule for which we are required to prepare an IRFA (i.e., those rules for which EPA does not certify that the rule will not, if promulgated, have a SISNOSE). As described in detail in Chapter 5, the Panels are required to consult with representatives of small entities that will be subject to the rule. Second, the amended RFA allows small entities adversely affected by the final rule to sue agencies in court for failure to comply with specified RFA provisions, including section 609(a), which requires agencies to **assure** that small entities have an opportunity to participate in rulemakings that will have a SISNOSE.

4.6 Where Can I Get Assistance with My Small Entity Outreach?

You should first consult your Regulatory Steering Committee representative to determine what resources are available to you within your program office. EPA also has several offices that may be able to assist you with outreach throughout different stages of rule development. EPA's Small Business Ombudsman (SBO) can provide support and assistance in your outreach activities to small entities. The SBO maintains an updated list of key small entity contacts, which will be made available to you upon request. These small entity contacts include:

- national small entity trade association executives and contact persons;
- contacts for the CAA State section 507 Program, including the Small Business Ombudsman, Small Business Assistance Program, and the Compliance Advisory Panels; and
- EPA Regional Small Business Liaisons.

Additional support and assistance with outreach and development of small entity contacts is available from the Office of Public Affairs (OPA) and the Office of Congressional and Intergovernmental Relations (OCIR). Also, OCIR supports a small town FACA group, the Small Community Advisory Subcommittee of the Local Government Advisory Committee. OCIR assistance may include: 1) help creating an outreach strategy to support the rulemaking; 2) supporting the distribution of information; and 3) help developing and maintaining a comprehensive list of small entity contacts for use by individual program offices.

The RFA defines "small governmental jurisdiction" as the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000

(5 U.S.C. section 601(5)). There are about 40,000 such small governmental jurisdictions in the United States, with 33,000 of those having populations of less than 10,000. Broken down further, roughly 26,000 governmental jurisdictions have populations under 2,500. All told, over 90% of U.S. governmental jurisdictions have populations under 50,000.[39]

In addition to experiencing many of the problems and concerns that affect large cities, small governmental jurisdictions in the U.S. often face other hardships due to their individual characteristics and situations. Small governmental jurisdictions often experience disproportionate impacts from Federal regulations, particularly with regard to the cumulative impact of environmental regulations. In many small jurisdictions, while the pressure for services and infrastructure maintenance and repair continues to grow, the capacity to provide all necessary services remains quite limited. Over one-third of small governmental jurisdictions in the U.S. have no employees, while others operate on part-time assistance from dedicated citizens. These communities most often have no engineering or environmental management capacity of their own. Their limited financial resources due to small tax bases and often declining economic activity only serve to further exacerbate the problem.

These are but a few of the reasons why RFA-mandated consultation with small governmental jurisdictions is so important. With the Small Community Advisory Subcommittee's finding that EPA should increase direct involvement of small jurisdictions in the regulatory process, the Agency is prepared to ensure that RFA-mandated consultation is carried out with optimal effectiveness. While timely, substantive involvement of small governmental jurisdictions in the regulatory process will involve additional preparation and early outreach, such efforts will invariably reduce costs later in the process and produce rules that small jurisdictions can more reliably implement. With this in mind, the Office of Congressional and Intergovernmental Relations' guide entitled *Planning for Intergovernmental Outreach and Consultation* can serve as a valuable resource in your consultation efforts. To obtain the guidance and consult about small governmental jurisdictions and outreach to them, contact OCIR's Intergovernmental Relations Team.

In addition to these general resources, each program office is encouraged to develop and maintain a comprehensive contact list of small entity representatives, keyed to their program area of responsibility. These could include:

- small business trade associations; and
- organizations representing townships, counties and municipalities, and decision-making individuals within these organizations (public and private non-profit).

You could use this contact list to help identify knowledgeable individuals who may serve as small entity representatives for your rulemaking.

EPA's Small Business Advocacy Chair (SBAC) is responsible for overseeing policy decisions regarding certifying that a rule will not have a SISNOSE, as well as decisions to convene

[39] *Results of the 1994 EPA Survey of Small Local Governments,* September 1997.

a Small Business Advocacy Review Panel. The SBAC and SBAC staff are responsible for coordination of SBAR Panels, including communication with SBA and OMB and Panel logistics.

4.7 What Steps Can I Take to Reach Small Entities?

The following sections outline some suggested steps you can take in developing a proposed rule, particularly if it appears that it may not be possible to certify that your rule will not have a SISNOSE. As noted above, you should also check with your Regulatory Steering Committee representative to explore what resources are available to you within your own program office.

4.7.1 Contact SBAC Staff

If you believe that it may not be possible to certify your rule as not having a SISNOSE (according to the screening analysis in Chapter 2), you should contact the SBAC staff through your Regulatory Steering Committee representative. The SBAC staff will work to provide you with the support and service needed to make each SBAR Panel process as efficient and productive as possible. SBAC staff can advise you on how the Panel process can fit into your rulemaking schedule, potential inclusion of SBA and OMB in outreach efforts, and the implications of the results of your screening analysis, among other things.

4.7.2 Identify and Contact Small Entities

Stakeholders are those who have an interest -- direct or indirect -- in the action the Agency is planning to take. Small entities --those that meet the statutory definition of small business, small government or small non-profit enterprise--are a subset of your broader stakeholder group.[40] As part of your outreach efforts, you should make informal contact with potential small entities to confirm their small entity status.

There is an important distinction to note at this time between small entities which should be included as stakeholders through your broader outreach efforts and official Small Entity Representatives for a Small Business Advocacy Review Panel process. Official Small Entity Representatives are chosen through a process of consultation with the EPA Small Business Advocacy Chair and the Small Business Administration. This process is described in more detail in Chapter 5. While small entities with whom the Agency has consulted from the beginning are the chief candidates to serve later as official advisors to a Panel, **small entities do not become official Small Entity Representatives (known as SERs) until they are officially designated as such by the Small Business Advocacy Chair.** The formal selection of Small Entity Representatives is made after SBA's response to formal notification from the SBAC, which is typically very close to the time a Panel convenes.

4.7.3 Consider Drafting Informal Notification to SBA

During the outreach process, if you believe that your rule may not be able to be certified

[40] See Chapter 2 for more information on the definition of 'small entity.'

as not having a SISNOSE (according to the screening analysis in Chapter 2), you should consider drafting an informal notification to the Small Business Administration. You should route both informal and formal notifications, as well as any communications regarding potential RFA issues, through your Regulatory Steering Committee representative to the SBAC. Section 5.7.2 provides more information on drafting an informal notification. Outreach to small entities or informal notification to SBA do not represent an EPA finding that your rule will have a significant economic impact on a substantial number of small entities, nor does it commit you to preparing a regulatory flexibility analysis or convening a Small Business Advocacy Review Panel. Small entities can provide input to help the Agency ultimately determine if either of these activities are required. Further, they can offer ideas to help the agency formulate alternatives that achieve your environmental objective and do not impose a SISNOSE.

4.7.4 Conduct Outreach to Small Entities (i.e., substantive engagement)

It is clear from the specific requirements set forth by the RFA that Congress intended agencies to provide small entities with a meaningful opportunity to participate in the development of rules that may significantly affect them. One of the keys to fostering productive participation is effective outreach and exchange of information. In conducting small entity outreach, you should distribute sufficient information to your small entity representatives about your regulation so that they can provide you with informed feedback on the elements of an Initial Regulatory Flexibility Analysis under section 603 of the RFA which Congress identified in SBREFA as key issues. Those elements are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of 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 requirements and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- 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.

For small entities, it is advisable to request comments in writing since these will be used later as part of your SBAR Panel convening document or as documentation of your factual basis for a certification of no SISNOSE (see also Keep Records section, below). You may want to include the SBAC and staff, OMB, and SBA in your outreach efforts. Much of the success of previous SBAR Panel processes can be attributed to the level of familiarity that the Small Entity Representatives and the Panel members (described in Chapter 5) have gained with provisions under consideration for the regulation, as well as with the program staff developing the regulation, prior to convening the Panel.

So long as you ensure genuine engagement with small entities, you can include this

responsibility as part of your overall outreach efforts. EPA's guidance on stakeholder involvement, *EPA's Public Involvement Policy* (http://www.epa.gov/publicinvolvement/policy2003/index.htm) offers guidance as to what process to use for public involvement in your rulemaking and what steps to take to maximize your outreach efforts. Sections 4.2 and 4.5 (above) list some suggested venues for small entity outreach. In conducting outreach to small entities, however, it is important to ensure these parties have an opportunity to address their concerns separately and specifically to the Agency. While small entities may participate in public meetings designed for a broader group of participants, such a forum should provide an opportunity for EPA to hear separately and particularly from smaller interests. A particular reason that the Congress passed, and the President signed SBREFA was to "level the playing field" by affording smaller interests a chance to be heard independently from competing interests, including large entities likely to be regulated.

4.7.5 Keep Records

For any rule for which the Agency is required to prepare a Regulatory Flexibility Analysis (see Chapter 3), you are responsible for keeping a record of your outreach efforts and including that record in the rulemaking docket for purposes of judicial review. It is crucial for you to demonstrate and document a pattern of dialogue with and outreach to all interested stakeholders with particular attention to the interests of small entities that may be subject to your regulation. For each meeting, formal or informal, with your stakeholders you should take notes regarding the major topics of discussion and create meeting summaries. You should append any materials you distribute or present, including agendas, outreach packages, fact sheets, and overheads to your meeting summaries.

It is also a good practice to maintain a file documenting outreach even for rules not requiring an IRFA. This will allow the program to demonstrate its adherence to the Agency's standing policy of outreach and, when feasible, accommodation of small entities in any rule to which they will be subject. In addition, since the Agency can be judicially challenged on the factual basis it presents supporting its certification that a rule does not impose a SISNOSE, such documentation may prove necessary to demonstrate how the Agency considered small entities' concerns in reaching its decision to certify.

4.8 Where Can I Get More Information?

For more information, you can contact your office's Regulatory Steering Committee representatives, EPA's Small Business Advocacy Chair (OPEI), staff to the Small Business Advocacy Chair (OPEI), and EPA's Small Business Ombudsman Program.

Chapter 5
The Small Business Advocacy Review Panel Process for Proposed Rules

5.1 What is a Small Business Advocacy Review Panel?

A Small Business Advocacy Review Panel (SBAR Panel or Panel) is an additional means for small entities to provide input into certain EPA rulemakings to ensure that the unique concerns of small entities are carefully considered during the rulemaking process. The Small Business Regulatory Enforcement Fairness Act (SBREFA) amended the Regulatory Flexibility Act (RFA) to require EPA to convene a SBAR Panel for any proposed rule for which EPA is required to prepare an initial regulatory flexibility analysis (IRFA).

The RFA requires that we prepare an IRFA for all rules for which EPA is required by statute to publish a NPRM **unless** the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities (SISNOSE)."[41] If an IRFA is required for a proposed rule under the RFA, we must also convene a SBAR Panel. Each Panel consists of representatives from EPA, the Small Business Administration, and the Office of Management and Budget. Although the statutory name for the Panel refers only to small businesses, **each Panel must solicit and consider the concerns of all small entities directly regulated by the rule, including small governmental jurisdictions and small nonprofit organizations, in addition to small businesses.**

5.2 What are the Statutory Panel Requirements?

Since the RFA was enacted in 1980, RFA section 609 has required all agencies to facilitate small entities' participation in rulemakings that will have a significant economic impact on a substantial number of small entities (see Chapter 4 for further discussion of general outreach provisions). SBREFA expanded RFA section 609 to require EPA to convene SBAR Panels to ensure that small entity representatives are involved in the development of certain rules.[42]

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[41] Because the term 'significant economic impact on a substantial number of small entities' is cumbersome, it is commonly called a "SISNOSE". When we determine that there will **not** be a significant adverse economic impact on a substantial number of small entities, we call that a "No SISNOSE" finding or "making the RFA certification."

[42] The Occupational Health and Safety Administration is also subject to the Panel requirement.

Under RFA section 609(b), we must convene a Small Business Advocacy Review Panel for any rule for which the Agency is required to prepare an IRFA. If we exercise our discretion to make the RFA certification (i.e., certify that a proposed rule will have No SISNOSE), we do not need to convene a Panel. **Even if we convene a Panel, EPA may defer the decision to certify a rule until after a Panel has concluded its work.** Also, RFA section 609(c) authorizes us to convene a Panel for a rule that we intend to certify, but that we believe may have "a greater than de minimis impact on substantial number of small entities." Section 609(b) requires that the Panel process occur **before** publication of the IRFA, which must be made publicly available at the same time the proposed rule is published, except in cases of emergency. Accordingly, we generally must convene a Panel **before** a rule is proposed.

Section 609(b) establishes the following statutory framework for the Panel process:

- For any rule subject to the Panel requirement, EPA is to notify the Chief Counsel for Advocacy of the Small Business Administration (SBA) and provide the SBA Chief Counsel with information on the potential impact of the proposed rule on small entities and the type of small entities that might be affected.

- The SBA Chief Counsel has 15 days from receiving notification of a proposed rule to identify individuals representative of the small entities likely to be regulated by the rule.

- EPA is to convene a review Panel consisting **only** of full-time federal employees, including representatives of the Agency office responsible for developing the rule, the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), and the SBA Chief Counsel.

- The Panel is to review any material EPA has prepared in connection with the rulemaking, including any draft proposed rule, and collect the advice and recommendations of each individual small entity representative selected by EPA, after consultation with the SBA Chief Counsel for Advocacy, on issues related to specific elements of an IRFA for the proposed rule under development. The specific elements of an IRFA are:

  - a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;

  - a description of 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 record or report;

  - an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule; and

  - 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.

- Not later than 60 days after EPA convenes the Panel, the Panel must report on the comments of the small entity representatives and the Panel's findings with regard to the issues related to the IRFA elements listed above. The Panel Report must be included in the rulemaking record.

- In light of the Panel Report, the Agency is to modify, where appropriate, the proposed rule, the IRFA or the decision on whether an IRFA is required.

5.3 What Help is Available to Me in Preparing for a Panel?

First, you should check with your Regulatory Steering Committee representative to see what resources are available to you within your own program office. EPA's Office of Policy, Economics and Innovation has created this guidance document and a variety of other supporting documents (e.g. checklists, worksheet and SBAR Panel manual) which should answer most of your procedural and substantive questions about the SBAR Panel process. OPEI also has a team of RFA experts who serve as staff to the SBAC to help you manage your Panel and answer questions before, throughout and after the Panel process. The team contact information can be found at: http://epa.gov/sbrefa/staff.htm.

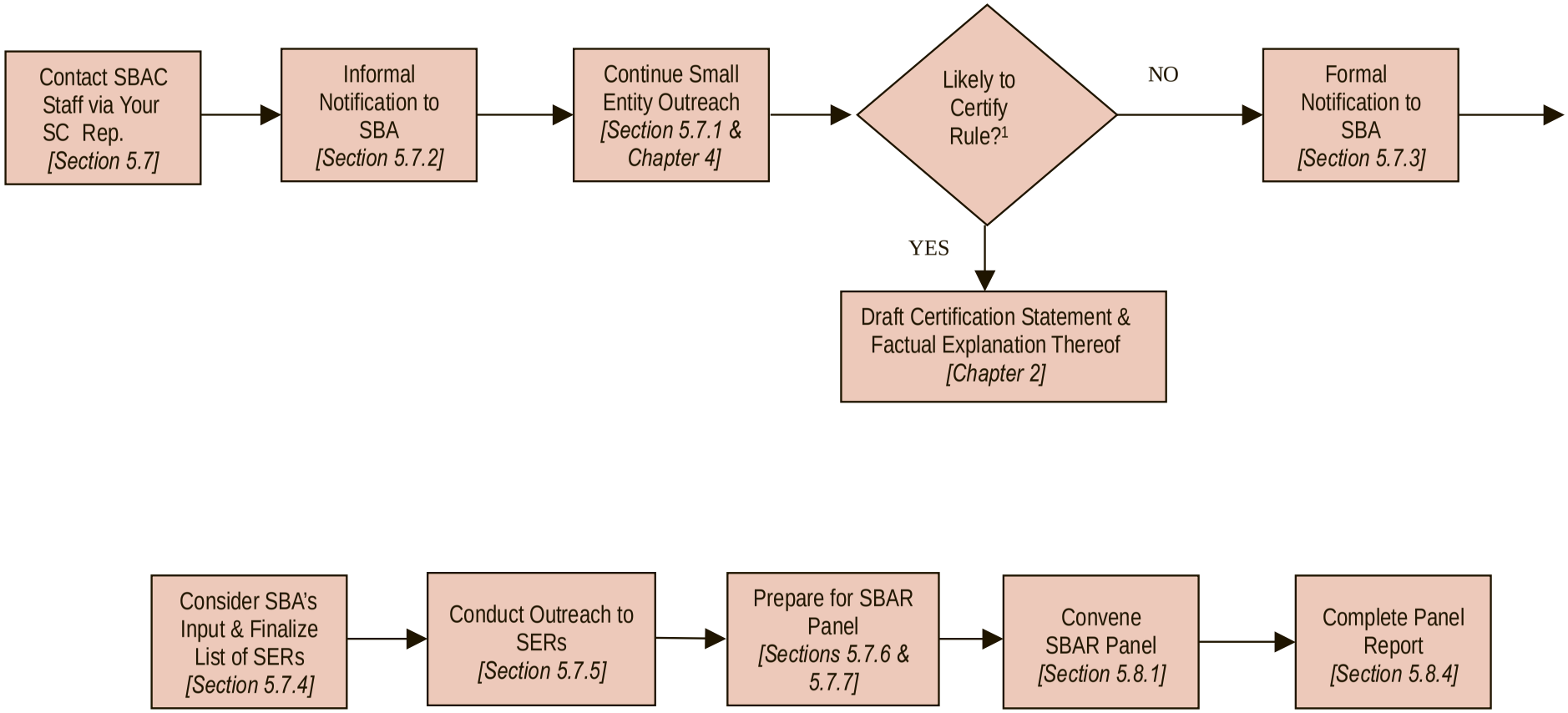
5.3.1 How Can this Guidance Help Me with My Panel?

This chapter provides you with a step-by-step approach to implementing the SBAR Panel requirement. Our suggested approach is further illustrated in Figure 4. While the SBREFA amendments to the RFA establish the basic outline of the Panel process (described below), it also leaves us with discretion to determine many details of that process, including when to convene a Panel prior to proposing a rule. EPA has, therefore, developed a suggested process that will typically involve small entity representatives early in the rulemaking process. **Early involvement helps ensure that small entity comments and insights inform EPA's thinking about fundamental issues of rule design and scope, as well as more specific issues posed by the particular regulatory program at issue.**

This Guidance reflects agency policy and practice in implementation of the RFA. At the same time, we recognize the need for flexibility in implementing the RFA. Some rules subject to the Panel requirement may have developed in such a way that the Panel process must take place later in the rulemaking process than this guidance suggests. Nevertheless, this suggested process should work in most situations.

Our suggested Panel process is divided into several parts. You may not need to complete each part of the process if, during the course of rule development, you (or, more accurately, your Assistant Administrator, who is responsible to the Administrator for the certification decision) determine that your rule will not have a SISNOSE. However, even if your rule will **not** have a SISNOSE (i.e., you are making the RFA certification), but may have *some* impact on one or more small entities, it is important for you to engage in consultation with the relevant small entity stakeholders (see Chapter 4 on small entity outreach).

Small Business Advocacy Review Panel Process for Proposed Rules
Figure 4



Notes:

General: References to "Sections" in the flowchart refer to the sections in Chapter 5 in this guidance document [see Table of Contents). In addition, references to "Chapters" in the flowchart refer to the chapters in this guidance document.

[1] It is EPA's policy to assess impacts on small entities and minimize impacts to the extent feasible. If you do not have enough information to determine with confidence that the Agency can certify (no SISNOSE), proceed with "NO." The decision to certify can be made at any time before proposal.

5.3.2 Who Will Help Me with My Panel?

Under SBREFA section 244(b),[43] SBAR Panels are chaired by a Small Business Advocacy Chair designated by EPA's Administrator. The Chair is responsible for implementing the Panel review process. The Small Business Advocacy Chair heads a small staff (SBAC staff) who mainly work on RFA issues.

The SBAC staff can help you in several ways. Two of the most important are:

- the SBAC staff serve as EPA's experts in the Panel process, providing support to program offices in resolving both complex and day to day issues; and
- the SBAC staff provide support for many of the mechanics of convening and operating the Panel.

A Small Business Advocacy Chair staff member will be assigned to work with you on your Panel. We encourage you to make contact with the SBAC staff as early as possible in the rule development process. This staff-level informal contact should also include your Regulatory Steering Committee representative. You should also check with your Regulatory Steering Committee representative to explore what resources are available to you within your own program office.

5.4 What Circumstances Require EPA to Convene a Panel?

The first step you must take to determine whether we must convene a Panel is to conduct the screening analysis detailed in Chapter 2. As noted above, unless you can certify that your proposed rule will not have a SISNOSE, you must prepare an Initial Regulatory Flexibility Analysis, and EPA must convene a Panel prior to proposal. Because the determination to convene a Panel can have a significant impact on your rulemaking schedule, you should identify the rule's potential impact on small entities as soon as possible. After the screening analysis is completed, you should consult with your Regulatory Steering Committee representative and the SBAC and SBAC staff. At this early stage, you should consider ways of structuring the rule to avoid any undue burden on small entities while still meeting the environmental objective of the statute. In doing so, you may find that it may be possible to certify the rule as not having a SISNOSE.

As stated in Chapter 2, we believe that only rules which may have a **direct** significant **adverse** economic impact on a substantial number of small entities require an IRFA, since the primary purpose of the IRFA is to identify and address regulatory alternatives "which **minimize** any significant economic impact of the proposed rule on small entities." (RFA section 603, emphasis added). Thus, if your rule will exclusively relieve regulatory burden, or otherwise have

[43] Pub. L. No. 104-121, Sec. 244(b). SBREFA has several provisions that are not codified into the RFA but that still have an impact upon RFA implementation. SBREFA section 244(b) is one such provision.

a positive economic effect on the small entities subject to the rule, your rule may be certified and, therefore, you are not required to prepare an IRFA or convene a Panel.

> EPA'S decision to convene a Panel is not a commitment to prepare an IRFA (for rule proposal) or a FRFA (for rule promulgation) nor does it prevent you from certifying your proposed or final rule.

In any case, our decision to convene a Panel is not a commitment to prepare an IRFA (for rule proposal) or a FRFA (for rule promulgation), nor does it prevent EPA from certifying your proposed or final rule if its substance so warrants. In fact, each step in the RFA process, from informal notification through completion of the Panel Report, leaves open the prospect that your rule can be certified as not having a SISNOSE, should the provisions of your rule change or new information be discovered. For example, you may adopt Panel recommendations that would result in a proposed rule no longer having a SISNOSE. In that case, EPA could properly certify the rule and you would not be required to complete an IRFA.

5.5 Can I Request a Waiver from the SBAR Panel Process?

Under RFA section 609(e), EPA may request that the SBA Chief Counsel for Advocacy waive the Panel requirement for a rule. The SBA Chief Counsel may grant a waiver if he or she finds that convening a Panel would not advance the effective participation of small entities in the rulemaking process. (Note, however that the waiver applies only to the requirement to convene a Panel; it does not relieve you from preparing an IRFA or notifying the SBA Chief Counsel of the rule nor does it relieve the SBA Chief Counsel from identifying small entity representatives.)

The SBA Chief Counsel will consider the extent to which you have already consulted with small entity representatives and taken their concerns into account; "special circumstances necessitating prompt issuance of the rule;" and whether the Panel process would provide the small entity representatives involved in the process a competitive advantage over other small entities. Before granting the waiver, the SBA Chief Counsel must consult with OMB and the small entity representatives identified by the SBA Chief Counsel after receiving formal notification of the rule. The SBA Chief Counsel must also provide you with a written explanation of the waiver decision for the rulemaking record.

Your waiver request must be submitted through your Regulatory Steering Committee representative to the Agency SBAC. EPA will only request the waiver of a Panel requirement in exceptional circumstances (e.g., when a rule is subject to a near-term legal deadline) or when you have already engaged in extensive outreach to representatives of potentially regulated small entities such that a Panel would be demonstrably redundant.

Even if the Agency decides to request a waiver, you, in cooperation with your Regulatory Steering Committee representative and SBAC staff contact, will still need to complete the formal notification step of the process as outlined below. The SBAC will also informally notify the SBA Chief Counsel of the Agency's intent to request a waiver before formally requesting it. If the SBA Chief Counsel grants the waiver, you are not required to complete the remaining steps of the Panel process, but you should conduct as much outreach as time permits or as appropriate under the circumstances.

5.6 When Should We Convene a Panel?

It is EPA's policy to convene Panels relatively early in the proposed rule development process to give the Panel the best opportunity to inform decision makers during the initial stages of rule development (i.e., prior to option selection). This is balanced with the need for sufficient shape and development such that the small entity representatives and the Panel members will have adequate information to critically appraise EPA's intention. Generally, the Agency SBAC will consult the other standing Panel members with respect to an appropriate time to convene a Panel. However, no matter when in the regulatory development process a Panel is convened, the Panel's final report must be completed within 60 days of convening the Panel. EPA expects that the Panel process will normally be concluded well in advance of Final Agency Review (or equivalent stage for Tier 3 rules), in order to be most useful to the development of the proposed rule.

5.7 What Should Be Done Before My Panel Can Be Convened?

Once you determine that we must convene a Panel for your rule, you should make contact with the SBAC staff through your Regulatory Steering Committee representative to find out who you will be working with on your Panel. You should share information about your expectations for the Panel process and the rulemaking schedule. Bear in mind that **the Panel itself should take no more than the 60 days provided by the statute to conduct its review; however, the entire Panel process-- once begun in earnest with focused small entity outreach, through SBA notifications, preparation for and convening of the Panel and completion of the Panel Report -- will usually take between four and ten months.** The amount of time is dependent on the complexity of the rule and the amount of outreach done prior to the initiation of the Panel process. This time line may result in a change your rulemaking schedule or resource commitments. When negotiating court schedules, program staff and management should take into consideration the time and resources that may be needed to comply with the RFA Panel requirement. The Agency does not recommend asking for an extension of any court-ordered deadlines solely to comply with the RFA Panel requirements, so it is vital that the program fully consider these responsibilities in setting its initial rulemaking schedule.

Prior to convening a Panel, the typical steps include:

- identifying and making contact with small entity representatives (SERs) among your stakeholders;
- providing informal notification of the Panel to SBA and OMB;
- creating a dialogue with your SERs;
- providing formal notification of the Panel to SBA and OMB;
- hosting a final pre-Panel outreach meeting with the SERs to which SBA and OMB are invited;
- participating in one or more pre-Panel meeting(s) with SBA and OMB staff to discuss

available data, materials for the SERs and other related issues; and

- creating a convening document for the Panel.

You, as the program office representative or rulewriter, are responsible for each of these steps (discussed further below). Your SBAC staff contact and your Regulatory Steering Committee representative are available to give you support, review drafts and provide you with examples of documents from previous Panels.

It is very important for you to keep records of all your small entity outreach efforts. An important part of convening your Panel will be demonstrating that your office has worked with small entities throughout development of the rule. When you begin to involve SBA and OMB in your small entity outreach efforts, it is important to ensure that your SBAC staff contact is also provided with any outreach material, notices, or announcements. Your SBAC staff contact keeps the Agency's official record of the Panel process including all communication between Panel members regarding Panel issues.

5.7.1 Identify and Contact Small Entity Representatives

After it is determined that you will need to convene a Panel and you make contact with the SBAC staff through your Regulatory Steering Committee representative, your next step in the Panel process is to identify potential small entity representatives that may be formally appointed later in the process. Small entity representatives (SERs) are typically a subset of your broader stakeholder group -- those representative of *small* entities likely to be *directly* subject to your regulation. Specifically, EPA prefers that SERs be owner-operators of small businesses, small organizations or small government officials[44] potentially subject to the rule. Other representatives, such as trade associations that exclusively or at least *primarily* represent potentially regulated small entities may serve as small entity representatives. Persons other than owner-operators who wish to act as SERs are evaluated on a case by case basis. To avoid the appearance of conflict of interest, you should apply a general “reasonable person" rule, that is, ask yourself if a “reasonable person” would conclude that this potential representative is capable of truly representing only the interests of small entities.

> Small entity representatives (SERs) are typically a subset of your broader stakeholder group - those representative of *small* entities likely to be *directly* subject to your regulation.

For each rule, or group of related rules,[45] you should identify as early as possible what types of small entities are likely to be directly and adversely affected by the rule, and what those

[44] Small businesses are defined by the Small Business Administration through the Small Business Act (codified at 13 CFR 121.201). See Chapter 2 for more information on the definition of 'small entity' for RFA purposes.

[45] RFA section 605(c) permits, but does not require, EPA to "consider a series of closely related rules as one rule for the purposes of preparing an IRFA. In certain circumstances, it may also be appropriate to convene one Panel to consider a series of closely related rules as well.

adverse impacts are apt to be (to the extent feasible at this early stage). An important resource for the Panel process will be the list of small entities that you developed under Chapter 4 to support your rulemaking activities generally. Once you identify candidate SERs, you must contact them to confirm their small entity status and ask if they would agree to serve as a small entity representative for your Panel, if so requested. Unless the program is in a position to sponsor necessary travel, each SER is responsible for his or her own expenses. It is advisable to let any potential SERs know what to expect from the Panel process. The SBAC staff have developed information sheets that will answer questions such as:

- Why Does EPA Need Small Entity Representatives?
- What Is an EPA Small Entity Representative?
- Who Is Eligible to be a Small Entity Representative?
- Who Chooses Small Entity Representatives?
- At What Stage in the Rulemaking Does the Panel Process Occur?
- What Will Being a Small Entity Representative Entail?
- What Will Be Done with Small Entity Input?
- How Can I Get More Information?

Fact sheets and other supporting documents are available on the RFA/SBREFA website (http://www.epa.gov/sbrefa). You may distribute these fact sheets as part of your outreach materials. More information and ideas regarding small entity outreach are detailed in Chapter 4. Although this stage of the process will most likely take place before your rule is drafted, you should provide each potential SER with an outline describing the important components of your rule and any significant alternative approaches under consideration. Indeed, these early discussions with your potential SERs may bring to light other ways of structuring the rule to avoid any significant economic impact on a substantial number of small entities, in which case a Panel need not be convened.

To the extent that comments from potential SERs (or any other information) confirm the rule is likely to have impacts warranting preparation of an IRFA, you must continue to prepare for the Panel process. If comments received or changes made to the rule so warrant, it may still be possible to certify your rule. You should always consult with the SBAC staff and your Regulatory Steering Committee representative if you stop preparations for a Panel.

5.7.2 Prepare Informal Notification to SBA

Once you complete your screening analysis and it has been determined that your rule may have a significant economic impact on a substantial number of small entities, through your Regulatory Steering Committee representative, you must request that the Agency SBAC give the SBA Chief Counsel **informal** notification that EPA is developing a rule that may be subject to the Panel requirement, and that EPA may shortly ask SBA to nominate small entity representatives

according to the statutory procedure. This preliminary notification is a courtesy to the Chief Counsel for Advocacy in order to provide SBA time to inform itself about the rule and review its own list of small entity contacts. At this time, the SBAC will provide the SBA Chief Counsel with a program office staff contact (normally this will be the workgroup chair), and will also ask for an SBA staff contact. Typically, the SBAC sends the informal notification via e-mail, with a courtesy copy also directed to OMB. Keep in mind that SBAC staff are always available to facilitate communication with SBA staff. Again, because the office of the SBAC is responsible for keeping the Agency's record for each Panel, you should copy them on any written exchanges with SBA and OMB regarding the Panel process. Also note your informal notification should be approved by your management and OGC attorney before you send it forward for SBAC staff review.

You will need to draft the informal notification for the SBAC to transmit to SBA. The informal notification could include:

- the title of the rule,
- requested Panel convening date and projected NPRM date,
- the statutory authority for this action and the environmental objective,
- an explanation of any alternatives that are or have been under serious consideration,
- the potential impacts of the rule on small entities, and
- a list of any potential SERs already identified.

SBAC staff are available to help you with this task and a model informal notification is available from the SBAC staff.

5.7.3 Prepare Formal Notification to SBA

To the extent that it continues to appear that your rule may have significant economic impacts on a substantial number of small entities, you should work through your Regulatory Steering Committee representative to request that the Agency SBAC provide **formal** notification to the SBA Chief Counsel that a rule is being developed that may be subject to the Panel requirement. EPA transmits the formal notification in hard copy under the SBAC's signature with a courtesy copy directed to OMB. Formal notification triggers the SBA Chief Counsel's statutory obligation to nominate small entity representatives within 15 days of receiving the notification. Formal notification does **not** commit the Agency to convening a Panel. The program office may still learn as a result of further consultations with small entity representatives and the SBA Chief Counsel's Office, or further analysis, that the rule will not have a SISNOSE, and thus neither an IRFA nor a Panel would be required.

Beyond the basic rule identifying information, you should provide the SBAC with the following information for the formal notification:

- a description of the problem the rule is trying to solve;

- a list of the types of small entities likely to be affected;
- a list of potential small entity representatives you've already identified, if any;
- any material you have already shared with small entity representatives; and
- preliminary rulemaking schedule (e.g., preferred convening Panel date, proposed publication date, any court deadlines, etc.,)

The notice, prepared by you for the SBAC, will emphasize that the request to identify small entity representatives does not represent an EPA finding that the rule will necessarily have a SISNOSE, nor does it commit EPA to preparing a formal regulatory flexibility analysis or convening a formal Small Business Advocacy Review Panel. The formal notification should be reviewed and approved by your management and OGC attorney before it is forwarded to SBAC staff. A sample of a formal notification to the SBA Chief Counsel is available from the SBAC staff.

5.7.4 Respond to SBA Input; Complete Recommendations for Small Entity Representatives

In response to your formal notification to SBA, you will receive a list of suggested SERs from SBA's Chief Counsel for Advocacy through the Agency SBAC. If EPA's outreach has been strong, the Chief Counsel may identify individuals with whom the Agency has already been consulting, and possibly add new names from SBA's own experience. After consultation with your SBAC staff contact and SBA staff on the names under consideration, you should recommend an official list of SERs for appointment by the SBAC. You should take great care to ensure that SERs are truly representing small entities likely to be directly regulated by the rule under consideration. It is better to take time to confirm a small entity's status than to be forced to exclude someone later if he or she is not eligible. As stated earlier, EPA prefers that SERs be owner-operators or officials of small entities potentially subject to the rule. Other representatives such as trade associations that exclusively or primarily represent potentially regulated small entities may serve as SERs, and SBA's Chief Counsel for Advocacy has sometimes nominated such representatives (see Section 5.7.1 for more discussion of SER selection).

While the RFA authorizes the SBAC to select the SERs for the Panel process, you should ordinarily include the SERs identified by the SBA Chief Counsel among those you recommend for appointment unless you discover any reason that one or more should be considered ineligible. You should consult with your SBAC staff contact before deciding whether or not to recommend any SBA-suggested representative for the official list. You can include among your recommendations additional small entities not suggested by SBA, but ultimately it is desirable that EPA reach consensus with the SBA Chief Counsel on the roster of small entity representatives. The SBAC will rely heavily on the Program's recommendations in appointing SERs for the Panel.

5.7.5 Conduct Outreach to Small Entity Representatives

In preparation for a Panel, you may need to conduct outreach to potentially regulated small entities. This outreach meeting should be conducted well in advance of the convening Panel date. Panel members (SBA, OMB, and SBAC) should be invited to the meeting. Your SBAC contact can assist you in this coordination.

There is additional information regarding small entity outreach in Chapter 4.

- You should provide the SERs with enough information about the rule for them to be able to judge the likely impacts of the rulemaking on small entities. Outreach materials could include any draft of the rule or preamble text, if such materials are available.

- You should solicit information, advice and recommendations on issues relating to the specific elements of an initial regulatory flexibility analysis (listed in Section 5.2) from each SER.[46]

- You should encourage SERs to put their comments and suggestions in writing for inclusion in the convening document and your rulemaking record.

- You should keep detailed records of the SERs' participation for later use in developing the rule and any regulatory flexibility analysis or certification for the rule. The outreach process may lead to, and help substantiate, a determination that the rule will **not** have a significant economic impact on a substantial number of small entities. Also, document your outreach efforts.

If the outreach process indicates that there will be no significant adverse economic impact on a substantial number of small entities, it may be possible to certify your rule. In that case, the remaining steps of the Panel process would no longer apply to your rule.

5.7.6 Prepare a Convening Document for the Panel

The convening document is critical to the operation of a Panel. It provides the context and analytical framework for the Panel's deliberations and much of the Panel's report will be based upon the convening document you prepare. By following the outline suggested below, you will reduce the amount of work you must do to complete the Panel Report. The organization outlined below has been used for most of the previous Panel Reports, so it offers the benefit of being familiar to the standing Panel members (i.e., the Chair, OMB and SBA). The convening document should include the following information in approximately the following order:

1. Introduction;

2. Background and Regulatory History;

3. Overview of Proposal Under Consideration;

4. Applicable Small Entity Definitions;

5. Small Entities that May Be Subject to the Proposed Regulation;

[46] Small entity representatives can be consulted individually, particularly since the RFA requires that the Panel collect the advice and recommendations of "each" representative. If, however, you choose to consult with small entity representatives as a group, be careful not to solicit a group recommendation because issues under the Federal Advisory Committee Act (FACA) may be raised.

6. Summary of Small Entity Outreach;

7. List of Small Entity Representatives; and

8. Summary of Input from Small Entity Representatives.

Typically, there are two opportunities for written SER comments, once during the outreach process, and once during the Panel process. The Agency typically provides outreach materials to the potential SERs in advance of the outreach meeting, and sets a deadline of about two weeks subsequent to the meeting for the written comments. Written comments are normally scheduled to arrive at least two weeks before the Panel convening, allowing the Agency to develop materials for the Panel, after being informed by the written comments.

You should attach copies of any materials previously shared with the SERs and the written comments submitted by the small entity representatives to EPA as an appendix to the convening document. The convening document should **not** contain a discussion of the regulatory option or options actually selected by the Agency, since this document generally should be prepared before such decisions are made. The convening document should be forwarded to the SBAC staff assigned to your Panel at least one week prior to the convening date for the Panel. The SBAC staff are also available to review drafts of your convening document. A sample of a convening document and template are available from the SBAC staff.

5.7.7 Consider a Pre-Panel Meeting with SBA and OMB

Several program offices have consented to pre-Panel meetings with SBA and OMB to discuss information needs, and we have found this to be an increasingly valuable planning step. SBA and OMB tend to request a great deal of background information that they consider potentially relevant to developing significant alternatives to minimize burdens on small entities. SBREFA charges the Panel to review "any material the Agency has prepared in connection with this chapter."[47] At a minimum, SBA and OMB typically expect to review any materials that describe the regulatory alternatives under consideration (to which small entities would be subject), their environmental rationale and/or benefits, and the costs they would impose on small parties, as well as the analysis and methods supporting these descriptions and estimates. OMB and SBA normally expect to review such information if reasonably available and accurate, to enable the Panel members to make informed decisions. Such materials could also include narrative discussions of the advantages and disadvantages of these approaches. These materials, or a subset of these materials, may also be provided to the SERs as part of the outreach package.

Since the full range of data and analysis needed to construct a publishable IRFA may not become available until relatively late in the rulemaking, the "materials the agency has prepared," as well as their stage of completion and level of supporting detail at the time of convening, will vary from rule to rule. In effect, the Panel encounters the rulemaking as a work in progress, with the opportunity to affect its future development to avoid unnecessary burden on small entities.

[47] "This chapter" refers to the RFA itself and suggests the elements of an IRFA, which include "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."

EPA supports the Panel's thorough, meaningful consideration of such impacts and the design of justifiable accommodations for small entities. We seek to provide the Panel with whatever information may be available to promote those objectives, and it has been our practice to respond generously to SBA's and OMB's requests for existing data, reports, and surveys. Nevertheless, because each rule presents its own special circumstances bearing on what information is both available and relevant for the Panel's review, a preliminary meeting to consider what materials the Panel will receive, as well as what may be suitably provided to our non-Federal advisors, may be useful in clarifying the expectations of all members. See further discussion of data needs under 5.8.2 below.

5.8 What Can I Expect from Panel Review?

Each Small Business Advocacy Review Panel is chaired by the Agency Small Business Advocacy Chair (SBAC). The three other statutory Panel members are:

1. an EPA senior manager from the program office developing the rule;
2. the SBA Chief Counsel for Advocacy; and
3. the Administrator of OMB's Office of Information and Regulatory Affairs.

Each of these officials signs the final Panel Report, though, as a practical matter, one or more may be represented by a designee during a portion of the Panel's deliberations. The Panel member representing the EPA program should be a senior manager familiar with your rule who has the authority to negotiate the program's position on potential regulatory alternatives for small entities. **Remember, small entity representatives (SERs) are not members of the Panel** -- they provide input to the Panel, but by statute the Panel comprises only Federal employees, as identified above.

5.8.1 When is the Panel Officially Convened?

The SBAC convenes the Panel at the first formal meeting of the Panel members. The SBAC sets the convening date in coordination with all the Panel members through consultation facilitated by the SBAC staff. The convening document and a program office presentation on the regulation are generally used as the main vehicles for initiating review. Once the Panel convenes, it is critical that all Panel members review the same set of information. Accordingly, during a Panel, all communication to the Panel members should be channeled through the SBAC's staff. **Materials not for public release can be marked deliberative and circulated to Panel members as Federal employees. Such materials are intended to be kept confidential and are not be released to the public nor included as part of the Panel Report.**

5.8.2 What Information Am I Required to Provide to the Panel?

The program office Panel member should be prepared to negotiate with SBA and OMB on the type and amount of data and supporting information that is needed to support the Panel's discussions. We have found that a pre-convening meeting(s) can provide a useful forum for arriving at workable understandings on this matter, but unexpected issues can arise during the 60-day Panel term as well. SBA and OMB sometimes request information and analyses that have not yet been performed. As detailed below, according to the statute, the Panel is to review any

existing RFA-related materials and any draft proposed rule, if those materials have been prepared by the time the Panel convenes. **The RFA does not require EPA to develop materials or perform analyses specifically for the Panel process.**

The following describes the information the RFA requires you to provide to the Panel:

- Draft regulatory text - Section 609(b)(4) states that "the Panel shall review any material the agency has prepared in connection with this chapter, including any draft proposed rule." While this language does not require EPA to prepare a draft proposed rule prior to convening a Panel, if you convene the Panel after you have prepared a draft NPRM, you must provide it to the Panel members;

- Economic impact data - Section 609(b)(l) requires EPA to provide SBA "information on the potential impacts of the proposed rule on small entities and the type of small entities that might be affected." Section 609(b)(l) does not specify the requisite level of analysis of the potential impacts. EPA does not believe the RFA requires you to prepare a full economic analysis of potential impacts for the Panel process, nonetheless, EPA clearly must provide some information - either quantitative or qualitative - on the potential impacts;

- Regulatory Alternatives - Section 603(c) requires the IRFA to include "a description of any significant regulatory 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." [Emphasis added] The RFA does not require you to prepare for comment by the Panel what essentially would be a draft IRFA for all regulatory alternatives you have identified. You do, however, need to describe in sufficient detail, including some analysis of the impact on small entities and environmental benefits, each significant regulatory alternative you have identified that accomplishes the statutory mandate. It is important to note that the Panel process precedes and is intended to contribute to the development of the IRFA, not the reverse; and

- Technical and legal supporting materials - Pursuant to subsection 603(b)(2), an IRFA must address the legal basis for a proposed rule. However, section 603(b)(2) is not one of the expressly enumerated subsections on which the Panel is to collect advice and recommendations. Since the RFA places the legal basis for the proposed rule outside the purview of the Panel, the RFA does not require EPA to provide such information to the Panel.

Although the above list describes what the RFA does and does not require you to provide to the Panel, as a matter of policy, EPA typically provides information beyond the statutory minimum. When doing so, you should consult with staff to the SBAC and establish clearly that the provision of such information is not statutorily mandated. In previous Panel processes, several EPA program offices have made it a practice to provide requested information to the Panel as long as the information has been cleared by OGC for public release or otherwise would have been provided to any requestor. We have also honored requests for materials not already prepared if fulfilling the request would not consume excessive resources or delay the rulemaking/Panel schedule.

It is vital that program regulatory staff remain in close consultation with its own management to ensure that its provision of non-statutory information is neither inappropriately restrictive nor unacceptably intrusive on the program organization's internal priorities and schedules. SBAC staff can be helpful to you in establishing how the Agency has viewed and treated similar requests for information in other Panel settings. (See 5.7.7 for further discussion of how we typically anticipate such requests and determine whether and when the Agency can fulfill them.)

5.8.3 Panel Outreach to Small Entity Representatives

The RFA also tasks the Panel with performing its own outreach to the Small Entity Representatives. Typically, this consists of a meeting with the SERs, either in person or via teleconference. Prior to this meeting, the Panel generally sends a letter from the SBAC inviting SERs to the outreach meeting and a package of information that provides them with additional information about the rule for them to be able to judge the likely impacts of the rulemaking on themselves and other small entities. The Panel agrees on the content, but development of this outreach package is the responsibility of the EPA program office responsible for the rule. The outreach letter will request written comments from each small entity representative on the four elements of an IRFA (see Section 5.2) as well as other issues identified by the Panel. The program office should try to anticipate what information the Panel would like to provide to the SERs and develop the SER outreach package prior to convening the Panel. We encourage you to circulate the draft outreach package to the Panel members within one week of convening. The outreach materials are circulated and agreed upon by all Panel members before they are sent out under the signature of the SBAC. An example of an outreach package is available from SBAC staff.

At the outreach meeting, chaired by the SBAC, the program office is generally responsible for a brief presentation on the proposal under consideration and the remainder of the time is devoted to feedback from and dialogue with the SERs. **The program office is responsible for creating a summary of this meeting for inclusion in the Panel Report.** The SER outreach meeting should generally take place within the first 30 days of the Panel process.

5.8.4 Panel Deliberations and Generating the Panel Report

The Panel generally meets very soon after the SER outreach meeting to discuss the SER comments. It is useful at this point, for each Panel member to be able to bring to the table proposals for regulatory options that may minimize economic impacts on small entities. Panel deliberations can occur through a series of face-to-face meetings of the Panel members (or their designees), conference calls, e-mail exchanges or facsimile transmissions. Deliberations generally center around the language that will be contained in the Panel Report. You should be prepared to devote a significant amount of time and effort to drafting materials for your SBREFA Panel, especially toward the end of the 60-day process. **The program office has the primary responsibility for drafting the Panel Report.** The first complete draft of the Panel Report is based primarily on SBA and OMB's input (based on the SER comments) to the convening document. Each of the Panel members will sign the completed Panel Report, therefore, each Panel member has a vested interest in the specifics of the Panel Report language. The program office Panel member should be prepared to negotiate with OMB and SBA on Panel recommendations; this could require a substantial amount of time as well as direct, immediate feedback from management.

By statute, the Panel only has 60 days from the date it is convened to produce its official final report. The Panel is not required to take the full 60 days, and should issue its report as soon as possible to provide timely input to the development of the proposed rule. The Panel need not reach consensus in order to issue a final report; the views of each of the members can simply be reflected in that report. When possible, the report should state matters of Panel agreement, but no Panel member is under compulsion to agree to any position. Indeed, any member may demur and even insert into the Panel Report a contrary position, with the knowledge that the Report will be part of the public record offered for comment when the proposed rule is published. Since an EPA program office representative signs the Panel Report, **it is generally recognized that any recommendations agreed upon by the entire Panel are acceptable to the Agency, whether as modifications to the regulatory proposal, or as issues to be discussed in the preamble. Even if there are subsequent data findings or circumstances that warrant a change in EPA's position after the Panel closes, it is important to discuss the Panel's recommendations and the Agency's response in the NPRM.** The program office Panel member should not agree to any Panel recommendation if it appears that the Agency cannot implement it. The final Panel Report will **not** contain a discussion of the option or options actually selected by the Agency, since the report will normally be prepared before such decisions are made.

5.9 Consideration of the Panel Report During Development of the Proposed Rule and Initial Regulatory Flexibility Analysis

The RFA requires the Agency to consider the Panel Report in selecting proposed regulatory options to address small entity concerns, and where appropriate, to modify the proposed rule, the initial regulatory flexibility analysis or the decision on whether an initial regulatory flexibility analysis is required. As stated earlier, it is generally recognized that any recommendations agreed upon by the entire Panel will be addressed in the proposed rule unless unforseen circumstances intervene between completion of the Panel Report and the time of proposal. You should document the results of the outreach and Panel process, and their role in the Agency's deliberations in the initial regulatory flexibility analysis prepared for the rule. You should integrate the substantive Panel recommendations into your preamble text in the appropriate sections and also summarize these results in the Regulatory Flexibility section of the preamble of your proposed rule. The Regulatory Management Division of EPA's Office of Policy, Economics and Innovation, which is responsible for the review of regulations prior to OMB review and signature by the Administrator, will, in conjunction with OGC, ensure that your preamble language is sufficient.

EPA's policy is to keep the Panel Report confidential until the rule is proposed, since we consider its recommendations to be protected under the Federal deliberative process. Upon proposal, the Panel Report must be placed in the docket for the rulemaking so that it will be accessible to all parties interested in the rulemaking.

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CHAPTER 6
Small Entity Compliance Guides

6.1 EPA's Approach to Small Entity Compliance Guides

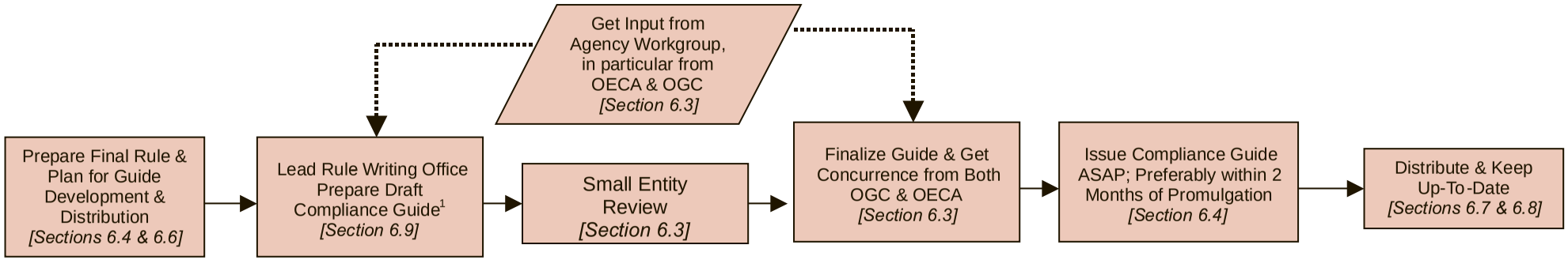
When the Agency is required to prepare a regulatory flexibility analysis for a final rule, SBREFA section 212[48] also requires the Agency to:

- prepare and publish one or more documents regarding such a rule or group of rules as small entity compliance guides and specifically "entitle such publications as small entity compliance guides;"
- explain in the compliance guide actions that a small entity must take to comply with a rule or group of rules;
- distribute the guides to small entities through "comprehensive sources of information;"
- post the guide in an easily identified location on the website of the agency and publish each guide - "on the same date as the date of publication of the final rule (or as soon as possible after that date);" and "not later than the date on which the requirements of that rule become effective;" and
- report annually on the agency's compliance.

While compliance guides are not judicially reviewable, they may be considered as evidence of the reasonableness or appropriateness of any penalties or damages in any civil or administrative action against a small entity. Accordingly, the statute gives us broad discretion with regard to implementing these requirements particularly in regard to designation, development and distribution of the guides. Although guides are required only for final rules for which a regulatory flexibility analysis was prepared, rulewriters should start their planning for the guide

[48] Pub. L. No. 104-121, Sec. 212. SBREFA has several provisions that are not codified into the RFA but that still have an impact upon RFA implementation. SBREFA section 212 is one such provision. SBREFA section 212 has also been amended by Pub. L. Number 110-28.

Small Entity Compliance Guides
Figure 5



Notes:

General: References to "Sections" in the flowchart refer to the sections in Chapter 6 in this guidance document (see Table of Contents).

[1] If you are doing an Analytic Blueprint you should include plans for developing the Guide, including a timeline, and the resources needed. If there is no Blueprint, you should integrate Compliance Guide development into your action or work plan.

during the proposed rule phase. Timing is discussed further in Section 6.4

The sections that follow describe how the Agency has chosen to exercise this discretion, the specifics of which may not necessarily be required by SBREFA. As we continue to gain experience, we may issue additional guidance. Figure 5 illustrates our approach to developing a small entity compliance guide.

6.2 What is the Goal in Writing a Compliance Guide?

As mentioned above, SBREFA section 212 requires the Agency to prepare and publish one or more documents as small entity compliance guides for a rule or group of rules for which we've prepared a final regulatory flexibility analysis and specifically "entitle such publications as small entity compliance guides." Beyond meeting the statutory obligation, the primary goal of the guide is to help small entities--whether they are small businesses, small governments or small non-profit organizations--to comply with the regulation. You should therefore write your guide using language suitable for a non-technical audience. President Clinton's memorandum of June 1, 1998 entitled "Plain Language in Government Writing," directs agencies to use plain language in all documents that explain how to obtain a benefit or service or comply with a regulation. You should focus your guide on what a small entity will need to know to comply with your regulation and minimize the inclusion of any other information (see the template in section 6.10, below). While small entities are the primary audience for the guides, some of the compliance information may also be applicable to large entities and you may choose to present these similarities/differences as you develop your guide.

6.3 Who Participates in the Development of a Compliance Guide?

The lead rule-writing office is responsible for developing the rule-specific compliance guide as part of the rulemaking process. You should have your draft guide reviewed by both the Office of General Counsel attorney assigned to your rule and by a representative from OECA. Your regulatory development workgroup, as well as representatives from SBO, OPPT's Pollution Prevention Division, regional offices and the SBAC's staff can also provide assistance/support, or develop sections of the guide, as appropriate. If your regulatory development workgroup does not include representatives of the appropriate offices, you should work through your Regulatory Steering Committee representative to identify such individuals.

Small entity representatives should typically be involved in reviewing the draft compliance guide after the rule is promulgated so that we have the benefit of their comments and advice in preparing the final version of the guide. Generally, draft compliance guides should not be released to outside parties prior to the rule's promulgation. In those unusual circumstances where the outline of the compliance guide is clear to you at pre-proposal, then you may seek review and feedback from small entity stakeholders at that stage. You should share the draft compliance guide and solicit comment from small entity stakeholders after promulgation, but will need to balance such review with equal concern for timely issuance of the guide.

Before issuing a compliance guide, obtain concurrence from both OGC and OECA. Normally, you can ask members of your workgroup from these offices to ensure that appropriate levels of management in their offices approve the draft. (OGC and OECA will determine the level of concurrence from their offices.)

6.4 When Should I Develop a Compliance Guide?

You should integrate development of the guide into the rulemaking process. Generally, you should begin work on your guide as soon as you have enough information to do so. This point will vary from rule to rule; sometimes it is clear even before the rule is proposed, and in other cases not enough is known until just prior to final promulgation. In either event, **you should plan to devote time during the rulemaking process for development of a guide. However, the Agency will not ask for an extension of any court-ordered deadlines in order to complete compliance guides.**

Keep in mind that the goal is to make the guide available after promulgation in sufficient time for it to be of practical help to small entities in evaluating and implementing their compliance options before the compliance deadline. **It is required that the guide be published "not later than the date on which the requirements of that rule become effective."** In any case, you should make every effort to issue the guide within two months of the promulgation of the final rule.

The constraints on outside participation during the final rule phase in development of the guide leave a relatively short time after promulgation to both take comment from small entity stakeholders and issue the final guide. This makes advance planning and drafting essential.

> **Tip:** Identify your small entity reviewers early in the process. You may want to consider using those small entity representatives who participated in the Panel process during the development of the proposed rule.

If the issuance of your guide may be delayed beyond a month or two, you should issue a Fact Sheet or other brief description of the rule as an interim measure. If your rule has a distant compliance date (e.g., two years or more), closer to the compliance date you may want to ensure the information in your compliance guide is still current and re-issue the guide, if appropriate.

6.5 What Sorts of Questions Should I Ask My Small Entity Reviewers?

Some suggestions include:

Is the format appropriate?

Is the guide clear and easy to read and understand? (use Plain Language-refer to http://intranet.epa.gov/plainlanguage)

Does the guide accurately describe the rule as published?

Is the guide useful in planning for compliance?

6.6 How Do I Document Development of the Guide?

If you are doing an Analytic Blueprint, it should include plans for developing a small entity compliance guide, including a time line, and the resources needed. If there is no Blueprint, you

should integrate development of a compliance guide into your action or work plan. Submit a schedule for development and completion of a compliance guide when you submit your final rule to the Administrator for signature. Include your distribution strategy for the guide in your Communications Plan. Information related to the development of the guide will be tracked in OPEI's Rule and Policy Information and Development System (RAPIDS). Lead offices are also encouraged to develop internal methods for tracking the development of the guides.

6.7 Who Can Help Me with Distribution?

In addition to internal office distribution mechanisms, you should provide copies of your completed guides to the staff of the Small Business Advocacy Chair, the Office of the Small Business Ombudsman, the Office of Regional and State/Local Relations, and the Office of Public Affairs. These offices will distribute the guide to their small entity contacts. (You should ensure, to the extent it is feasible, that these offices do not have duplicate distribution lists.) Other small business assistance providers include:

State Technical Assistance Programs for Pollution Prevention;

State Small Business Assistance Programs;

Small Business Development Centers;

Trade Associations;

Professional Organizations; and

the Small Business Administration, USDA and OSHA.

In addition, your small entity compliance guide must be made available to the public and must be made available to Congress through the Courtesy Copy Policy (CCP). Please refer to *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions*, June 30, 2004. EPA's Action Development guidance can be found at EPA's Action Development Process Library intranet site: http://intranet.epa.gov/adplibrary.

6.8 How Do We Ensure that Compliance Guides are Kept Up to Date?

As a statutory matter, compliance guides may have evidentiary uses in litigation so it is important that guides are reviewed and revised as needed. The guide should be revised when the rule for which it was developed is revised. It is the responsibility of the lead office to ensure compliance guides are kept current.

Other circumstances that may cause you to revise the compliance guide include:

Changes in the rule which affect compliance.

Comments from the public suggesting revisions, or from OECA based on their

experience in enforcing the regulation.

Litigation citing a guide as a reason to challenge the appropriateness of proposed penalties.

You should include in every compliance guide the following disclaimer on the cover page of your guide.

NOTICE

This guide was prepared pursuant to section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 ("SBREFA"), Pub. L. 104-121 as amended by Pub. L. Number 110-28. THIS DOCUMENT IS NOT INTENDED, NOR CAN IT BE RELIED UPON, TO CREATE ANY RIGHTS ENFORCEABLE BY ANY PARTY IN LITIGATION WITH THE UNITED STATES. The statements in this document are intended solely as guidance to aid you in complying with **[insert name of your rule and its CFR citation].** EPA may decide to revise this guide without public notice to reflect changes in EPA's approach to implementing **[insert the name of your rule]** or to clarify and update text. To determine whether EPA has revised this guide and/or to obtain copies, contact EPA's **[insert Small Business Ombudsman Office and phone number and name of program office that issued the rule and its main phone number and/or website address].** The full text of the rule is available online at: **[insert name of your website].**

Note: OECA may, at a later date, develop sector-specific, multimedia guides which would integrate rule-specific guides. OECA will notify program offices if and when it undertakes this project and will coordinate development of such guides through the Agency's Regulatory Steering Committee.

You also should send a copy of your compliance guide to EPA's Small Business Ombudsman's office and place the most current guide in the appropriate docket, on a special secion in EPA's internet page or other electronic bulletin boards.

6.9 Template for Compliance Guides

An Agency workgroup has developed the following template to help you in structuring your compliance guide, and you should use it in accordance with the guidance given earlier in the chapter. While SBREFA does not mandate a particular format, we urge you to use this template so that we may have general consistency across the Agency and to assure that significant compliance issues are adequately covered. If your rule does not, for some reason, lend itself to this template, you may use it as a checklist to ensure that all potentially relevant compliance issues are covered.

The template is organized as follows:

Non-italicized text indicates sections which should normally be included in the compliance guide.

Italicized text indicates standard language which you may choose to use if it is

appropriate to your rule. You should adapt this standard language to the specifics of your rule as necessary.

Program offices have lead responsibility unless otherwise designated in **bold.**

Please make your best effort to write your guide in plain language (see EPA's intranet site http://intranet.epa.gov/plainlanguage)

[Insert standard publication header, including the date and appropriate publication number]

SMALL ENTITY COMPLIANCE GUIDE
[insert title of rule or program...]

NOTICE

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INTRODUCTION

This document is published by the Environmental Protection Agency (EPA) as our official compliance guide for small entities, as required by the Small Business Regulatory Enforcement Fairness Act of 1996. Before you begin using the guide you should know that the information in this guide was compiled and published on [INSERT PUBLICATION DATE]. EPA is continually improving and upgrading its rules, policies, compliance programs, and outreach efforts. You can determine whether EPA has revised or supplemented the information in this guide by calling [INSERT HOTLINE NUMBER OR INTERNET ADDRESS].

Who Should Use this Guide?

1. To the extent possible, the guide should identify all the types/categories of small entities that will be subject to the rule's requirements. Bear in mind that other entities may be *indirectly* affected but may not be required to comply. This section needs to make this distinction clear to the reader.

   Tip: Use the compliance table from the "Summary" section of your rule's preamble to convey this information. Be sure to modify it if necessary to target small entities.

2. In many cases, the guide will also be useful to larger entities subject to the rule. You may wish

to point out any similarities or differences at this stage but you should not go into great detail on this subject.

What does the Guide Cover?

How do I use the Guide?

How do I Obtain a Complete Copy of the Rule?

List an 800 number, *Federal Register* citation or the Government Information Locator Service.

WHAT DOES THE REGULATION REQUIRE?

What environmental/human health issue(s) does this rule address and why it is important?

Summary of the New Regulation

1. Using plain English, summarize the rule in a narrative format. This should be a simplified adaptation of the issues you discussed in the rule's preamble.

2. Additionally, provide a visual description (e.g., chart or flowchart) of the rule's requirements as it applies to small entity operations or processes. "Operations" include traditional facility-based operations and non-traditional based operations such as farms, communities or schools.

Compliance Timetable

Identify in easy-to-read format (e.g., flowchart, time line, timetable) compliance dates for notifications and other requirements.

How Does this Regulation Relate to Other Federal, State, and Local Requirements?

1. Each Program should develop specific template language concerning program delegations and relationships to other requirements **generally,** or, where appropriate, referring back to general provisions applicable to all regulations in a subgroup to which the new regulation belongs (e.g., New Source Performance Standards under the Clean Air Act). Programs have the flexibility to expand this section as appropriate, to address this issue more **specifically.**

2. Meanwhile, this suggested template language which may be appropriate in many cases:

   This compliance guide explains your federal compliance obligations with respect to_____ rule. There may be other state or local requirements which apply to you which are different from, or more stringent than, the federal requirements. For example, some environmental statutes allow EPA to delegate environmental programs to a state. The state may then promulgate its own rules which may supersede the federal requirements. For more information on the rules that apply in your State, please contact [INSERT CONTACT POINT].

STEP-BY-STEP PROCEDURES FOR COMPLIANCE WITH THIS RULE

This is where you break down the rule into discrete subject areas using a step-by-step, question/answer approach. Questions in this section will depend on the particular rule. All the following questions are EXAMPLES of the types of questions that may be appropriate to include.

How can I tell if I am subject to this rule?

What requirements am I subject to?

When do I need to comply ? (elaborate on flowchart, as appropriate)

What do I need to do to comply?

Be sure to address such questions as:

How does this rule affect my existing permit?
How much will it cost to comply with this rule?

What, when and how must I monitor or test?

What records do I need to keep and for how long?

Include sample forms and calculations.

What, when and to whom must I report?

Include sample forms.

How do I minimize harm if I think I am out of compliance? (Program lead/OECA support)

Where do I go for help?

Give information on federal, State and local contacts, Agency hotlines, or State Small Business Assistance Program contacts.

What is pollution prevention and how can it affect my operations? (OPPT lead)

1. Discuss pollution prevention and its benefits, including how it may be used to help a facility/operation save money and/or possibly avoid regulation.

2. To the extent that there are other pollution prevention opportunities, including those which may make good business sense or could exempt a small entity from certain requirements, the program, with support from OPPT, has the option to expand this section and include this information.

Are there opportunities for flexibility or waivers?

If this is applicable in a given rule, these opportunities can be highlighted here. For example, there are circumstances in which the Safe Drinking Water Act allows temporary variances or exemptions from maximum contaminant levels.

OPTIONAL QUESTIONS AND ANSWERS ABOUT FACILITY/ OPERATIONS/ PROCESSES

Here you want to anticipate questions of potential concern to the regulated community, including how the rule fits into the overall regulatory program. Questions will depend on the rule; the questions below are only EXAMPLES. [*Tip*: A self-audit checklist can be very helpful to small entities and may be used alone or in conjunction with a question and answer format.]

How do I conduct a self-audit of my facility/firm/operation to help me evaluate whether I am in compliance with this rule?

Provide Self-Audit Checklist **(Program/OECA)**

What are the implications of this rule for my existing permits?

Adapt this to your particular rule or program.

How Does this Rule Change How I Handle/ Store Wastes? (if guide was written for RCRA rule)

THE COMPLIANCE ASSURANCE PROCESS (OECA LEAD)

This section should describe in clear, non-threatening terms why compliance is important, the potential consequences of violating the law, and how the entity can work with us to identify and correct its compliance problems, often without the need for a formal enforcement action or penalty.

Draft this section to ensure that small entities understand:

how EPA determines compliance

what they must do if they discover a violation, and

the available compliance assistance/enforcement options.

Include only information that is directly relevant to the rule. You may attach more detailed information, or information you feel may be helpful, in an Appendix.

How Is My Operation's Compliance With Environmental Requirements Determined?

Discuss compliance assistance, inspections, self-monitoring and the role of citizens.

If I Discover a Violation, How Can I Work With The Agency to Correct It?

Discuss compliance incentives policies: Small Communities Policy, Policy on Compliance Incentives for Small Businesses, Self-Disclosure Policy.

If the Agency Discovers a Violation, What Might Be Its Response?

To maximize compliance, EPA implements a balanced program of compliance assistance, compliance incentives, and traditional law enforcement. EPA knows that small businesses which must comply with complicated new statutes or rules often want to do the right thing, but may lack the requisite knowledge, resources, or skills. Compliance assistance information and technical advice helps small businesses to understand and meet their environmental obligations. Compliance incentives, such as our Small Business Policy, encourage persons to voluntarily discover, disclose, and correct violations before they're identified by the government. EPA's strong law enforcement program protects all of us by targeting persons who neither comply nor cooperate to address their problems.

EPA uses a variety of methods to determine whether businesses are complying, including inspecting facilities, reviewing records and reports, and responding to citizen complaints. If we learn a person is violating the law, EPA (or a State, if the program is delegated) may file an enforcement action seeking penalties of up to $[INSERT STATUTORY MAXIMUM AMOUNT], per violation, per day. The proposed penalty in a given case will depend on many factors, including the number, length, and severity of the violations, the economic benefit obtained by the violator, and its ability to pay. EPA has policies in place to ensure penalties are calculated fairly. These policies are available to the public. In addition, any company charged with a violation has the right to contest EPA's allegations and proposed penalty before an impartial judge or jury.

In summary, EPA recognizes that we can achieve the greatest possible protection by encouraging small businesses to work with us to discover, disclose, and correct violations. That's why we've issued self-disclosure, small business, and small community policies to eliminate or reduce penalties for small and large entities which cooperate with EPA to address compliance problems. In addition, we've established compliance assistance centers to serve over a million small businesses. For more information on these and other EPA programs for small businesses, please contact [INSERT POINT OF CONTACT].

What is the legal status of this guide?

A judge can look at a compliance guide in determining what penalty is appropriate and reasonable, although the content of the guide cannot otherwise be reviewed by the court.

In this Compliance Guide, we have tried to make clear what you must do to comply with the applicable law and regulation. This is the minimum required by SBREFA. You '11 notice, however, that here and there we have also included suggestions for alternative approaches that may make compliance easier and possibly even reduce costs. We hope you find this presentation of regulatory requirements useful and the additional information helpful in reaching and maintaining compliance.

APPENDIX

Glossary of Environmental Terms

Define terms which are relevant to the rule but which may be too basic to be defined in the rule itself. For example, "permit," "pollution prevention," "process."

Where to Obtain More Information

This section gives supplemental information. Examples might include other existing quality compliance guidance, pollution prevention guidance, pollution prevention case studies, other media contacts, trade associations, or university assistance programs.

How Useful Was This Guide?

Each guide should solicit feedback from users as to the usefulness, readability, and improvements needed for the guide.

Chapter 7
Ongoing Informal Small Entity Guidance

This chapter provides a brief overview of our informal small entity compliance program and list of compliance assistance tools. **This information is provided here to help you understand what resources are available to assist you in your small entity compliance assistance efforts.**

7.1 Overview of EPA's Section 213 Program

Section 213 of the Small Business Regulatory Enforcement and Fairness Act (SBREFA) requires us to: 1) provide guidance to small entities "whenever appropriate in the interest of administering statutes and regulations", 2) establish a program for providing the guidance, and 3) issue a report to Congress regarding the program. Under section 213(a), we are required to answer inquiries from small entities regarding compliance with all Agency statutes and final regulations. In particular, we are required to provide advice based on the application of the law to specific sets of facts supplied by small entities. **This advice and guidance can be considered as evidence of the reasonableness or appropriateness of penalties sought against a small entity.**

EPA's Informal Guidance Program consists of four main components:

- the EPA Small Business Ombudsman (SBO), located at EPA Headquarters;
- regional small business liaisons, who serve as local resources to assist small entities who contact the EPA regional offices;
- various hotlines and clearinghouses that serve entities of any size, including large percentages of small entities; and
- technical and program staff located throughout Headquarters and the regions who are available to answer questions in their subject area or who refer small entities to the appropriate State and local resources.

In designing this program, EPA's guiding principles were to: 1) ensure the accessibility of the

informal guidance program to the small entity community, and 2) avoid duplication with existing activities. As provided in section 213(b), we have applied existing functions and personnel in creating the program. By incorporating our Small Business Ombudsman (SBO) and other existing services into the core of the Agency's Informal Guidance Program, we have been able to achieve both goals.

> Informal small entity advice and guidance can be considered as evidence of the reasonableness or appropriateness of penalties sought against a small entity.

The SBO is already well-known in the small entity community, serving as a "first-stop shop" for multi-media compliance information. The SBO administers a free hotline handling approximately 1,100 to 1,500 calls per month, answering fact-specific compliance questions, distributing supporting documentation, and providing information on additional sources of assistance. Callers may remain anonymous at their own discretion. In addition to these calls to the hotline, SBO staffers respond to another 1,000 or more calls annually that are made directly to their desks.

In addition to the SBO, EPA has numerous other resources to answer compliance questions from small entities, such as the small business liaisons, program-specific hotlines and clearinghouses, and technical and program media staff, some of which are listed below. For example, we sponsor approximately 89 hotlines and clearinghouses throughout Headquarters and the regions, which are available to customers of any size, including small entities.

We have a long history of developing authoritative materials to aid the regulatory community in its compliance efforts. These documents include such items as Sector Notebooks, Plain English Guides, and Fact Sheets. Through the issuance of such documents, you can often preclude the need for a small entity to contact us with a related inquiry. In addition to these written materials, you can make numerous resources easily accessible through the main EPA home page (www.epa.gov) or through your program office web site.

If you provide informal guidance to small entities, whether as a technical or program expert answering questions in your field of expertise or via a hotline or clearinghouse, you should be aware that the Office of General Counsel has provided guidance that applies to all EPA personnel providing informal guidance regarding the kinds of assurances EPA can make about the confidentiality of information provided by callers to EPA hotlines. As a matter of law, the Agency generally is unable to guarantee that any information received by EPA personnel or hotline staff will remain "confidential." As stated in EPA's SBREFA section 213 Report to Congress, it is EPA's position that callers to an Agency hotline who request compliance assistance may choose to remain anonymous. Callers speaking with program or technical experts may similarly choose to remain anonymous. This means that the caller is not required to provide specific information such as her/her name, phone number, or address, that could be used to identify the caller. The caller may simply choose to provide whatever information is necessary to describe his/her situation and to seek EPA's assistance in answering their questions. *Anonymity,* however, is not the same as *confidentiality.* For instance, EPA staff may not suggest or guarantee that (1) the information provided would not be viewed by other parts of EPA; or (2) the information would not be released by EPA to a third party if it were the subject of a Freedom of Information Act request.

7.2 List of Compliance Assistance Resources

EPA offers small businesses a wide variety of compliance assistance resources and tools designed to assist small businesses in complying with federal and state environmental laws. These resources can help businesses understand their obligations, improve compliance and find cost-effective ways to comply through the use of pollution prevention and other innovative technologies. You and your management should assess which of these venues would be the most effective means to provide small entity compliance assistance regarding your rule.

Websites. EPA offers a great deal of compliance assistance information and materials for small businesses on the following Websites:

EPA's Home Page	www.epa.gov
EPA's Enforcement Policy and Guidance	www.epa.gov/compliance
EPA's Office of Enforcement and Compliance Home Page	www.epa.gov/compliance
EPA's Small Business Assistance Programs	http://www.epa.gov/smallbusiness
EPA' Small Business Compliance Policy	www.epa.gov/Compliance/resources/policies/incentives/smallbusiness/sbcp2000.pdf
EPA's Small Business Ombudsman	www.epa.gov/sbo
Small Business Home Page	www.smallbiz-enviroweb.org

Hotlines. EPA sponsors approximately 89 hotlines and clearinghouses that provide free and convenient avenues to obtain assistance with environmental requirements. The Small Business Ombudsman Hotline can provide you with a list of all the hot lines and assist you with determining which hotline will best meet your needs. Key hotlines that may be of interest to you include:

Clean Air Technical Center	(919) 541 -0800
RCRA/UST/CERCLA Hotline	(800) 424-9346
Safe Drinking Water	(800) 426-4791
Small Business Ombudsman	(800) 368-5888
Stratospheric Ozone/CFC Information	(800) 296-1996
Toxic Substances and Asbestos Information	(202) 554-1404
Wetlands Hotline	(800) 832-7828

Compliance Assistance Centers. EPA has established national compliance assistance centers, in partnership with industry, academic institutions, and other federal and state agencies, that provide on-line and fax back assistance services in several industry sectors heavily populated with small businesses. You can access each center directly at:

http://www.epa.gov/compliance/assistance/centers/index.html.

Agriculture	1-888-633-2155 or http://www.epa.gov/compliance/assistance/sectors/agriculture.html
Automotive	1-888-GRN-LINK www. ccar-greenlink. org
Local Governments	1-877-TO-LGEAN www.lgean.org
Metal Finishing	www.nmfrc.org
Paints and Coatings	www.paintcenter.org
Printing	1-888-USPNEAC www.pneac.org
Transportation	1-888-459-0656 www.transource. org

State Agencies. Many state agencies have established compliance assistance programs that provide on-site as well as other types of assistance. Please contact your local state environmental agency for more information. EPA's Small Business Ombudsman can provide you with state agency contacts by calling (800) 368-5888.

Compliance Policies Incentive. EPA's Small Business Policy and Small Communities Policy are intended to promote environmental compliance among small businesses by providing incentives such as penalty waivers and reductions for participation in compliance assistance programs, and encouraging voluntary disclosure and prompt correction of violations. These policies can not be applied to enforcement actions that have already been initiated.

Chapter 8
Periodic Review of Final Rules as Required by RFA Section 610

8.1 Introduction

The Regulatory Flexibility Act (RFA) generally requires agencies to examine the impact of their proposed and final regulations on small entities.[49] Under section 610, the RFA also requires that agencies review rules which have or will have a significant economic impact on a substantial number of small entities (SISNOSE) within ten years of promulgation. The Small Business Regulatory Enforcement Fairness Act (SBREFA), enacted in 1996, added a judicial review provision to the RFA, which means the Agency can be challenged in court as to its compliance with the provisions of this section on a rule-by-rule basis.

This chapter provides information on:

- identifying rules subject to review,
- performing a section 610 review,
- ensuring your review meets section 610 requirements, and
- publishing your results.

8.2 What's a Section 610 Review?

In general, a section 610 review involves:

- identifying a promulgated rule that was not certified, (i.e. did not contain a finding that there was no SISNOSE);[50]
- determining if the rule should be amended, rescinded, or left unchanged, based on five statutorily prescribed factors; and

[49] Small entities are defined as small businesses, small governments, and non-profits that are not dominant in their field, see Chapter 2 for more information.

[50] "Certification" means that the Agency determined that the rule had no SISNOSE, and stated this to be the case in the published rule, see Chapter 1 for more information.

- documenting the review and conclusions within 10 years of the date the rule was promulgated.

8.3 Are there Some Rules that are not Certified by EPA that will not have a Section 610 Review?

Yes. For EPA rules issued in 1992-1997, EPA went beyond the requirements of the RFA by preparing regulatory flexibility analyses for rules that would have any adverse impact on any number of small entities, regardless of the size of impact or number of small entities. In effect, many rules that we would otherwise have certified as not having a SISNOSE were not formally certified during this time period. After the RFA was amended in 1996 by the Small Business Regulatory Enforcement Fairness Act (SBREFA), EPA returned to its earlier practice of formally certifying rules with no SISNOSE under the RFA while continuing to offer outreach and accommodation to regulated small entities for those rules. EPA has identified eight rules issued before SBREFA was passed that were not formally certified yet do not and will not have a SISNOSE. EPA has determined that these eight rules are not subject to section 610 review, and, even if a section 610 review were conducted, revision of the rules would not be warranted. The rules were published in EPA's Regulatory Plan and semi-annual Regulatory Agenda, Spring 2003 (Published May 19, 2003).

8.4 How Do We Identify and Track Rules for Review?

Final rules that have or will have a significant economic impact on a substantial number of small entities (SISNOSE) are subject to section 610 review. Following promulgation of the final rule that EPA does not certify as not having a SISNOSE, we identify the rule in our Agency's database, the Rule and Policy Information and Development System (RAPIDS), as a rule that will require a Section 610 review.

EPA tracks rules that may be subject to section 610 reviews through the use of an electronic section 610 Tracking Report in EPA's Rule and Policy Information and Development System (RAPIDS). The Report consists of three categories, as follows:

I. Rules for which EPA has announced section 610 reviews, either completed or under way. Rules are listed in this category once an entry has been published in the semi-annual Regulatory Agenda announcing the section 610 review. This category tracks the rule title, date of final publication, initiation and completion dates of the section 610 review and the review decision,

II. Rules that do not require section 610 reviews, and

III. Rules that will need a section 610 review within ten years of promulgation. Rules are listed in this category if the rule is subject to notice-and-comment and promulgated without being certified. This category tracks the rule title, date of final publication, and review due date.

EPA's Office of Policy, Economics and Innovation (OPEI) monitors the rules tracked in

this database.

8.5 Scheduling Section 610 Reviews

The RFA requires that we **complete** the review by the tenth year anniversary date of final publication. You may undertake a review any time within ten years of publication of the original final rule. Conducting the review close to the ten-year anniversary, however, allows a more focused perspective on any changed impacts on small entities.

We will use the semi-annual Regulatory Agenda (published in the Federal Register) to provide public notice of the review. You must complete the review within one year of that public notice. The RFA does not require that you initiate or complete any regulatory action to amend or rescind the rule within that year, if it is determined that such action is necessary.

8.6 Must We Review a Rule More than Once?

There is no requirement to review a rule more than once. After you complete a review, and decide to rescind the rule, amend the rule or leave the rule unchanged, that completes the obligation under section 610.

8.7 What If a Rule has been Subsequently Amended?

The original, final rule as published in the Federal Register is the basis for section 610 review. In some cases, a subsequent amendment may eliminate impacts on small entities so that there is no longer a SISNOSE. Under these circumstances, when the original rule comes up for its section 610 review, you must be able to adequately document the elimination of the SISNOSE, and publish this finding in the "Completed Actions" section of the semi-annual Regulatory Agenda.

If an amendment reduces, but does not eliminate, a SISNOSE, then you should evaluate the need for a section 610 review based on current guidelines for SISNOSE thresholds (see Chapter 2).

If a subsequent amendment has created, rather than eliminated, a SISNOSE **based on current guidelines for SISNOSE thresholds,** then the rule must be reviewed within ten years of the date of the published amendment.

8.8 Do We Review a Rule or a CFR Part or Section?

The RFA explicitly stipulates a review by rule, rather than by sections or parts in the Code of Federal Regulations (CFR). While we recognize that rules subsequently become amalgamated into the CFR and may lose their individual identity, the final rule as published in the Federal Register remains the basis for section 610 reviews. You will need to decide on a case-by-case basis if the rule can be sufficiently separated from its context in the CFR to do an adequate review. You may decide to include additional regulatory material to conduct a coherent and meaningful review.

8.9 Conducting the Review

Once you have determined that your rule:

(1) is subject to the RFA, and
(2) was not certified, either at the time of promulgation or when amended, you are ready to conduct the section 610 review.[51] Bear in mind that section 610 does not require that you initiate a regulatory action to rescind or amend a rule within the one-year review period. It only requires that you complete the review in that time frame, publish your determination, and explain the basis for your decision.

To conduct a section 610 review follow the three steps described below:

1. Before you begin your review, develop an entry for each rule for the "Prerule" section of the Unified Agenda (also known as the semi-annual Regulatory Agenda), indicating that you will be conducting this review over the next year, and requesting public comment. You should also indicate in the abstract the length of the public comment period. Normally, this is 60 to 90 days. Contact your Regulatory Steering Committee representative for specific information about the semi-annual Regulatory Agenda exercise.

   The "Prerule" entry must:

   - state your intent to review the rule under section 610;
   - give a brief description of the rule;
   - explain the need for and legal basis of the rule; and
   - invite public comment on the factors listed below.

2. You must specifically address and ask the public for comment on the following factors when performing a review under section 610:

   - the continued need for the rule;
   - the nature of complaints or comments received concerning the rule from the public since promulgation;
   - the complexity of the rule (i.e., can you make the rule less complex so that small entities can comply more easily?);
   - 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
   - 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. (Evaluate these factors to the extent that they affect small

[51] Over time, EPA's definition of SISNOSE has evolved to meet new statutory and administrative requirements, and therefore the threshold for performing a regulatory flexibility analysis has changed as well. If your section 610 rule does not meet **current** guidelines for SISNOSE, you should take this into account when conducting the section 610 review, e.g., if a final regulatory flexibility analysis was performed under a more expansive reading of SISNOSE, you should note this in a justification for letting a rule stand. For guidance on SISNOSE, see Chapter 2.

entities, not the entire regulated universe.)

See Section 8.13 for an example of a "Prerule" section 610 entry in the semi-annual Regulatory Agenda.

3. You must explicitly consider **all** of these factors in your review, and document the results, either positive or negative. The results of the review - either to rescind, amend or leave the rule unchanged - are published in the "Completed Actions"section of the semi-annual Regulatory Agenda and are placed in your program office docket.

8.10 Does the Line-by-line Review also Satisfy Section 610 Requirements?

A line-by-line reinvention review qualifies as a section 610 review if you address the required factors stated above, request public comments, and adequately document the review. Contact your Regulatory Steering Committee representative or OGC if you are not sure that the review meets the section 610 requirements. In most cases you will need to develop a separate "Prerule" entry for the section 610 portion of the line-by-line review, and proceed with an independent analysis.

8.11 Announcing the Results of the Review

The results of this review -- either to rescind, amend or leave the rule unchanged -- will be published in the "Completed Actions" section of the semi-annual Regulatory Agenda one year from the time it was identified in the "Prerule" section of the semi-annual Regulatory Agenda. You should use the "long form", i.e., the one that allows an abstract, so that you can explain your determinations. Supporting documents should be placed in the public docket. (See Section 8.14 for an example of a "Completed Action" entry in the semi-annual Regulatory Agenda.)

8.12 Follow-up to the Section 610 Review

You should follow any decision to amend or rescind the rule with an entry in the "Prerule" or "Proposed Rules" section of a subsequent semi-annual Regulatory Agenda

8.13 Example of "Prerule" Semi-annual Regulatory Agenda Entry

The following example is intended to be used as a guide, not a template.

To initiate a 610 Review, you should prepare a semi-annual Regulatory Agenda entry by completing an Action Initiation Form (AIF). Each office has different procedures for preparing and submitting their AIF's. Your Regulatory Steering Committee representative can tell you what the procedure is for your office. Regulatory Steering Committee members are listed in the "Contacts" section of the Action Development Process Library. The address is: http://intranet.epa.gov/adplibrary.

Title: ACCIDENTAL RELEASE PREVENTION REQUIREMENTS: RISK MANAGEMENT PROGRAMS UNDER THE CLEAN AIR ACT, SECTION 112(R)(7) (SECTION 610 REVIEW)
Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 7412 (r)
CFR Citation: 40 CFR 68
Legal Deadline: None
Abstract:

The Agency promulgated the Accidental Release Prevention Requirements on June 20, 1996 (61 FR 31668). The regulations apply to all stationary sources with processes that contain more than a threshold quantity of a regulated substance. Processes are divided into three categories based on the potential for offsite consequences associated with a worst-case accidental release; accident history; or compliance with the prevention requirements under OSHA's Process Safety Management (PSM). Processes that have no potential impact on the public in the case of an accidental release have minimal requirements. For other processes, sources must implement a risk management program that includes more detailed requirements for hazard assessment, prevention, and emergency response. Processes in industry categories with a history of accidental releases and processes already complying with OSHA's PSM are subject to prevention program requirements that are virtually identical to parallel elements of the OSHA standard. All other processes are subject to streamlined prevention requirements. All sources must prepare a risk management plan based on the risk management programs established at the source. The sources submit the plan to EPA. The first submission was on June 20, 1999. Some sources re-submitted their plans or revised their plans after the first submission. The second submission was due on June 20, 2004. There are approximately 15,000 sources subject to the accidental release prevention regulations. This new entry in the Regulatory Agenda announces that EPA will review this regulation pursuant to section 610 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 610). EPA solicits comments on the following factors: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public since promulgation; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rule, 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. In the Agency's view, there is a continued need for the rule because it calls on sources to reduce the probability and adverse consequences of accidental releases of substances that have the potential to cause immediate harm to public health and the environment, and stimulates dialogue between industry and the public to improve accident prevention and emergency response practices. The Agency has received few complaints about this rule from small businesses. The Agency has developed many guidance documents to help small entities comply with the rule. Efforts were made to minimize the burden and complexity of the rule by taking a tiered approach. In other words, entities with complex processes have to follow more rigorous requirements and those with simple processes follow only some of the requirements. EPA believes that there is no conflict or overlap between this rule and any other rule except for OSHA's PSM rule as indicated above. This is the first time the rule has been evaluated under the RFA section 610. EPA has established a public docket for this effort, Docket No. OAR-2005-0166 at http://www.epa.gov/edocket.

Timetable:

Action	Date
Begin Review	10/00/05
Comment Period End	01/00/06
End Review	04/00/06

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None

Additional Information: SAN No. 5018

Agency Contact: Sicy Jacob, Environmental Protection Agency, Solid Waste and Emergency Response, 5104A, Washington, DC 20004 Phone: 202 564-8019 Fax: 202 564-2625 Email: jacob.sicy@epa.govVanessa Rodriguez, Environmental Protection Agency, Solid Waste and Emergency Response, 5104A, Washington, DC 20460 Phone: 202 564-7913 Fax: 202 564-2625 Email: rodriquez.vanessa@epa.gov RIN: 2050-AG26

8.14 Example Entry for Completed Section 610 Review

The following example is intended to be used as a guide, not a template.

All of EPA's semi-annual Regulatory Agenda entries are submitted to OMB via EPA's Rule and Policy Information and Development System (RAPIDS). Your pre-rule entry announcing the review (Regulatory Agenda Review Form) is still in RAPIDS. Update your abstract to indicate the results of your review. Insert the date the review ended, and insert either "Rule will remain in effect without modification", or "New rulemaking started, see SAN # (insert SAN# of newly started rulemaking.) Each office has a different system for updating and submitting Agenda entries. Your Regulatory Steering Committee representative will give you appropriate instructions when it is time to prepare your semi-annual Regulatory Agenda entry.

Title: LEAD; REQUIREMENTS FOR LEAD-BASED PAINT ACTIVITIES IN TARGET HOUSING AND CHILD-OCCUPIED FACILITIES (Completion of a SECTION 610 REVIEW)

Priority: Info./Admin./Other
Legal Authority: TSCA 402 and 404; 15 USC 2682; 15 USC 2684 CFR
Citation: 40 CFR 745 subpart L; 40 CFR 745 subpart Q
Legal Deadline: None
Abstract: In August, 1996, the Environmental Protection Agency (EPA) promulgated regulations under section 402 of the Toxic Substances Control Act (TSCA) to ensure that individuals conducting lead-based paint activities in target housing and child-occupied facilities are properly trained and certified, that training programs providing instruction in such activities are accredited and that these activities are conducted according to reliable, effective and safe work practice standards. EPA also finalized a Federal regulation under section 404 of TSCA that allows States and Indian tribes to seek authorization to administer and enforce the regulations developed under section 402 for the training and certification of individuals conducting LBP activities and the accreditation of training programs for LBP activities in 1996 (August 29, 1996, 61 FR 45778). EPA performed an analysis of the potential impacts on small entities and determined that this action is likely to have a modest adverse economic impact on a substantial number of small entities. The TSCA section 404 regulations became effective August 29, 1998. The final rule then provided for an additional phase- in period for the requirements for training program accreditation, individual and firm certification, and work practice standards. Regulations for accreditation of training programs became effective on March 1, 1999. Regulations for certification of individuals and firms became fully effective on March 1, 2000. EPA is reviewing the 1996 regulation pursuant to section 610 of the Regulatory Flexibility Act (5 USC 610). The purpose of this review is to determine whether the rule should be continued without change, or should be amended or rescinded, to minimize economic impacts on small entities while still complying with the provisions of the Toxic Substances Control Act (TSCA).

EPA has already solicited comment on the continued need for the rule; the complexity of the rule; the extent to which it overlaps, duplicates, or conflicts with other Federal, State, or local government rules; and the degree to which technology, economic conditions or other relevant factors have changed since the rule was promulgated. No comments were received, and EPA has concluded that the rule needs no revisions at this time to minimize impacts on small entities. See EPA Docket ID number OPPT-2003-0015 at www.epa.gov/edocket.

Timetable:

Action	Date	FR Cite
Final Action 1	08/29/96	61 FR 45778
Begin Review	05/27/03	68 FR 30942
Comment Period End	12/22/03	68 FR 73 543
End Review	12/13/04	69 FR 73889

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Additional Information: SAN No. 4788, EDocket No. OPPT-2003-0015;
Agency Contact: Cindy Wheeler, Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, 7404T, Washington, DC 20460 Phone: 202-566-0484 Fax: 202 566-0470 Email: wheeler.cindy@epamail.epa.gov Julie Simpson, Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, 7404T, Washington, DC 20460 Phone: 202-566-1980 Fax: 202 566-0471
Email: simpson.julie@epamail.epa.gov
RIN: 2070-AD65

8.15 Section 610 Judicial Review

The 1996 SBREFA amendments to the RFA gave small entities adversely affected by a rule the right to seek judicial review of our compliance with the requirements of section 610. A reviewing court has wide discretion in deciding what the appropriate remedy should be for an Agency's failure to comply with section 610, including remanding the rule or deferring enforcement of the rule against small entities, unless the court finds that continued enforcement of the rule is in the public's interest.

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Environmental Protection Agency
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