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Advocacy: the voice of small business in government

A Guide for Government Agencies

How to Comply with the Regulatory Flexibility Act

Implementing the President's Small Business Agenda and Executive Order 13272

June 2010

FOREWORD

Economic freedom is the foundation for individual success and prosperity. This freedom is evident in the entrepreneurial small business sector, which creates most of the new jobs and a large share of the innovations in the American economy. When government takes small businesses into consideration in developing regulations, it saves time and money for the nation's most productive sector.

Executive Order 13272, signed August 13, 2002, gave federal agencies new direction in their efforts to assess the impact of their proposed rulemakings on small businesses and other small organizations under the Regulatory Flexibility Act (RFA). It also directed the Small Business Administration's Office of Advocacy to provide agencies with information on how to comply with the President's directive.

This compliance guide, prepared with input from regulatory agencies, is designed to be used by agency rule writers and policy analysts as a step-by-step manual for complying with the RFA. A careful review of the requirements is recommended before policy analysts begin to draft regulations, and then again at each stage of the process.

The Office of Advocacy continues to provide training to agency personnel in RFA compliance and has worked with many agencies since the executive order was signed. Advocacy welcomes additional opportunities to assist in new phases of training.

Thanks to all who contributed by reviewing and commenting on this guide. Further suggestions for improvements are welcome. For more information about the RFA and E.O. 13272, visit the Advocacy website at www.sba.gov/advo, or call us at (202) 205-6533.

To those charged to carry out the nation's regulatory flexibility requirements, the Office of Advocacy offers its strong support and encouragement. You have a crucial role in keeping the nation on track for sustained economic growth by ensuring the continued strength of the resilient small business sector.

ACKNOWLEDGMENTS

The Office of Advocacy's deep appreciation is extended to all reviewers of this guide, including those representing the Department of Labor, the Environmental Protection Agency, the Food and Drug Administration's Center for Food Safety and Applied Nutrition, the Office of Management and Budget's Office of Information and Regulatory Affairs, the House Committee on Small Business, and Advocacy staff.

As a tool for effective implementation of the Regulatory Flexibility Act, the guide helps create fairer and more effective regulation for all small entities, especially small businesses.

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INTRODUCTION

In June 1976, Congress created the Office of Advocacy, headed by a Chief Counsel appointed by the President from the private sector and confirmed by the Senate. Congress concluded that small businesses needed a voice in the councils of government—a voice that was both independent and credible. Congress specifically required the Office of Advocacy to measure the costs and impacts of regulation on small business. The Chief Counsel's mandate, therefore, is to be an independent voice for small business in policy deliberations—a unique mission in the federal government.

The Regulatory Flexibility Act (RFA),[1] enacted in September 1980, requires agencies to consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment. The RFA applies to a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

The RFA does not seek preferential treatment for small entities, require agencies to adopt regulations that impose the least burden on small entities, or mandate exemptions for small entities. Rather, it requires agencies to examine public policy issues using an analytical process that identifies, among other things, barriers to small business competitiveness and seeks a level playing field for small entities, not an unfair advantage.

The size of the business, government unit, or not-for-profit organization being regulated has a bearing on its ability to comply with federal regulations. For example, the costs of complying with a particular regulation—measured in staff time, recordkeeping, outside expertise, and other direct compliance costs—might be roughly the same for a company with sales of $10 million as for a company with sales of $1 million. In a larger business, however, the costs of compliance can be spread over a larger volume of production. For small entities, a burdensome regulation could affect the ability to set competitive prices, to devise innovations, or even to make a profit.[2] In some cases, a small business may be unable to stay in business because of the cost of a regulation. Simply stated, fixed costs have a greater impact on small entities because small entities have fewer options for recovering them. For firms employing fewer than 20 employees, the annual regulatory burden is nearly $6,975 per employee—almost 60 percent more than that of firms with more than 500 employees.[3] Without the necessary facts, it is possible for an agency to cause serious unintended or unforeseen adverse impacts on small businesses.

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[1] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (codified at 5 U.S.C. § 601).

[2] *See* Todd A. Morrison, *Economies of Scale in Regulatory Compliance: Evidence of the Differential Impacts of Regulation by Firm Size*, report no. PB85-178861, prepared by Jack Faucett Associates, Inc., for the U.S. Small Business Administration, Office of Advocacy (Springfield, Va.: National Technical Information Service, 1985).

[3] *See* W. Mark Crain and Thomas D. Hopkins, *The Impact of Regulatory Costs on Small Firms*, report no. PB2001-107067, prepared by Hopkins and Crain for the U.S. Small Business Administration, Office of Advocacy (Springfield, Va.: National Technical Information Service, 2001).

In essence, the RFA asks agencies to be aware of the economic structure of the entities they regulate and the effect their regulations may have on small entities. To this end, the RFA requires agencies to analyze the economic impact of proposed regulations when there is likely to be a significant economic impact on a substantial number of small entities, and to consider regulatory alternatives that will achieve the agency's goal while minimizing the burden on small entities. The concept underlying this analytical requirement is that agencies will revise their decisionmaking processes to take account of small entity concerns in the same manner that agency decisionmaking processes were modified subsequent to the enactment of the National Environmental Policy Act (NEPA).[4] The RFA then acts as a statutorily mandated analytical tool to further assist agencies in meeting the rational rulemaking standard set forth in the Administrative Procedure Act, just as NEPA was intended to rationalize decisions concerning major federal actions that would affect the environment.

The Small Business Regulatory Enforcement Fairness Act (SBREFA), enacted in March 1996,[5] amended the RFA and provided additional tools to aid small business in the fight for regulatory fairness. The most significant amendments made by SBREFA were:

- Judicial review of agency compliance with some of the RFA's provisions.
- Requirements for more detailed and substantive regulatory flexibility analyses.
- Expanded participation by small entities in the development of rules by the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA).

This compliance guide should be utilized by regulatory agencies as a tool for following the requirements of the Regulatory Flexibility Act. In preparing this guide, the Office of Advocacy has received input from regulatory agencies, the Office of Management and Budget, small business associations, and Congress. This new compliance guide also reflects Advocacy's 22 years of experience with the RFA and contains the spirit of interagency cooperation and small business' vital importance to the economy recognized in Executive Order 13272.[6] Advocacy hopes the guide will be a useful tool and welcomes comments on ways to improve its usefulness to regulatory agencies.

The guide includes how-to information on determining when the RFA applies to a proposed regulation, performing initial and final regulatory flexibility analyses, and meeting other RFA requirements, including periodic review of existing rules and small business compliance guides. Also included are a section on litigation so that agencies may learn how courts have ruled on RFA compliance, as well as examples, where available, of actual agency regulatory analyses. For more assistance, contact the Office of Advocacy at (202) 205-6533, or one of the Advocacy contacts listed in Appendix F.

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[4] *See* Associated Fisheries of Maine v. Daley, 127 F.3d 104, 114 (1st Cir. 1997) noting parallels between NEPA and the RFA.

[5] Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 857 (codified at 5 U.S.C. § 601 et seq.).

[6] Exec. Order No. 13,272, 67 Fed. Reg. 53,462 (Aug. 16, 2002). The Executive Order was signed by President George W. Bush on August 13, 2002. See Appendix E.

CHAPTER 1 WHERE DO WE BEGIN? FIRST STEPS OF RFA ANALYSIS

We begin by briefly examining the general purpose of the Regulatory Flexibility Act and its overall requirements. The Regulatory Flexibility Act requires agencies to consider the impact of their rules on small entities.[7] When the proposed regulation will impose a significant economic impact on a substantial number of small entities, the agency must evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities. Inherent in the RFA is a desire to remove barriers to competition and encourage agencies to consider ways of tailoring regulations to the size of the regulated entities.[8]

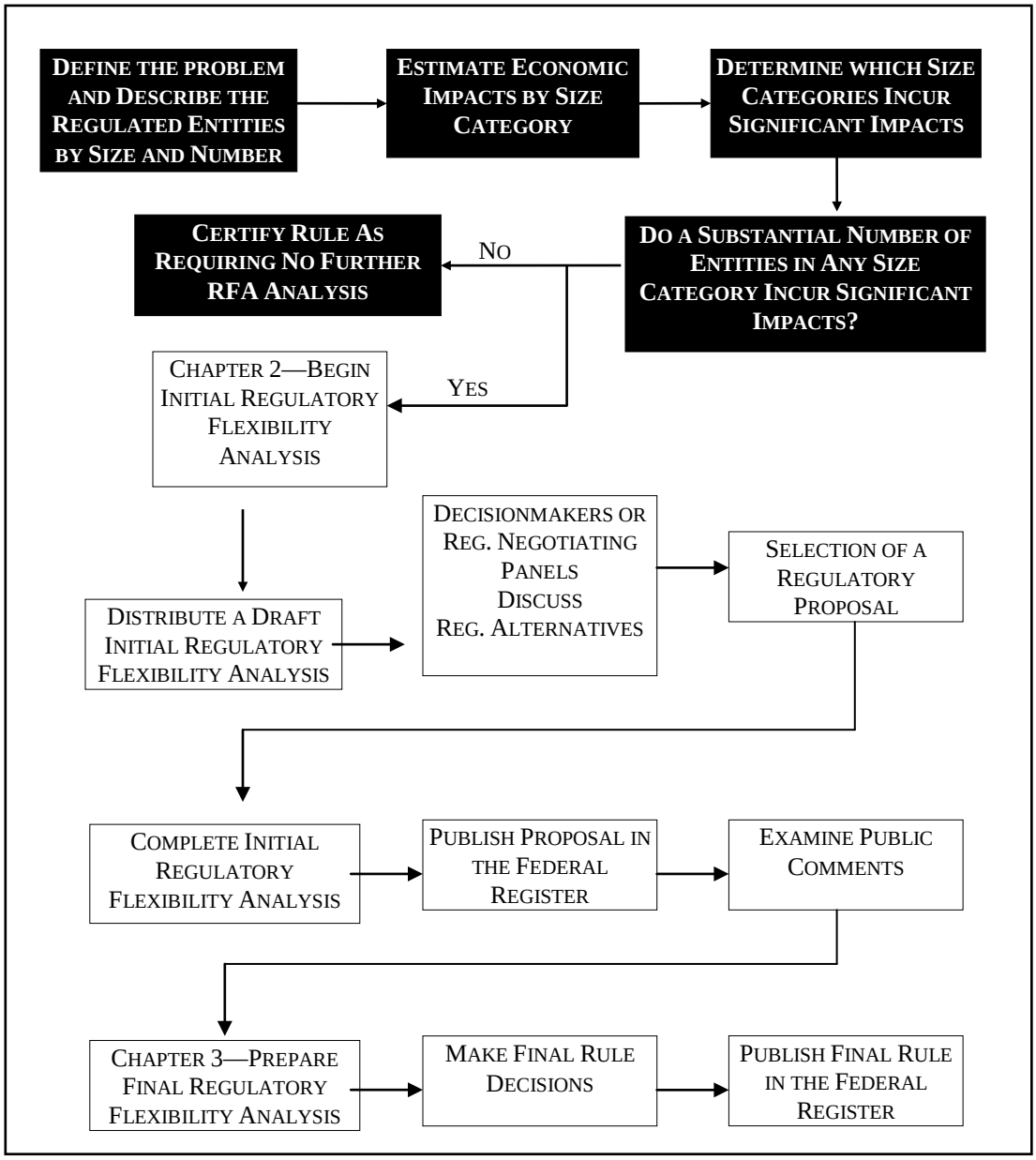
The RFA, like the National Environmental Policy Act, imposes analytical requirements on federal agencies. Both statutes require disclosure of effects and mechanisms to reduce adverse consequences and improve beneficial consequences.[9] The RFA does not require that agencies necessarily minimize a rule's impact on small entities if there are significant, legal, policy, factual, or other reasons for not minimizing impact. The RFA requires only that agencies determine, to the extent practicable, the rule's economic impact on small entities and to explore regulatory alternatives for reducing any significant economic impact on a substantial number of such entities. Once that process is finished, agencies must explain the reasons for their ultimate regulatory choices.

The goal of Congress in creating the RFA was to change the regulatory culture in agencies and mandate that they consider regulatory alternatives that achieve statutory purposes, while still minimizing the impacts on small entities. Regulatory flexibility analyses built into the regulatory development process at the earliest stages will help agency decisionmakers achieve regulatory goals with realistic, cost-effective, and less burdensome regulations.

The following chart shows an overall picture of the RFA decisionmaking process. This chapter focuses on the first steps, highlighted in the chart.

[7] See this chapter's section on p. 11 titled "What is the definition of a small entity?"
[8] *See generally*, FINDINGS AND PURPOSES, SEC. 2(a)–(b).
[9] Nothing in the RFA states that an economic impact must be adverse prior to performing an analysis.

The RFA decision process



Does the RFA apply?

One of the first decisions to make is whether the Regulatory Flexibility Act applies to the particular regulation. Application of the RFA is tied to rulemakings required to be published pursuant to the notice and comment requirements of the Administrative Procedure Act (APA) or some other statute. After having determined the scope of the problem and the potential entities affected by the rule under consideration, the agency must decide whether the RFA applies to its decision. This requires the agency to ascertain whether the regulation must be issued pursuant to notice and comment by the APA or some other statute or whether one of the exemptions to notice and comment rulemaking in the APA applies and therefore the RFA does not apply.

Relevance of the Administrative Procedure Act

The RFA applies to any rule subject to notice and comment rulemaking under section 553(b) of the Administrative Procedure Act (APA)[10] or any other law. This includes any rule of general applicability governing federal grants to state and local governments, for which agency procedures provide opportunity for notice and comment. For instance, some agencies, such as the Rural Utilities Service, have their own administrative rules that require notice and comment even though the agency's rules may be exempt from the APA notice and comment requirement.

The APA and RFA exemptions

The RFA requires analysis of a proposed regulation only where notice and comment rulemaking is required. Rules are exempt from APA notice and comment requirements, and therefore from the RFA requirements, when any of the following is involved: (1) a military or foreign affairs function of the United States, or (2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.[11] In addition, except where notice or hearing is required by statute, the APA does not apply (1) to interpretative rules, general statements of policy, or rules of agency organization, procedure or practice; or (2) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.[12] Under the circumstances described above, the RFA would not apply.

Interpretative rules generally interpret the intent expressed by Congress. The easiest type of interpretative rule to recognize is one in which an agency does not insert its own judgments or interpretations in implementing a rule, and simply regurgitates statutory language. One legal treatise on the subject says that interpretative rules are any rules that

[10] 5 U.S.C § 553(b).
[11] *Id* .at § 553(a). There are statutes, such as the Competition in Contracting Act, the Federal Acquisition Streamlining Act, and the Federal Acquisition Reform Act, that mandate that changes to contracting rules be issued pursuant to notice and comment. These acts represent some other statute requiring notice and comment rulemaking.
[12] *Id.* at § 553(b)(A).

an agency issues without exercising delegated legislative power to make law through rules.[13] The treatise goes on to state that the difference between legislative and interpretative rulemaking is the weight courts give the agency decisions on review.[14]

In the case of legislative rules, agencies are given the authority to establish requirements not specifically mentioned in the authorizing statute that may be the basis for a rule. An example of this would be setting an ambient air quality standard or regulating in the public interest as set out in the Communications Act of 1934. See *Whitman v. American Trucking Associations* for a discussion of what constitutes a standard governing delegation of legislative authority by Congress to the executive branch.[15]

The RFA presents its own exemptions as well. Section 601(2) states that the RFA does not apply to rules of particular applicability relating to rates, wages, corporate or financial structures, or reorganizations thereof, prices, facilities, appliances, services or allowances.[16]

RFA now applies to certain Internal Revenue Service interpretative rules

The Small Business Regulatory Enforcement Fairness Act amended the RFA to bring certain interpretative rulemakings of the Internal Revenue Service (IRS) within the scope of the RFA. The law now applies to those IRS rules published in the *Federal Register* (that would normally be exempt from the RFA as interpretative rules) that impose a "collection of information" requirement on small entities.[17] Congress took care to define the term "collection of information" to be identical to the term used in the Paperwork Reduction Act, which means that a collection of information includes any reporting or recordkeeping requirement for more than nine people.[18]

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[13] K. Davis, Administrative Law Treatise, § 7:8 (1958).
[14] Davis at §§ 7:8-7:13.
[15] American Trucking Ass'ns v. EPA, 175 F.3d 1027, 1044 (D.C. Cir. 1999); Whitman v. American Trucking Ass'ns, 531 I/S/ 457 (2001).
[16] 5 U.S.C. § 601(2).
[17] *Id.* at § 601(b)(1)(a).
[18] *Id.* at § 601(7).

> (7) The term "collection of information"
>
> a) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either—
>
> (i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons, other than agencies, instrumentalities, or employees of the United States; or
>
> (ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes; and
>
> (8) The term "record-keeping requirement" means a requirement imposed by an agency on persons to maintain specified records.

Executive orders and interagency cooperation

Executive Order 12866 lays out additional analytical requirements for agencies when promulgating rules pursuant to delegations from Congress and the overarching mandate of the APA. The President's order establishes regulatory goals that can help agencies to which the executive order applies[19] understand the importance of conducting regulatory flexibility analyses. This goal may add context to discussions preceding an agency's certification decision.

> The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits should include both quantifiable measures (to the fullest extent possible) and qualitative measures of costs and benefits that are difficult to quantify, but essential to consider.[20]

In addition, Executive Order 12866 specifies 12 principles agencies should use when developing regulations. Of the 12, number 11 has particular relevance to the RFA certification decision[21] and the analysis needed to prepare a factual basis for that decision:

> (11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.[22]

Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," was signed by President George W. Bush on August 13, 2002, and requires federal agencies to publish how they will comply with the statutory mandates of the RFA.[23] The purpose of E.O. 13272 is to ensure that agencies work closely with Advocacy to address small business issues as early as possible in the regulatory process, particularly as they relate to disproportionate regulatory burden. The order sets out a series of responsibilities for both regulating agencies and the Office of Advocacy.

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[19] Exec. Order No. 12,866 does not apply to independent regulatory commissions such as the Federal Election Commission, the Federal Communications Commission, and the Securities and Exchange Commission.

[20] Exec. Order No. 12,866 § 1(a), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

[21] 5 U.S.C. § 605(b). The RFA permits an agency to certify that a proposed rule would not have a significant economic impact on a substantial number of small entities, if the preliminary (threshold) analysis supports such a decision.

[22] Exec. Order No. 12,866 § 1(b). Note that Exec. Order No. 12,866 applies to individuals and requires that regulations impose the least burden on society—standards that differ from those of the RFA. However, the fact that application of the order must be "consistent with" maintaining an agency's regulatory objectives makes the order somewhat parallel to the RFA.

[23] Exec. Order No. 13,272, 67 Fed. Reg. 53,461 (Aug. 13, 2002).

- Agencies will establish policies on how to measure their impact on small entities and will work with Advocacy to establish those procedures.
- The Office of Advocacy is instructed to train agencies on how to properly account for small entity impact when agencies draft regulations and to continue to work with agencies from time to time as required.
- Agencies are to submit proposed rules with significant small entity effects to the Office of Advocacy prior to publication and are required to consider the Office of Advocacy's comments on the rule.
- The Office of Advocacy is required to report annually to the Office of Management and Budget (OMB) on whether agencies are complying with this executive order.

Both executive orders reinforce executive intent that agencies give serious attention to impacts on small entities and develop a comprehensive set of regulatory alternatives to reduce the regulatory burden on small entities.

How to certify: The RFA threshold analysis

After an agency begins regulatory development and determines that the RFA applies, it must decide whether to conduct a full regulatory flexibility analysis or to certify that the proposed rule will not "have a significant economic impact on a substantial number of small entities."[24] The record an agency builds to support a decision to certify is subject to judicial review.[25]

In order to certify a rule under the RFA, an agency should be able to answer the following types of questions:

- Which small entities will be affected?
- Have adequate economic data been obtained?
- What are the economic implications/impacts of the proposal or do the data reveal a significant economic impact on a substantial number of small entities?

If, after conducting an analysis for a proposed or final rule, an agency determines that a rule will not have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify. The certification must include a statement providing the *factual* basis for this determination, and the certification may be published in the *Federal Register* at the time the proposed or final rule is published for public comment.[26] A certification must include, at a minimum, a

[24] 5 U.S.C. § 605(b). The decision to certify a rule parallels the finding of no significant impact under NEPA. As with that NEPA determination, the decision to certify, because it is subject to judicial review, should be based on a sound threshold analysis similar to the environmental assessment mandated in Council on Environmental Quality regulations to support a finding of no significant impact or laying the groundwork for a full environmental impact statement.
[25] *Id*. at § 611(a).
[26] There are circumstances where it may be appropriate to publish an IRFA for the proposed rule, and based on comments received, publish a certification for the first time in the final rule. See Chapter 3 of this guide for a detailed discussion of final regulatory flexibility analyses.

description of the affected entities and the impacts that clearly justify the "no impact" certification. The agency's reasoning and assumptions underlying its certification should be explicit in order to obtain public comment and thus receive information that would be used to re-evaluate the certification.

Clearly, an agency should identify the scope of the problem and the impact of the solution on affected entities before moving forward with a regulatory proposal. At times, despite a good-faith effort on the part of an agency to obtain data, an agency may still be uncertain about whether to certify. In those instances, an advance notice of proposed rulemaking (ANPRM) may be necessary to solicit data. As a final recourse, the agency should err on the side of caution and perform an initial regulatory flexibility analysis (IRFA) with the available data and information, and solicit comments from small entities regarding impact. [27] Then, if appropriate, the agency can certify the final rule. If an agency lacks sufficient information to make a certification decision, the agency should engage in reasonable outreach efforts.[28]

Organizing the threshold report

Certification analysis discussed in this chapter does not require the depth of analysis necessary in an initial regulatory flexibility analysis,[29] as discussed in Chapter 2 of this guide. Nevertheless, this "threshold" analysis can offer important insights into the nature of regulatory impacts. Although a study of alternatives is not required at this stage, it often leads to the skeleton of regulatory alternatives that can reduce or eliminate any disproportionate impacts on small entities. For this reason, Advocacy encourages certification analysis as early in the rule development process as possible.

Agency certifications of final rules are subject to judicial review[30] and courts evaluate them by determining whether the statement of basis and purpose accompanying the rule identifies a "factual basis" to support the certification.[31] A helpful threshold report will directly support the elements that must appear in the *Federal Register* Notice of Proposed Rulemaking preamble. The Office of Advocacy believes the threshold analysis should discuss the following items:[32]

1) Description of small entities affected

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[27] 5 U.S.C. § 605(b). The Office of Advocacy would expect this situation to be rare because agency efforts to develop the rule should include a reasonable effort to explore all the effects of the rule, including the effects on small entities. For more information on preparing an initial regulatory flexibility analysis, see Chapter 2.

[28] *Id.* at § 609. Outreach is important to obtain information required by the RFA, to obtain relevant input from affected small entities. See Chapter 6 for a discussion of agency outreach to small entities.

[29] An initial regulatory flexibility analysis (IRFA) is a document containing the agency's data and analysis regarding the potential impact of the proposed rule. A detailed description of the requirements of an IRFA can be found in Chapter 2 of this guide.

[30] 5 U.S.C. § 611.

[31] *Id.* at § 605(b).

[32] For additional detail, see the certification checklist at the end of this chapter.

- A brief economic and technical statement on the regulated community, describing some of the following types of information:[33]
    a) The diversity in size of regulated entities
    b) Revenues in each size grouping
    c) Profitability in each size grouping

2) Economic impacts on small entities
- A fair, first estimate of expected cost impacts, or a reasonable basis for assuming costs would be *de minimis* or insignificant within all economic or size groupings of the "small" regulated community
- The rationale for the certification decision, based on the analysis presented

3) Significant economic impact criteria
- The criteria used to examine whether first-estimate costs are significant

4) Substantial number criteria
- The criteria used to examine whether the entities experiencing significant impacts constitute a substantial number of entities in any of the regulated size groupings

5) Description of assumptions and uncertainties
- The sources of data used in the economic and technical analysis[34]
- The degree of uncertainty in the cost estimates, when uncertainty is large

6) Certification statement

"Factual basis" requirement for certification

What is a "factual basis?" The Office of Advocacy interprets the "factual basis" requirement to mean that, at a minimum, a certification should contain a description of the number of affected entities and the size of the economic impacts and why either the number of entities or the size of the impacts justifies the certification.

The agency's reasoning and assumptions underlying its certification should be explicit in order to elicit public comment. Again, agency certifications in final rules are subject to

[33] When an agency does not have quantitative data to support its certification, the agency should explain why such data are not available and request comments.

[34] Section 607 of the RFA directs agencies to provide a "quantifiable or numerical description of the effects of the proposed rule or alternatives to the proposed rule" and allows a qualitative approach if "quantification is not practical or reliable." Thus, agencies are expected to make reasonable efforts to acquire quantitative or other information to support analysis of the rules under sections 603 and 604 of the RFA. Such a standard is not required for section 605 certifications, but some agencies use section 607 as a model for preparing certifications. With regard to certification analyses, EPA wisely advises its rulewriters to employ the same approach: use quantitative analysis unless the "information necessary to conduct a quantitative analysis is not reasonably available." *Revised Interim Guidance for EPA Rulewriters: Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act*, Regulatory Management Division, EPA Office of Policy, p. 20 (March 29, 1999). This guidance is currently under revision.

judicial review. Thus, certifications of "no significant economic impact on a substantial number of small entities" have major legal implications for agencies. Consequently, certifications that simply state that the agency has found that the proposed or final rule will not have a significant economic impact on a substantial number of small entities are not sufficient under section 605(b).

The "more than just a few" standard for determining if a rule will have an impact on a "substantial number of small entities" is a rigorous test for agencies to follow. However, the Office of Advocacy encourages a conservative approach.[35] In other words, if an agency has miscalculated the impacts of a regulation because its standard for determining "substantial number" was set too high, the certification may give rise to avoidable court challenges.[36]

Prior to the enactment of SBREFA amendments in 1996, the RFA required only that a certification be supported by a "succinct statement explaining the reasons for the certification,"[37] and since such statements were not subject to judicial review, even as part of the record on review, agencies could avoid substantive explanations by using boilerplate certifications. The amended version of the RFA now requires that certifications be supported by a "statement of factual basis." In amending the RFA, Congress intended that agencies should do more than provide boilerplate and unsubstantiated statements to support their RFA certifications. Courts will overturn an agency's final certification if it is not adequate.[38]

What is the definition of a small entity?

The definition of "small entity" is important because it is the starting point for determining the degree of impact a regulation will have on small entities. Three types of small entities are defined in the RFA: [39]

Small business. Section 601(3) of the RFA defines a "small business" as having the same meaning as "small business concern" under section 3 of the Small Business Act. This includes any firm that is "independently owned and operated" and is "not dominant in its field of operation."[40] The Small Business Administration (SBA) has developed size standards to carry out the purposes of the Small Business Act and those size standards can be found in 13 C.F.R., section 121.201. The Small Business Act prohibits an agency from adopting a different definition of small business when promulgating regulations to

[35] Five small firms in an industry with more than 1,000 small firms is not likely to be interpreted as a "substantial number"; on the other hand, the same five small firms in an industry with only 20 firms would be a substantial number. See the discussion of the definitions of "significant" and "substantial" later in this chapter.
[36] See Chapter 5 of this guide for information on what the courts have held in these types of cases.
[37] *See* Lehigh Valley Farmers, Inc., v. Block, 640 F. Supp. (E.D. Pa. 1986), *aff'd on other grounds*, 828 F.2d.
[38] *See* North Carolina Fisheries Ass'n v. Daley, 27 F. Supp. 2d 650 (E.D. Va. 1998).
[39] Appendix C lists data sources that may be helpful in drawing distinctions between large and small entities.
[40] 15 U.S.C. § 632.

carry out a delegation of authority from Congress unless the agency follows the procedures set forth in SBA's regulations.[41] In addition, an agency may feel that the classification used by the Administrator for a particular sector is inappropriate in doing the analysis required by the RFA. The agency is then authorized to use a different definition, solely for purposes of complying with the RFA, after consultation with the Chief Counsel. That consultation does not obviate the need for the agency to comply with section 3 of the Small Business Act should the agency be interested in promulgating a regulation that utilizes a different definition of small business than that developed by the Administrator.[42]

Small organization. Section 601(4) defines a small organization as any not-for-profit enterprise that is independently owned and operated and not dominant in its field (for example, private hospitals and educational institutions). Agencies may develop one or more alternative definitions of "small organization" for purposes of this chapter, provided that they: (1) give an opportunity for public comment and (2) publish the final definition in the *Federal Register*. However, an agency that decides a different definition is appropriate for purposes of complying with the RFA is required to follow the procedures set forth in section 601(4).

Small governmental jurisdiction. Section 601(5) defines small governmental jurisdictions as governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000. Agencies may develop one or more alternative definitions for this term provided that they: (1) give opportunity for public comment, (2) base definitions on factors such as low population density and limited revenues, and (3) publish final definitions in the *Federal Register*. The alternative definition developed under this section applies only to the agency's compliance with the RFA. The agency may develop different size standards for small governmental jurisdictions in the development of its regulations. .

Agency decisions under section 601 of the RFA are subject to judicial review. Thus, any agency size standard determination that differs from the SBA's size standard is subject to review.[43]

Changing a size standard

It is important to draw a distinction when it comes to determining appropriate size standards. If an agency chooses to change a size standard after a determination that SBA's size standard is inadequate, the agency must either consult with the Office of Advocacy or seek approval of SBA's Administrator, depending on the circumstances. As stated in section 601(3) of the RFA, "the term small business has the same meaning as

[41] 13 C.F.R. § 121.902(b).
[42] Northwest Mining Ass'n v. Babbitt, 5 F. Supp. 2d 9 (D.D.C. 1998).
[43] 5 U.S.C. § 611(a); see also Chapter 5 of this guide for a discussion of how the courts have handled this issue.

the term 'small business concern' under section 3 of the Small Business Act."[44] Section 3(a)(1) of the Small Business Act states that:

> a small business concern, including but not limited to enterprises that are engaged in the business of production of food and fiber, ranching and raising of livestock, aquaculture, and all other farming and agricultural related industries, shall be deemed to be one which is independently owned and operated and which is not dominant it its field of operation.[45]

Once this test is met, SBA's regulations further define small businesses by industry in terms of annual revenues or number of employees.[46]

For RFA analysis purposes, if an agency wants to use a different size standard, the agency can do so only after consultation with the Office of Advocacy and after an opportunity for public comment. In addition, that new size standard must be published in the *Federal Register*.

For RFA purposes, the same procedures are required for small organizations and small governmental jurisdictions. If an agency wants to use a different definition than those provided in sections 601(4) and 601(5) of the RFA, then consultation, public comment, and publication in the *Federal Register* are required.

On the other hand, if an agency seeks to change the definition of a small business for rulemaking purposes (i.e., for purposes of determining how to apply a regulation to a business of a certain size), the agency must use the procedures outlined in section 3(a)(2)(C)(i)-(ii) of the Small Business Act and SBA's regulations found in 13 CFR 121.902(b). Those procedures essentially outline the information an agency needs to submit in order for SBA's Administrator to approve a new size standard, as well as when in the rulemaking process an agency needs to obtain that approval.

Note, however, that section 3(a)(2)(C) indicates that an agency need not obtain SBA's approval of a different standard if it is specifically authorized by statute relevant to the rulemaking. For example, the Department of Labor cannot use the SBA definition of small business in developing the regulations for the Family and Medical Leave Act because that statute provides a specific definition of what constitutes a small business.

Certification using alternative definitions of "small business"

A certification of a rule that regulates business (rather than small organizations or small governmental jurisdictions) means that the agency is using the SBA's definition of small business, unless the rulemaking agency states otherwise.

If an agency intends to rely on a small business definition for its certification that differs from the definition detailed in section 601(3) of the RFA as amended, it must first consult

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[44] Small Business Act, Pub. L. No. 85-536, codified as amended, 15 U.S.C. § 631 et seq.
[45] *Id.*
[46] 13 CFR 121.201. *See http://www.sba.gov/size/.*

with the Office of Advocacy on an appropriate definition or size standard. In addition, the preamble to the rule must notify the public that it is using a different standard in order to provide an opportunity for comment. The agency must publish its proposed definition(s) in the *Federal Register.*

The following is an example of an acceptable certification statement indicating that a different size standard has been used by the agency to certify a rule:

> Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. §605 (b), the head of ***(name of agency or department)*** certifies that this rule will not have a significant economic impact on a substantial number of small entities ***(explain the factual basis for the certification).*** In making this determination, the agency ***(used or did not use)*** the SBA definition of small business found at 13 C.F.R. 121.201) ***(quote the SBA size standard used or insert a statement such as the following)***. Instead, after consultation with the Office of Advocacy, the small business definition used by the ***(name of the agency)*** for this certification is: ***(insert definition used and explain rationale for the alternative).*** Comments are solicited on the appropriateness of this size standard in certifying that this rule will not have a significant impact on a substantial number of small entities.

Assessing the impact on small entities

Determining a rule's impact on small entities is an important part of the rulemaking process. The RFA requires agencies to conduct sufficient analyses to measure and consider the regulatory impacts of the rule to determine whether there will be a significant economic impact on a substantial number of small entities. No single definition can apply to all rules, given the dynamics of the economy and changes that are constantly occurring in the structure of small-entity sectors.

Every rule is different. The level, scope, and complexity of analysis may vary significantly depending on the characteristics and composition of the industry or small-entity sectors to be regulated. This is why it is important that agencies make every effort to conduct a sufficient and meaningful analysis when promulgating rules. The preparation of the required analysis calls for due diligence, knowledge of the regulated small entity community, sound economic and technical analysis, and good professional judgment.[47] One of the first steps in the analytical process includes understanding the nature and economics of the industry/entities being regulated, and identifying how much each sector is contributing to the problem the agency is trying to address and mitigate. A goal of the entire APA/RFA process is to give the public a complete understanding of what the agency is doing. Small businesses cannot provide informed comments if the agency fails to identify the rule as one that will have a significant impact on a substantial number of small businesses. In turn, informed comments provide useful tools for the agency to construct the least burdensome, most effective regulations.

[47] See OMB's government-wide information guidelines, 67 Fed. Reg. 842 (Feb. 22, 2002). These guidelines were issued under authority contained in the Information Quality Law, Pub. L. 106-554.

Because almost every industrial category will have more small than large businesses,[48] determining the impact on small businesses plays a key role in compliance with the RFA. In turn, to the extent that the costs of compliance are sufficiently significant that some entities will be unable to comply, the agency's selected regulatory solution probably will not achieve its statutory goal. Thus the analytical requirements, including the decision to certify, play a key role in the agency meeting its overall requirement of rational rulemaking, i.e., that the solution selected by the agency will meet the objectives the agency is attempting to meet.

As discussed in the previous section defining a small entity, it is important that agencies also examine the impact of their proposed regulations on small governmental jurisdictions. There are tens of thousands of these small jurisdictions throughout the United States that fall under the RFA's threshold of a population of less than 50,000. The growing demand for government services has far exceeded the financial capacities of many local governments, particularly the smallest ones, to provide those services while maintaining long-term fiscal viability. Costly federal regulations, both new and existing, often exacerbate an already difficult situation for many small communities. Like small businesses, small communities face economic challenges, lack the economies of scale, and in many cases have fewer technical and financial options available to them. All of these factors increase a small jurisdiction's cost to undertake and complete mandated regulatory initiatives.

Which segment of the economy or industry will be regulated?

To know whether a regulatory proposal affects a substantial number of small entities, the regulator must first know how many regulated entities exist and which are small. In examining this, the analyst best serves the process by identifying each group of regulated entities with similar economic and industrial characteristics. Each group constitutes its own universe of regulated small entities that the proposal may influence significantly. If the regulated community is segmented properly, each group will have similar economic characteristics, and an examination of a typical entity or use of the group's mean characteristics will normally allow very rapid economic analysis for the group. This approach allows identification of those groups covered by the RFA.

Congress enacted the Small Business Regulatory Enforcement Fairness Act to achieve "fundamental changes . . . needed in the regulatory and enforcement culture of Federal agencies to make agencies more responsive to small business . . . without compromising the statutory missions of the agencies."[49] Thus, to meet the basic SBREFA goal, analysts will routinely want to economically segment industrial sectors into several appropriate size categories smaller than the Small Business Act section 3 definition. Only by so doing will the analyst accurately identify and analyze those entities covered by the RFA.

[48] This does not mean that small businesses dominate that sector of the market; for example, in telecommunications, although there are many small businesses, four large regional telephone companies still dominate the market.
[49] SBREFA § 202(3).

Consider the following example of how the SBA definition of a small business may not adequately address the nuances that exist within the universe of affected small entities:

> SBA established a size standard for the drinking water supply industry at $5 million in revenues, equating approximately to a city serving 30,000 people. EPA has proposed an alternative definition—a small water supply would serve no more than 10,000 people. Such a system generates somewhat less than a million dollars in annual revenue. However, EPA does not stop by looking only at the supply serving 10,000 people. It also examines sub-populations of the water supply industry serving fewer than 100 people, 101-500 people, 501-3,300 and 3,300-10,000. Water supplies in the smallest size category generate revenues less than one-tenth that of those in the 10,000-25,000 size category. More significantly, 90 percent of regulated water supplies serve fewer than 500 people, and on average, water supplies in those two size categories have net losses, costs being spread to other municipal revenue streams. EPA typically examines each of these small water supply size categories and, in keeping with the Regulatory Flexibility Act, has proposed different "available treatment technologies" for each water supply size, reflecting the wide range in economic viability within the industry. Each of the size categories below the "small water supply" size cut-off stands as its own universe of economically similar regulated entities. EPA recognized the regulatory significance of this and incorporated it into its analysis.[50]

Agencies should identify and examine various economically similar small regulated entities so that they will have a baseline from which to determine whether a significant regulatory cost will have an impact on a substantial number of small entities. An understanding of the differences in economic impacts across the various regulated communities often generates different regulatory alternatives. When the agency is ready to prepare its IRFA, sound analysis implies that agencies look at the various subsectors of the regulated community, the differences among them, and additional sound regulatory alternatives that can achieve the statutory mission while mitigating unnecessary economic impacts on small entities.

How to categorize small entity sectors

The agency's first step in a threshold analysis consists of identifying the industry, governmental and nonprofit sectors they intend to regulate. In the past, many agencies used the Standard Industrial Classification (SIC) codes to categorize regulated businesses on an industry-by-industry basis. In 1999, the SIC system was replaced by the North American Industry Classification System (NAICS), which breaks down industry sectors in much greater detail.[51]

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[50] For a full discussion of this issue, see EPA's National Primary Drinking Water Regulations; Arsenic Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976, 6987 (Jan. 22, 2001).

[51] Effective January 1, 1997, the federal government, for statistical purposes, replaced the SIC system with NAICS. For purposes of small business size standards, SBA adopted the NAICS definitions for all industries effective October 1, 2000. Because NAICS is a new statistical system, there were changes to the descriptions of many industry structures in the shift from SIC to NAICS.

Using the NAICS classifications, SBA defines small businesses in terms of firm revenues or employees. Different criteria may be helpful to agencies in assessing the composition of a small entity sector. The IRS categorizes firm (corporation and partnership) size by assets. Industry associations apply some or all of these three criteria (revenues, employment, and/or assets) and often add to or replace them with their own technical criteria. In addition to SBA definitions, federal regulators may use any one or multiple criteria to identify their universes of small regulated entities.[52]

Definition of "significant" and "substantial"

The agency's second step in a threshold analysis is to determine whether there is a significant economic impact on a substantial number of small entities. The RFA does not define "significant" or "substantial." In the absence of statutory specificity, what is "significant" or "substantial" will vary depending on the problem that needs to be addressed, the rule's requirements, and the preliminary assessment of the rule's impact. The agency is in the best position to gauge the small entity impacts of its regulations.

Significance should not be viewed in absolute terms, but should be seen as relative to the size of the business, the size of the competitor's business, and the impact the regulation has on larger competitors. For example, a regulation may be significant solely because the disparity in impact on small entities may make it more difficult for them to compete in a particular sector of the economy than large businesses. This may relate to their ability to pass costs through to customers or to reduce the marginal cost of such a regulation to an insignificant element of their production functions.

One measure for determining economic impact is the percentage of revenue or percentage of profits affected. For example, if the cost of implementing a particular rule represents 3 percent of the profits in a particular sector of the economy and the profit margin in that industry is 2 percent of gross revenues (an economic structure that occurs in the food marketing industry, where profits are often less than 2 percent), the implementation of the proposal would drive many businesses out of business (all except the ones that beat a 3 percent profit margin). That would be a significant economic impact.

However, the economic impact does not have to completely erase profit margins to be significant. For example, the implementation of a rule might reduce the ability of the firm to make future capital investment, thereby severely harming its competitive ability, particularly against larger firms. This scenario may occur in the telecommunications industry, where a regulatory regime that harms the ability of small companies to invest in needed capital will not put them out of business immediately, but over time may make it impossible for them to compete against companies with significantly larger capitalizations. The impact of that rule would then be significant for smaller telecommunications companies.

[52] The SBA definitions here are found in § 3(a)(2) of the Small Business Act and are not the RFA definitions referenced above.

Other measures may be used; to illustrate, the impact could be significant if the cost of the proposed regulation (a) eliminates more than 10 percent of the businesses' profits; (b) exceeds 1 percent of the gross revenues of the entities in a particular sector or (c) exceeds 5 percent of the labor costs of the entities in the sector.

Some agencies have already developed criteria for determining whether a particular economic impact is significant and whether the proposed action will affect a substantial number of small entities. Standards must be flexible enough to work for the individual agency. The following examples are meant to be illustrative of different types of criteria that may be used. They are not meant to imply a standard, acceptable formula. Advocacy welcomes input from other agencies on their standards.

- The Department of Health and Human Services has determined that a rule is significant if it would reduce revenues or raise costs of any class of affected entities by more than 3 to 5 percent within five years. This approach may work well for an agency, depending upon the circumstances. It becomes complex, however, in the attempt to apply a simple rule fairly to varied industries and regulatory schemes. A 2 percent reduction in revenues in one industrial category would be significant if the industry's profits are only 3 percent of revenues. More than 60 percent of small businesses do not claim a profit and do not pay taxes; therefore, an agency would not be able to apply a profit-based criterion to these firms.

- The EPA has prepared extensive guidance for its rulewriters concerning "significant economic impact" and "substantial number." With respect to small businesses, the agency advises that the offices compare the annualized costs as a percentage of sales ("sales test") to examine significant economic effect. For the same purpose, it also discusses alternative uses of a cash flow test and a profits test.[53]

The absence of a particularized definition of either "significant" or "substantial" does not mean that Congress left the terms completely ambiguous or open to unreasonable interpretations. Thus, the Office of Advocacy relies on legislative history for general guidance in defining these terms.[54]

Legislative history of "significant economic impact." With regard to the term "significant economic impact," Congress said:

[53] *Revised Interim Guidance for EPA Rulewriters*.

[54] Admittedly, throughout this guide, references are made to "adverse" impacts and efforts to "mitigate" impacts. This, after all, is the primary concern of the law. Legislative history, however, makes it clear that Congress intended that regulatory flexibility analyses also address "beneficial" impacts. Therefore, an agency cannot certify a proposed rule if the economic impact will be significant but positive. If an agency so finds, it should conduct a regulatory flexibility analysis to determine if alternatives can enhance the economic benefits flowing to small entities. See discussion in this chapter on adverse versus beneficial impacts.

> The term 'significant economic impact' is, of necessity, not an exact standard. Because of the diversity of both the community of small entities and of rules themselves, any more precise definition is virtually impossible and may be counterproductive. Any more specific definition would require preliminary work to determine whether the regulatory analysis must be prepared.[55]

Congress also stated that,

> Agencies should not give a narrow reading to what constitutes a "significant economic impact"…a determination of significant economic effect is not limited to easily quantifiable costs.[56]

Congress has identified several examples of "significant impact": a rule that provides a strong disincentive to seek capital;[57] 175 staff hours per year for recordkeeping;[58] impacts greater than the $500 fine (in 1980 dollars) imposed for noncompliance;[59] new capital requirements beyond the reach of the entity;[60] and any impact less cost-efficient than another reasonable regulatory alternative.[61] Note that even below these thresholds, impacts may be significant. Other, more specific examples are contained in the House of Representatives Report on the RFA.[62]

Legislative history of "substantial number." To affect a substantial number, a proposed regulation must certainly have an impact on at least one small entity. At the other end of the range, legislative history would not require agencies "to find that an overwhelming percentage [more than half] of small [entities] would be affected" before requiring an IRFA.[63] Legislative history also says that the term "substantial" is intended to mean a substantial number of entities within a particular economic or other activity.[64] The intent of the RFA, therefore, was not to require that agencies find that a large number of the entire universe of small entities would be affected by a rule. Quantification of "substantial" may be industry- or rule-specific. However, it is very important that agencies use the broadest category, "more than just a few," when initially reviewing a

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[55] 126 Cong. Rec. S10,942 (Aug. 6, 1980).
[56] *Id.* at S10,940.
[57] *Id.* at S10,938.
[58] *Id.*
[59] 126 Cong. Rec. H24,578 (Sept. 8, 1980).
[60] *Id.* at H24,593.
[61] *Id.* at H24,595.
[62] "A gas station owner spent 600 hours last year filling out just his federal reporting forms. An Idaho businessman paid a $500 fine [in 1980 dollars] rather than fill out a federal form that was 63 feet long. A New Hampshire radio station paid $26.23 in postage to mail its license renewal back to Washington. A dairy plant licensed by 250 local governments, three states, and 20 agencies had 47 inspections in one month. A butcher had one federal agency tell him to put a grated floor in his shop one month and then the next month was told by another federal agency he could not have a grated floor. A company was forced out of the toy business because one of its main products was inadvertently placed on a federal ban list. An Oregon company with three small shops received federal forms weighing 45 pounds." 126 Cong. Rec. H8,467 (Sept. 8, 1980).
[63] 126 Cong. Rec. S10,941 and 10,942 (Aug. 8, 1980) (Section-by-Section Analysis of the Regulatory Flexibility Act).
[64] *Id.* at S10,938.

regulation before making the decision to certify or do an initial regulatory flexibility analysis. The goal at this stage of the process is to ensure that the broadest possible impacts are fully considered. The interpretation of the term "substantial number" is not likely to be five small firms in an industry with more than 1,000 small firms. On the other hand, it is important to recognize that five small firms in an industry with only 20 small firms would be a substantial number. Depending on the rule, the substantiality of the number of small businesses affected should be determined on an industry-specific basis and/or on the number of small businesses overall. For example, the Internal Revenue Service, when changing the tax deposit rules, would examine the entire universe of small businesses to see how many would be affected. On the other hand, a change by the Food and Drug Administration in the regulation of meat irradiators might affect only 15 firms, but that would be the entire industry.

Direct versus indirect impact

The courts have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates them.

The primary case on the issue of direct versus indirect impacts for RFA purposes is *Mid-Tex Electric Cooperative, Inc., v. FERC* (*Mid-Tex*).[65] In *Mid-Tex*, the Federal Energy Regulatory Commission (FERC) was proposing regulations affecting how generating utilities included construction work in progress in their rates. Generating utilities were large businesses, but their customers included numerous small entities, such as electric cooperatives. FERC authorized large electric utilities to pass these costs through to their transmitting and retail utility customers. This increased the cost to the transmitting utilities, which may or may not have been able (because of regulation by their rates commissions) to pass the costs on to their residential and business customers. These smaller utilities challenged the rule, asserting that the impact on them should have been considered. The court concluded that an agency may certify the rule pursuant to section 605(b) when it determines that the rule will not have a direct impact on small entities.[66]

The U.S. Court of Appeals for the District of Columbia applied the holding of the *Mid-Tex* case in *American Trucking Associations, Inc., v. EPA*[67] (hereafter *ATA*). In the *ATA* case, EPA established a primary national ambient air quality standard (NAAQS) for ozone and particulate matter. The basis of the EPA's certification was that the NAAQS regulated small entities indirectly through state implementation plans. The court found that since the states, not EPA, had the direct authority to impose the burden on small entities, EPA's regulation did not have a direct impact on small entities.

Although it is not required by the RFA, the Office of Advocacy believes that it is good public policy for the agency to perform a regulatory flexibility analysis even when the impacts of its regulation are indirect. In the case of the NAAQS standard at issue in *ATA*,

[65] Mid-Tex Elec. Coop v. FERC, 773 F.2d 327 (D.C. Cir. 1985).
[66] *Id.* at 342.
[67] American Trucking Ass'ns v. EPA, 175 F.3d 1027, 1044 (D.C. Cir. 1999), *aff'd in part and rev'd in part on other grounds,* Whitman v. American Trucking Ass'ns, 531 I/S/ 457 (2001).

EPA had to estimate the impacts of the proposed rules on small entities in order to comply with the mandate of E.O. 12866. Therefore, the agency could have examined alternatives that would have been less burdensome on small entities. If an agency can accomplish its statutory mission in a more cost-effective manner, the Office of Advocacy believes that it is good public policy to do so. The only way an agency can determine this is if it does not certify regulations that it knows will have a significant impact on small entities even if the small entities are regulated by a delegation of authority from the federal agency to some other governing body.[68]

Adverse versus beneficial impact

Congress considered the term "significant" to be neutral with respect to whether the impact is beneficial or harmful to small businesses. Therefore, agencies need to consider both beneficial and adverse impacts in an analysis. The RFA legislative history has explicit insights into congressional intent with respect to beneficial impacts:

> Agencies may undertake initiatives which would directly benefit such small entities. Thus, the term 'significant economic impact' is neutral with respect to whether such impact is beneficial or adverse. The statute is designed not only to avoid harm to small entities but also to promote the growth and well-being of such entities.[69]

Moreover, early drafts of the RFA used the term "significant adverse" impact, but the final bill used only the term "significant impact."[70]

Courts have applied definitions for "significant impact" in cases involving other statutes. For example, in a case involving the National Environmental Policy Act (NEPA), *Friends of Fiery Gizzard v. Farmers Home Administration,*[71] the court held that a full environmental impact statement (EIS) does not need to be prepared if the only impact of the project will be beneficial. However, the court acknowledged that when both negative and beneficial effects are present, an EIS must be prepared even if the agency feels that the beneficial effects outweigh the negative ones.[72] (This case does not say that beneficial impacts should not be considered for the preliminary assessment, nor does it say that beneficial impacts are never a factor.) Earlier cases interpreting NEPA held that beneficial impacts should be a consideration in the rulemaking process.[73]

Several agencies have taken issue with the Office of Advocacy's interpretation of significant economic impact. However, the Office of Advocacy believes that its

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[68] See Chapter 5 of this guide for a more detailed discussion of the direct versus indirect impact issue.
[69] 126 Cong. Rec. H8,468 (daily ed. Sept. 8, 1980).
[70] See an early draft of the RFA, S2147, 1st Sess. (1979).
[71] Friends of Fiery Gizzard v. Farmers Home Admin., 61 F.3d 501, 505 (6th Cir. 1995).
[72] *Id.* at 505.
[73] *See* Hiram Clarke Civic Club v. Lynn, 476 F.2d 421, 426-27 (5th Cir. 1973) (Considering only negative impacts "raises serious questions about the adequacy of the investigatory basis underlying the HUD decision not to file an EIS."); Environmental Defense Fund v. Marsh, 651 F.2d 983, 993 (5th Cir. 1981), stating "[A] beneficial impact must nevertheless be discussed in an EIS, so long as it's significant. NEPA is concerned with all significant environmental effects, not merely adverse ones."

interpretation is consistent with the legislative history and overall purposes of the RFA. The Office of Advocacy does not dispute that the RFA intends for agencies to "minimize the significant economic impact."[74] However, the Office of Advocacy's interpretation does not necessarily mean that agencies should minimize beneficial impacts—that certainly would be contrary to the purposes of the RFA. Instead, Advocacy believes that agencies can minimize the adverse impact by including beneficial impacts in the analysis. It is possible to do this with minimal effort and without necessarily triggering the need for an IRFA. Moreover, analyzing beneficial impacts lends credibility to the alternatives selected by the agency.

Once the certification decision is made, the agency must notify the Office of Advocacy and publish its certification in the *Federal Register*. It is good regulatory practice to get the notice to Advocacy as soon as possible. It has been useful to the agency to share a draft certification statement with Advocacy for confidential feedback on the adequacy of the statement. At a minimum, the notification should come at the same time as publication. Publication of a proposal alone can work for most certified regulations, but there will always be those proposals for which solid community comments in advance can be vitally important (e.g., through an advance notice of proposed rulemaking).

What adequate and inadequate certifications look like

Refer to the certification checklist at the end of this chapter for a review of the elements of a certification that meets all requirements.

An example of an adequate certification

The following example of an adequate certification by the U.S. Small Business Administration is from the proposed rule on Small Business Investment Companies.

> When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to "prepare and make available for public comment an initial regulatory flexibility analysis" which will "describe the impact of the proposed rule on small entities." (5 U.S.C. §. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.
>
> This proposed rule directly affects all SBICs, of which there are currently 432. SBA estimates that approximately 75 percent of these SBICs are small entities. Therefore, SBA has determined that this proposed rule will have an impact on a substantial number of small entities.
>
> However, SBA has determined that the impact on entities affected by the proposed rule will not be significant. The effect of the proposed rule will be to allow SBICs the flexibility to choose the optimal structure for their investments without having to notify or seek approval from SBA. SBA expects the impact of the proposed rule will be a reduction in the paperwork burden for SBICs. SBA asserts that the economic impact of

[74] 5 U.S.C. § 601, Congressional Findings and Declaration of Purpose.

> the reduction in paperwork, if any, will be minimal and entirely beneficial to small SBICs. Accordingly, the Administrator of the SBA hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. SBA invites comment from members of the public who believe there will be a significant impact either on SBICs, or on companies that receive funding from SBICs.[75]

Examples of inadequate certifications

Following are three examples of inadequate certifications that were effectively challenged and refuted through formal comments to the agency or through the courts.[76]

Shark Protection. *Southern Offshore Fishing Association v. Daley*[77] offers a landmark legal decision recognizing the failure of an agency to adequately examine the market to determine whether there was a significant impact on a substantial number of small entities. On December 20, 1996, the National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA) published the proposed rule for the Atlantic Shark Fisheries: Quotas, Bag Limits, Prohibitions, and Requirements.[78] While NMFS did not have a sufficient basis for certification of this particular rule, it is not an indication of an overall problem with NMFS' RFA compliance. The proposed rule, among other things, reduced the commercial quotas for sharks by 50 percent. NMFS prepared a certification in lieu of an IRFA for the proposal. As the basis for the certification NMFS stated, in part:

> Reducing the commercial quota is not expected to have a significant impact on a substantial number of small entities primarily because of the large degree of diversification in fishing operations that exist in the fleet and the already short shark fishing season, as outlined in the Regulatory Impact Review.

Advocacy submitted comments asserting that the certification was inappropriate. In its comments, Advocacy pointed out that NMFS' criteria for assessing regulatory impact indicated that the proposal would have a significant economic impact on a substantial number of small entities.[79] NMFS' regulatory impact review stated that the majority of the participants in the fishing industry are small businesses and that there were 326 fisherman, 134 of which qualified for direct permits in the shark fishery. Approximately 41 percent of the shark fishery consisted of fishermen who only fished for sharks. The

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[75] 67 Fed. Reg. 35,055, at 35,056 (May 17, 2002). Note that although this certification addressed beneficial impacts, the agency acknowledged that even those impacts would be minimal and therefore correctly certified the rule.

[76] For another example of an improper certification, see Chapter 5 under the discussion of North Carolina Fisheries v. Daley.

[77] Southern Offshore Fishing Ass'n v. Daley, 995 F. Supp. 1411 (M.S. Fla. 1998).

[78] 61 Fed. Reg. 67,295.

[79] At that time, NMFS criteria provided that a rule had a significant impact on a substantial number of small entities if 20 percent of those engaged in the fishery had either a reduction in gross revenues by more than 5 percent, an increase in total costs of production by more than 5 percent, or a 10 percent increase in compliance costs; or if 2 percent of small business entities were forced to cease business operations. NMFS no longer uses these criteria. Advocacy was pleased with NMFS's decision to abandon these criteria and institute new guidelines for determining economic impact on the fishing industry.

remaining fishermen were pelagic longline fishermen that also primarily fished for tuna and swordfish. Advocacy, therefore, concluded that the rule would have an impact on a substantial number of small entities.

In terms of significant economic impact, the Office of Advocacy argued that it was logical to infer that a 50 percent reduction in catch would result in a loss in revenue of at least 5 percent. The Office of Advocacy supported its inference with information obtained from fishery associations. For example, the Directed Shark Fishery Association asserted that the majority of the 134 directed shark vessels would lose more than 20 percent of their income. Some were expected to lose as much as 50 percent of their income. Similarly, the North Carolina Fisheries Association contended that more than 20 percent of their full-time shark fishermen would go out of business as a result the proposed rulemaking. Accordingly, Advocacy concluded that by the criteria set forth by NMFS, the impact of the proposed rulemaking would be significant.

Advocacy also presented information that indicated that NMFS' assumption that the affected industries would diversify was not realistic. Advocacy asserted that the cost of converting to another fishery could range from $3,000 to $25,000 per boat, depending on the vessel. At that time, Advocacy's statistics indicated that the average gross revenue of a sole fisherman was $139,000 per year. Obtaining the equipment necessary to diversify could amount to approximately 18 percent of the business' gross revenues, which would also be a significant economic impact.

The members of the fishing industry successfully challenged NMFS' RFA compliance in *Southern Offshore Fishing Association v. Daley.*[80]

Telecommunications System Construction and Specifications. In another case, the Rural Utilities Service (RUS) certified that the final rule did not have a significant economic impact on a substantial number of small entities because small entities were not subject to any requirements that were not applied equally to large entities. While the rule did subject all entities to the same regulation, this justification ignored the disproportionate impact regulations often have on small businesses. In addition, RUS was depriving itself of the opportunity to learn about the rule's impact on small businesses. The Office of Advocacy filed the following comment with the RUS:

> Congress knew about the tendency of agencies to impose "one-size-fits-all" regulations and specifically rejected it. As Congress states, one-size-fits-all regulations are unnecessary and disproportionately burdensome to small businesses. This has been born out by a recent economic study commissioned by Advocacy.[81] This study showed that a firm with less than 20 employees shouldered regulatory costs 60 percent greater per employee than firms with more than 500 employees. Because of the disparity of the impact of governmental regulations, the agency cannot certify a rule on the basis that all entities have the same regulatory obligations.[82]

[80] *Southern Offshore Fishing.* This case is discussed in Chapter 5 of this guide.
[81] W. Mark Crain and Thomas D. Hopkins, *The Impact of Regulatory Costs on Small Firms* (2001).
[82] *See http://www.sba.gov/advo/laws/comments/rus02_0308.pdf.*

Offshore Oil and Gas Well Operations. One of the responsibilities of the Minerals Management Service (MMS) of the Department of the Interior is to ensure safety in offshore oil and gas well operations. While MMS did not have a sufficient basis for certification of this particular rule, it is not an indication of an overall problem with MMS' RFA compliance. In February 1998, MMS proposed a rule to update and clarify MMS regulations on postlease operations.[83] MMS prepared a certification in lieu of an IRFA for the proposal. As a basis for the certification, MMS stated:

> In general, a company needs large technical and financial resources and experience to safely conduct offshore activities. However, many of the leases and operators have less than 500 employees and are small businesses. It is likely that a State lessee applying for a right-of-use and easement on the OCS may be a small business. The costs associated with obtaining the benefit (right-of-use and easement) would be minimal. The application fee is estimated to be $2,350 per application and the rental is estimated to be $5,000.

Advocacy submitted comments[84] asserting that the certification was based on generalizations and unsubstantiated assumptions. In its comments, Advocacy identified databases and a means for a threshold analysis to help determine whether the agency should have certified, finding that the MMS had not provided sufficient information to document a rational basis for its decision to certify the rule. Advocacy stated:

> For the purposes of its analysis, the Office of Advocacy referred to SIC 1381, Drilling Oil and Gas Wells. While Advocacy acknowledges that SIC 1381 may include more than drilling on the outer Continental Shelf, Advocacy submits the numbers for the sake of argument in an effort to point out the inherent weaknesses in MMS's certification.
>
> According to this SIC data, there are a total of 1,380 firms that drill oil and gas wells. Of that 1,380 firms, 1,341 or 97% qualify as small firms in that they have fewer than 500 employees; 654 firms have 1-4 employees. The 654 firms constitute 47% of all firms large and small. Needless to say, 47% of an industry represents a substantial number of firms and suggests that certification of this rulemaking may be improper.
>
> In the 1-4 employee sector, the estimated receipts for a firm are $46,774, with an annual payroll of $32,187. The estimated cost of the proposed rule is $7,350 ($2,350 per application and $5,000 for the rental) per year. The $7,350 amounts to approximately 16% of the annual receipts for that sector. Although there are no hard rules for defining significant economic impact on a substantial number of small entities, a proposal that will impose on 47% of an industry an additional cost of 16% of annual receipts should at least raise a warning sign for a regulatory agency that the proposal could interfere with profits and company survival. It should also indicate to the agency that certification may be improper under the RFA.

[83] 63 Fed. Reg. 7,335.

[84] It should be noted that in the comments Advocacy also commended MMS for the improvement that it made in its certification process. Instead of an unsupported allegation of no significant economic impact on a substantial number of small entities, MMS did provide a basis for the certification. MMS has continued to work with Advocacy to improve its RFA compliance.

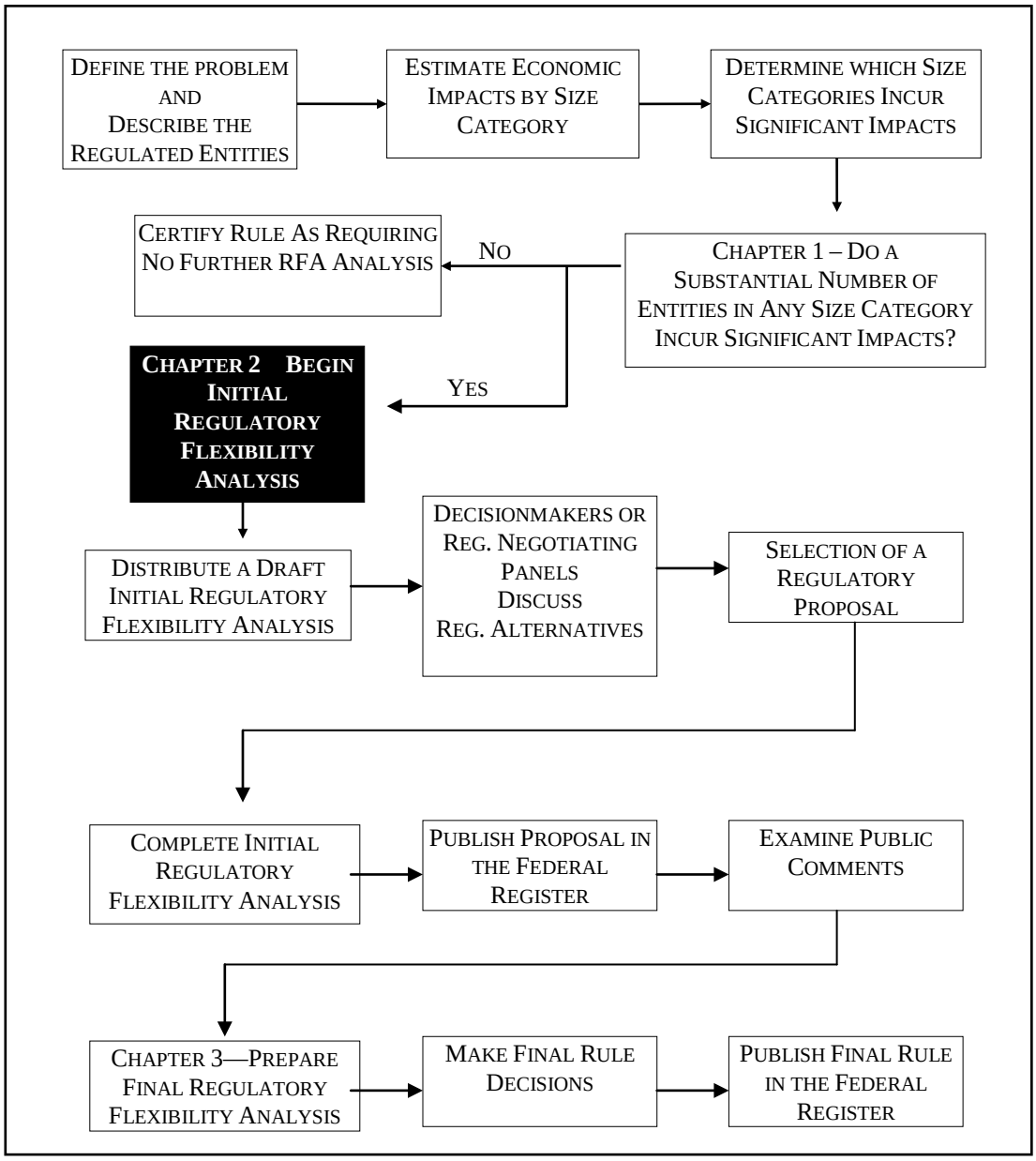
Certification checklist

1. Request for comment on proposed rules	Look for: √ A request for comment on the certification; and, √ A request for comment on the threshold economic analysis and its underlying assumptions.
2. Description and estimate of number of small entities to which the rule applies	Look for: √ The North American Industry Classification System (NAICS codes) categories for those entities subject to the regulation; √ A breakdown of each industry by several entity sizes, which should include the SBA size standard for each industry; √ Any alternative operational size definition used to tier requirements under the rule; √ For each size category in each industry, information on revenues, profit or other measures of economic sustainability.
3. Estimate of economic impacts on small entities	Look for: √ A set of tables, charts and discussion for a typical entity in each size category in each industry: √ Estimates of the cost impacts of the proposal; √ Estimates of the beneficial impacts of the proposal.
4. Criteria for "significant economic impacts"	The best analyses will not use a preset criterion, but instead will examine one or more of the following: √ Long-term insolvency, measured as regulatory costs significantly reducing typical profits for the size category; √ Short-term insolvency, measured as increased operating expenses or new debt larger than cash reserves and cash flow can support, causing nonmarginal firms to close; √ Disproportionality, based on whether regulations place small entities at a significant competitive disadvantage; √ Inefficiency based on whether the social costs imposed on small entities outweigh the social benefits of regulating them. Look for a cogent explanation underlying any conclusionary statements about preset "criteria."
5. Criteria for substantial number	Look for: √ The North American Industry Classification System (NAICS codes) of those regulated; √ A stratification of each industry by size, which should include the SBA size standard for each industry; √ Any alternative operational size definition used to tier requirements under the rule; √ Description of size categories demonstrating all entities within the category share similar economic characteristics; √ Whether a 'percentage of entities significantly affected' approach is used; √ Whether a 'minimum number' approach is used. (This is usually arbitrary and probably capricious); √ Justification of whatever criterion is used. Typically, if an industry is properly segmented, analysis of a typical entity within the segment will indicate whether most or few will be significantly affected, as all within the segment should have similar economic characteristics.

6. Examination of industry segments with significant economic impacts	Look for: √ An estimate of how many segments within an industry will experience significant impacts: if even one significant segment will, an IRFA is needed; √ An estimate of entities experiencing significant impacts. Other entities with similar economic characteristics should also be adversely impacted, and finding any adversely impacted tends to imply there is a segment that deserves special attention. The resulting IRFA should materially address the problems in that segment, recognizing the rest have few, if any impacts.
7 Disclosure of assumptions	Look for: √ A discussion on how sensitive underlying assumptions are to conclusions on whether there is no significant economic impact on a substantial number of small entities; √ A discussion on the uncertainty associated with the most significant underlying assumptions; √ A presentation on the range of potential findings, as reflects the underlying uncertainty in assumptions.
8. Certification statement by the head of the agency	Look for: √ A finding under 5 U.S.C. § 605, the Regulatory Flexibility Act, that “the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.”

CHAPTER 2 PREPARING A PROPOSED RULE: THE INITIAL REGULATORY FLEXIBILITY ANALYSIS

The RFA decision process



During the preparation of a proposed rule, an agency must prepare an initial regulatory flexibility analysis (IRFA) if it determines that a proposal may impose a significant economic impact on a substantial number of small entities.[85] (If the agency determines that the proposed rule does not have such an impact, it should certify the rule as discussed in Chapter 1 of this guide.)

The RFA requires agencies to publish the IRFA, or a summary thereof, in the *Federal Register* at the same time it publishes the proposed rulemaking.[86] The IRFA must include a discussion of each element required by section 603 of the RFA, and the agency must also send a copy of the IRFA to the Chief Counsel for Advocacy.[87] Executive Order 13272 requires agencies to notify Advocacy when the agency submits a draft proposed or final rule to the Office of Information and Regulatory Affairs (OIRA) under Executive Order 12866, or at a reasonable time prior to publication of the rule by the agency.[88] Moreover, the earlier a copy of the IRFA is provided to Advocacy, the more opportunity exists for constructive involvement and feedback to the agency. If an agency is preparing a series of closely related rules, it may, to avoid duplicative action, consider them one rule for the purposes of complying with the IRFA requirement.[89]

Issues to be addressed in the analysis

Section 603 of the RFA requires agencies to perform a detailed analysis of the potential impact of the proposed rule on small entities.[90] In order to perform this analysis, an agency must enumerate the objectives and goals of the rule, as well any additional reasons the agency is pursuing the rule.

The agency then must examine the costs and other economic implications for the industry sectors targeted by the rule.[91] Impacts include costs of compliance and economic implications that derive from additional compliance costs such as economic viability (including closure), competitiveness, productivity, and employment. The analysis should identify cost burdens for the industry sector and for the individual small entities affected. Costs might include engineering and hardware acquisition, maintenance and operation, employee skill and training, administrative practices (including recordkeeping and reporting), productivity, and promotion. The agency must also consider alternatives to the proposed regulation that would accomplish the agency's goals while not disproportionately burdening small businesses. As part of the discussion of the alternatives under section 603(c), it is recommended that the agency address, in less detail than in the proposal, the costs and other economic implications.

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[85] For a full discussion of "significant economic impact on a substantial number of small entities," and the requirements of a proper certification statement, see Chapter 1 of this guide.
[86] 5 U.S.C. § 603(a).
[87] *Id*.
[88] Exec. Order No. 13,272, § 3(b).
[89] 5 U.S.C. § 605(c).
[90] *Id.* at § 603(b)-(c).
[91] When such data are unavailable, the agency should state why and request comments.

Some of the important questions the agency should address in preparing an IRFA are:

- Should the agency redefine "small entity" for purposes of the IRFA?
- Which small entities are affected the most? Are all small entities in an industry affected equally or do some experience disparate impacts such that aggregation of the industry would dilute the magnitude of the economic effect on specific subgroups?[92]
- Are all the required elements of an IRFA present, including a clear explanation of the need for and objectives of the rule?[93]
- Has the agency identified and analyzed all major cost factors?
- Has the agency identified all significant alternatives that would allow the agency to accomplish its regulatory objectives while minimizing the adverse impact or maximizing the benefits to small entities?
- Can the agency use other statutorily required analyses to supplement or satisfy the IRFA requirements of the RFA?
- Are there circumstances under which preparation of an IRFA may be waived or delayed?
- What portion of the problem is attributable to small businesses (i.e., is regulation of small businesses needed to satisfy the statutory objectives)?
- Does the proposed solution meet the statutory objectives in a more cost-effective or cost-beneficial manner than any of the alternatives considered?

The results of the analysis should allow interested parties to compare the impacts of regulatory alternatives on the differing sizes and types of entities affected by the rule. It will enable direct comparison of small and large entities to determine the degree to which the alternatives chosen disproportionately affect small entities or a specific subset of small entities. Further, the analysis will examine whether the alternatives are effectively designed to achieve the statutory objectives.

The agency must balance the thoroughness of an analysis and practical limits of an agency's capacity to carry out the analysis. Agencies should consult available information on how to conduct an economic analysis, such as the guidelines in OMB's *Economic Analysis of Federal Regulations under Executive Order 12866* and should review small business data, including data referenced in Appendix C, "Small Business Statistics for Regulatory Analysis."

If economic data are available, an agency should utilize the data in preparing an IRFA. When data are not readily available, the agency should consult with industry sources or other third parties to collect data. If the data collection is inadequate, then agencies should solicit the data as part of the proposed rulemaking.

[92] See discussion on pp. 14-15 of this guide on this issue.

[93] An agency may want to avoid repeating relevant text by cross-referencing the needs and objectives of the rule in its IRFA.

Elements of an IRFA

The preparation of an IRFA should be coordinated with the development of the data and analysis the agency will use in preparing the proposed rule under the requirements of the Administrative Procedure Act. In doing so, the agency should be mindful of the requirements of the RFA and collect data based on size. The development of a rational rule will require the acquisition of data that describe the scope of the problem, the entities affected, and the extent of those effects. Without such information, the agency will be unable to develop a rational rule.[94]

Under section 603(b) of the RFA, an IRFA must describe the impact of the proposed rule on small entities and contain the following information:

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

Section 603(c) requires an agency to include a description of any significant alternatives to the proposed rule that minimize significant economic impacts on small entities while accomplishing the agency's objectives. The approach an agency takes while developing an IRFA depends on such factors as the quality and quantity of available information and the anticipated severity of a rule's impacts on small entities subject to the rule. Section 607 of the RFA requires agencies to develop a quantitative analysis of the effects of a rule and its alternatives using available data. If quantification is not practicable or reliable, agencies may provide general descriptive statements regarding the rule's effects.[95] This second option is a last resort when it is not practicable for the agency to complete a significant quantitative analysis.

The principal issues an agency should address in an IRFA are the impact of a proposed rule on small entities and the comparative effectiveness and costs of alternative regulatory options. Each of the specific elements of the IRFA is discussed in turn below.

[94] Bowen v. AHA, 476 U.S. 610, 643 (186); National Ass'n of Home Health Agencies v. Schweiker, 690 F.2d 932, 949 (D.C. Cir. 1982); Chocolate Mfrs. Ass'n v. Block, 755 F.2d 1098, 1103 (4th Cir. 1985).
[95] 5 U.S.C. § 607.

Reasons action is being considered

For the first element of the IRFA, the agency must discuss the reasons it is considering the proposed rule.[96] The agency should list any issue to be addressed in the rulemaking and should be thorough in listing its reasons as this section provides insight into the need for the rule.

Generally, the agency addresses this topic in the preamble to the rule. The agency can summarize its discussion in the rulemaking, if the rulemaking addresses all the reasons the agency is considering the action. The discussion of the reasons leads directly into the objectives of the rule, the next element of the IRFA.

Objectives of the proposed rule

For the second element of the IRFA, the agency must list the objectives of the proposed rule.[97] Again, the agency should be thorough when discussing its objectives, as this discussion conveys to the public the goals of the rulemaking and why the agency is taking specific actions contained within the proposed rule. This section provides the justification for the agency's actions, balancing the compliance requirements against the need for the rule. Such a discussion should include how the rule is achieving the statutory objectives. Compliance with this requirement should not be difficult since agencies are required to explain their proposed actions and the reasons underlying those proposed actions in order to elicit comment from the public as required by section 553 of the APA.[98]

As with the reasons for the proposed rule, the agency is likely to have addressed this topic in the rulemaking. The agency can draw from the language of the rulemaking to satisfy this section of the IRFA, as long as it lists all the objectives of the proposed rule that would entail compliance requirements with a significant economic impact on a substantial number of small entities.

Description and estimate of the number of small entities

The third element of the IRFA requires the agency to identify the classes of small entities affected by the proposed rule and provide an estimate of the number of small entities in each of those classes.[99] In particular, the agency should pay special attention to small entities expected to face disproportionate impacts relative to other entities in the industry, whether those entities are large or small. Classification requires the development of a profile for the affected industry or industries and categorization by various size classes within each affected industry. It is crucial that the agency list all industry classes affected by the rule. Specifically, if the agency imposes a compliance requirement on a class of small entities, it must identify that class of small entities in this section of the IRFA.

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[96] *Id.* at § 603(b)(1).
[97] *Id.* at § 603(b)(2).
[98] *See* Spartan Radiocasting v. FCC, 619 F.2d 314, 321 (4th Cir. 1980).
[99] 5 U.S.C. § 603(b)(3).

As a default, section 601 of the RFA requires agencies to use size standards set by the SBA in determining whether businesses are small businesses. SBA's Office of Size Standards set these standards using the North American Industry Classification System (NAICS).[100] Agencies must identify each of the affected classes according to their NAICS code. Once the agency has identified all the affected industries by code, it can use the NAICS code in combination with the U.S. Census data[101] to gain an estimate of the number of entities in each class. To help agencies with this element of the IRFA, the Office of Advocacy provides a full listing of NAICS codes along with the U.S. Census data for each class on its web page.[102]

If the agency determines that the existing SBA size standards for small businesses are not appropriate, the RFA permits the agency, after notice and comment, to establish one or more alternative definitions of a small entity that are appropriate for the rule.[103] The RFA requires an agency to consult with the Office of Advocacy when performing an RFA analysis using a different small business size standard than that provided by the SBA.[104]

Estimating compliance requirements

For the fourth element of the IRFA, the agency must describe and estimate the compliance requirements of the proposed rule.[105] This is one of the two most important elements in the IRFA, because the alternatives the agency examines in the IRFA will be designed to minimize these compliance burdens. Provision of a list in the IRFA enables small entities to more easily identify potential burdens and tailor their comments in the rulemaking process to those burdens that most affect them without wading through many *Federal Register* pages.

As stated by the RFA, some of the costs the agency must describe in the IRFA include the costs of any recordkeeping; professional expertise, such as lawyer, accountant, or engineering, needed to comply with recordkeeping; and reporting requirements. Section 603 also requires that the agencies examine other compliance requirements, which may include, for example, the following: (a) capital costs for equipment needed to meet the regulatory requirements; (b) costs of modifying existing processes and procedures to comply with the proposed rule; (c) lost sales and profits resulting from the proposed rule; (d) changes in market competition as a result of the proposed rule and its impact on small entities or specific submarkets of small entities; (e) extra costs associated with the payment of taxes or fees associated with the proposed rule; and (f) hiring employees dedicated to compliance with regulatory requirements.

Since all rules are different and impose different compliance requirements, the RFA contemplates that agencies will prepare analyses to determine all significant long- and

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[100] *See http://www.sba.gov/size/.*
[101] *See http://www.census.gov/.*
[102] Office of Advocacy, Economic Statistics and Research (visited Sept. 26, 2002), *http://www.sba.gov/advo/stats/us99_n6.pdf.*
[103] See the size standard discussion in Chapter 1.
[104] 5 U.S.C. § 601(3).
[105] *Id.*at § 603(b)(4).

short-term compliance costs. Agencies should list the compliance requirements separately to provide greater transparency.

The IRFA should also, to the extent practicable, compare the costs of compliance for small and large entities to determine whether the proposed rule affects small entities disproportionately, to analyze the ability of small entities to pass on these costs in the form of price increases or user fees, and to assess the effects on firms' profitability or their ability to provide services. This should be done in conjunction with an estimation of the costs of compliance relative to changes in market structure and the competitive status of various subclasses of small entities as well as the competitive positions of small entities in comparison with larger entities.[106]

Significant alternatives considered

The keystone of the IRFA is the description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize the rule's economic impact on small entities.[107] It is the development and adoption of these alternatives that provides regulatory relief to small entities.

Analyzing alternatives establishes a process for the agency to evaluate proposals that achieve the regulatory goals efficiently and effectively without unduly burdening small entities, erecting barriers to competition, or stifling innovation. This process provides an additional filter by which the agency conducts rational rulemaking mandated by the APA. Rather than focus on the overall costs and benefits of a particular regulation (as might be required by statute, such as the best achievable control technology, or by the regulatory analysis requirements of E.O. 12866), the RFA requires the agency to undertake an analysis in order to discover the least costly method of attaining the statutory objectives of the rulemaking agency. Instead of analyzing the impacts of its regulatory actions on all relevant sectors of the economy, the IRFA narrows the scope of the particular review to small entities. The premise underpinning the IRFA is that, everything else being equal, the most rational alternative is often the one that achieves the objective of the agency at the lowest cost. Since small entities typically constitute the vast majority of entities in a particular industry under the SBA size standards, it often makes the most economic sense

[106] Competitive status is not relevant when the small entities regulated by the proposed rule are not-for-profit organizations or governmental jurisdictions. In regulations that are limited to nonprofits or governmental jurisdictions, changes in regulatory costs should not affect the competitive status of the entities. However, there are certain nonprofit and governmental jurisdictions that do compete with for-profit enterprises, such as electric cooperatives. In preparing an IRFA, the agency must be mindful of the type of small entity regulated and tailor its analytical requirements to those entities.

[107] 5 U.S.C. at § 603(c). Since the RFA is an economically neutral statute, the IRFA should examine alternatives to ensure that the proposed rule is maximizing any beneficial impact on small entities. In the case of a rule that has a significant beneficial effect, the failure to consider alternatives that enhance the beneficial effect means that the agency has not examined alternatives that "minimize" the economic impact of the proposed rule. For example, if a rule increases revenue to a small entity by $100 and an alternative exists that meets the statutory objective of the agency and increases revenue by $200, then the agency has not complied with the RFA if it did not examine the second alternative. The failure to provide the small entity with a potential extra $100 in revenue in essence does not minimize the economic impact on small entities.

to adopt the regulatory strategy that imposes the least cost on small entities because that generally would represent the most cost-effective strategy meeting the agency's statutory objectives.

The kinds of alternatives that are possible will vary based on the particular regulatory objective and the characteristics of the regulated industry. However, section 603(c) of the RFA gives agencies some alternatives that they must consider at a minimum:

1. Establishment of different compliance or reporting requirements for small entities or timetables that take into account the resources available to small entities.
2. Clarification, consolidation, or simplification of compliance and reporting requirements for small entities.
3. Use of performance rather than design standards.
4. Exemption for certain or all small entities from coverage of the rule, in whole or in part.

Additional alternatives include adopting different standards for the size of businesses or modifying the types of equipment that are required for large and small entities. In short, the agency should consider a variety of mechanisms to reach the regulatory objective without regard to whether that mechanism is statutorily permitted. In some cases, the identification of regulatory alternatives that would be beneficial to the economy but cannot be implemented because of a statutory directive provides Congress with a clear legislative path. It is critical to remember that the IRFA is designed to explore less burdensome alternatives and not simply those alternatives it is legally permitted to implement. Returning to the analogy between RFA and NEPA, Council on Environmental Quality regulations providing guidance on NEPA compliance expect the agency to examine a "no-action" alternative even if such alternative would violate the statutory mandate, such as the need to protect a threatened and endangered species pursuant to the Endangered Species Act. Similarly, an agency might examine an exemption of small businesses even if the statute does not permit it because that informs Congress, the public, and the courts that it understands the implications of its regulatory action and is taking a less desirable course of action than it wishes. Such an assessment follows the parallels between the RFA and NEPA while providing information to the regulated community and decisionmakers in other branches of the federal government.

Agencies are not limited to alternatives that minimize burdens for small entities. As EPA's 1992 RFA guidance recognized, cost-effective alternatives for small entities often are cost-effective for all entities.[108] Agencies should identify regulatory alternatives at the earliest stage of rulemaking and not wait until after the proposed rule is finished to develop alternatives. This is crucial because otherwise the agency may have already bought into one particular regulatory solution without considering alternatives. Such predeterminations by the agency violate the basic tenet of rational rulemaking under the APA by making the notice and comment process irrelevant. Interpretations of the notice and comment provisions of the APA contemplate a dialogue between the agency and the

[108] *See Revised Interim Guidance for EPA Rulewriters,* p. 18.

regulated community.[109] An agency already predisposed to only one way of thinking undermines the notice and comment procedure, thereby leaving itself open to a finding by a court that the agency action was arbitrary, capricious, or otherwise not in accordance with the law under section 706 of the APA.[110] Thus, the development of alternatives in the RFA demonstrates to the court that an agency did not in the proposed rule have a predisposition to rule in a manner that eviscerates the notice and comment process. If an agency is unable to analyze small business alternatives separately, then alternatives that reduce the impact for businesses of all sizes must be considered.

Consistent with an agency's obligations under section 609 of the RFA, agencies should perform outreach to interested groups to help develop regulatory solutions. In doing so, agency personnel should recognize that different sectors of an industry may have very different perspectives on a particular regulatory approach. The agency, before adopting one approach, should ensure that it contacts small entities and their representatives as well as large entities and their representatives. This type of communication is not prohibited by the APA and will help the agency focus on potential benefits and costs of various approaches to small businesses.

In essence, this outreach is an informal approach to the advance notice of proposed rulemaking that agencies often undertake to flesh out the parameters of a particular rule. Except in cases of emergencies or statutory deadlines, the Office of Advocacy strongly recommends that agencies consider using advance notices of proposed rulemaking for the most significant rules to identify potentially interested small entities and obtain estimates on the costs and benefits to small entities of various regulatory options. In particular, advance notices of proposed rulemaking will be extremely useful in developing information on the economic and structural characteristics of the industry and small entities within that industry. Where the agency does not use an advance notice of proposed rulemaking, it should consider requesting information in the proposal regarding the economic and structural characteristics of the industry, including such items as the typical firm size, typical profits and losses, and the marginal costs of production.

Duplicative, overlapping, and conflicting rules

The sixth and final element of the IRFA is to identify any duplicative, overlapping, and conflicting federal rules.[111] Rules are duplicative or overlapping if they are based on the same or similar reasons for the regulation, the same or similar regulatory goals, and if they regulate the same classes of industry. Rules are conflicting when they impose two conflicting regulatory requirements on the same classes of industry.[112]

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[109] *See* Chocolate Mfrs. Ass'n v. Block, 755 f.2d 1098, 1103 (4th Cir. 1985).
[110] *See* McLouth Steel Prods. v. EPA, 838 F.2d 1317, 1324 (D.C. Cir. 1988); Levesque v. Block,723 F.2d 175, 187 (1st Cir. 1983); United States Steel Corp. v. EPA, 595 F.2d 207, 214 (5th Cir. 1979).
[111] 5 U.S.C. § 603(b)(5).
[112] For example, under the now repealed ergonomics rule, OSHA would have forced skilled nursing facilities to acquire mechanical lifts to move patients. On the other hand, regulations promulgated by the Centers for Medicare and Medicaid Services (CMS) mandated that patients have a right not to be moved using mechanical lifts. Thus, the OSHA and CMS regulations would have been at cross purposes with respect to providing ergonomic protection for employees.

This section of the IRFA requires the agency to examine the potential conflicting and duplicative rules that can unnecessarily add cumulative regulatory burdens on small entities without any gain in regulatory benefits. By identifying overlapping, duplicative, or inconsistent regulations, the agency might be able to avoid adding an additional regulatory burden (even one as simple as an additional report that is already filed elsewhere).[113]

Because of the breadth and volume of federal regulations, a review of all existing rules on a particular industry group can be an onerous task for a federal agency. Nevertheless, it is important that the agency try to identify potential conflicting, duplicative, and overlapping regulations. The IRFA should include a request for comments identifying such rules. At the very least, the agency should review its own rules and identify any rules that cover the same subject matter and affect the same classes of industry. In fact, the law already requires such a review under section 610 of the RFA.

Using other analyses to satisfy the IRFA requirements

The RFA permits agencies to prepare IRFAs in conjunction with, or as a part of, other analyses required by law as long as the RFA's requirements are satisfied.[114] Agencies need to exercise caution when relying on other analyses to satisfy the RFA, as they may not necessarily be a complete substitute for a regulatory flexibility analysis. In fact, these other analyses will prove far more useful as sources for data to be used in the IRFA than as substitutes for an IRFA. For major rules that require the preparation of a regulatory impact analysis (RIA) under Executive Order 12866, agencies may prepare the RIA and the regulatory flexibility analyses together. Nevertheless, the agency must keep in mind that the RIA is a much broader analysis of benefits and costs and does not focus on the cost effectiveness of regulatory compliance for small entities. Thus, the focus of the RIA under the executive order is not a substitute for the IRFA. Agencies can coordinate their preparation of regulatory flexibility analyses with any other analyses accompanying a rule.[115] In doing so, however, agencies should ensure that such analyses describe explicitly how the requirements of the Regulatory Flexibility Act are satisfied. Similarly, agencies can develop evaluations of administrative burdens associated with reporting and recordkeeping requirements in concert with the paperwork burden analysis prepared under the Paperwork Reduction Act. However, Paperwork Reduction Act analysis is not a substitute for RFA compliance analysis.

[113] In 1999, EPA relieved hundreds of thousands of facilities—facilities that were already filing federal underground storage tank forms for gasoline and diesel fuel with local authorities—from filing very similar reports for the same fuels under the federal community right-to-know law.
[114] 5 U.S.C. § 605(a).
[115] Many requirements of Exec. Order No. 12,866 parallel those in the RFA. See Chapter 1 for a detailed discussion.

When an IRFA may be waived or delayed

Section 608 of the RFA provides that an agency may waive or delay the completion of some or all the requirements of section 603 regarding preparation of IRFAs if the agency is promulgating the rule in response to an emergency that makes compliance with the RFA impracticable.[116] Promulgating agencies must publish the waiver or delay in the *Federal Register* no later than the date of publication of the final rule. If a true emergency exists, the agency must explain clearly why the circumstances constitute an emergency.

The RFA does not specifically allow certifications of proposed (or final) rules issued pursuant to section 605(b) to be waived or delayed. Certifications must be published at the time of the proposed or final rule. As discussed in Chapter 1, federal agencies must make a threshold assessment regarding the impact of proposed rules on small entities and this assessment, if it results in a certification, is judicially reviewable.

What an IRFA should look like: A real-life example

On the following pages, a satisfactory IRFA by the Federal Trade Commission contains the elements required by the RFA and a thorough analysis of the regulation's potential impact on small entities when insufficient data are available on cost or impact.[117]

[116] 5 U.S.C. § 608(a).

[117] For an example of a satisfactory IRFA when cost/impact data are available, see the CMS proposed rule on Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar 2003, 67 Fed. Reg. 43,846 (June 28, 2002). For another example, see U.S. Department of Transportation (DOT) proposed rule on Regulatory Assessment for Changes in Vessel and Facility Response Plans: 2003 Response Requirements, 67 Fed. Reg. 63,331, where DOT properly analyzed alternatives to the rule.

EXAMPLE OF AN INITIAL REGULATORY FLEXIBILITY ANALYSIS

FEDERAL TRADE COMMISSION

16 CFR PART 312

Children's Online Privacy Protection Rule

AGENCY: Federal Trade Commission

ACTION: Initial Regulatory Flexibility Analysis

SUMMARY: The Commission is publishing this initial regulatory flexibility analysis to aid the public in commenting upon the small business impact of its proposed rule implementing the Children's Online Privacy Protection Act ("COPPA" or "the Act").

DATES: Written comments must be submitted on or before August 6, 1999.

ADDRESSES: Written comments should be submitted to Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Avenue, NW, Washington, DC 20580. The Commission requests that commenters submit the original plus five copies, if feasible. To enable prompt review and public access, comments also should be submitted, if possible, in electronic form, on either a 5-1/4 or a 3-1/2 inch computer disk, with a disk label stating the name of the commenter and the name and version of the word processing program used to create the document. (Programs based on DOS or Windows are preferred. Files from other operating systems should be submitted in ASCII text format.) Alternatively, the Commission will accept comments submitted to the following e-mail address <kidsrule@ftc.gov>. Individual members of the public filing comments need not submit multiple copies or comments in electronic form. All submissions should be captioned: "Children's Online Privacy Protection Rule- IRFA Comment, P994504." Comments will be posted on the Commission's Web site: <http://www.ftc.gov>.

FOR FURTHER INFORMATION CONTACT: Toby Milgrom Levin, (202) 326-3156, Loren G. Thompson, (202) 326-2049, or Jill Samuels, (202) 326-2066, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 601 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: This notice supplements the Commission's initial notice of proposed rulemaking, 64 FR 22750 (Apr. 27, 1999), for a Children's Online Privacy Protection Rule, 16 CFR Part 312, to implement the requirements of the Children's Online Privacy Protection Act of 1998 ("the Act"), Title XIII, Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. 105-277, 1112 Stat. 2681, ___ (Oct. 21, 1998). The Commission's notice of proposed rulemaking did not include an initial regulatory flexibility analysis pursuant to the Regulatory Flexibility Act (5 U.S.C. 603) based on a certification that the proposed rule will not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605). See 64 FR at 22761.

In the Notice of Proposed Rulemaking, the Commission concluded that the proposed rule's requirements are expressly mandated by the COPPA. In the Commission's view, the Act's requirements account for most, if not, all of the economic impact of the proposed rule, and the Commission's proposal adds little, if any, additional independent compliance burden to the statutory requirements. For example, as reiterated below, the proposed rule consistently incorporates the overall "performance" standards set forth in the statute rather than mandating any particular compliance method or approach. See 5 U.S.C. 603(c)(3). Moreover, certain provisions of the rule (e.g., definitions taken directly from the statute, enforceability of rule by the Commission and the states, severability of the rule's provisions) would appear to have no material effect on the costs or burdens of compliance under the rule for regulated entities, regardless of size. Thus, the marginal cost, if any, that would be imposed by the rule on regulated entities, including small entities, would not be substantial. Since the Regulatory Flexibility Act does not require an initial (or final) regulatory flexibility analysis when a "rule" will not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605), such an analysis did not accompany the proposed rule. Nonetheless, in its Notice of Proposed Rulemaking to implement the COPPA, the Commission expressly invited public comment on the proposed rule's effect on the costs, profitability, competitiveness of, and employment in small entities to ensure that no significant economic impact on a substantial number of small entities would be overlooked. See 64 FR at 22761.

In response, the Commission received comments suggesting, among other things, that the Commission publish an initial regulatory flexibility analysis under the Regulatory Flexibility Act. While the Commission continues to believe that such an analysis is not technically required, the Commission has decided to publish the following analysis to provide further information and opportunity for public comment on the small business impact, if any, of the rule. The Commission notes that it has already afforded a period of public comment on the proposed rule for such comments, and will be conducting a public workshop on July 20, 1999, on the issue of obtaining parental consent under the rule. See 64 FR 34595 (June 28, 1999). The workshop will provide an additional opportunity for public comment on how compliance with that particular requirement might be achieved, while minimizing the potential impact of the requirement on regulated entities, including small entities, to the extent the Commission has any discretion on that issue. The July 30th deadline for comments in response to the initial regulatory flexibility analysis set forth below is scheduled to coincide with the close of the comment period that will follow the public workshop described earlier.

Description of the reasons that action by the agency is being considered.

The COPPA requires the Commission to promulgate this rule not later than one year after the date of enactment of the Act. COPPA § 1303(b)(1).

Succinct statement of the objectives of, and legal basis for, the proposed rule.

To prohibit unfair and deceptive acts and practices in connection with commercial websites' and online services' collection and use of personal information from and about children by: (1) enhancing parental involvement in a child's online activities in order to protect the privacy of children in the online environment; (2) helping to protect the safety of children in online fora such as chat rooms, home pages, and pen-pal services in which children may make public postings of identifying information; (3) maintaining the security of children's personal information collected online; and (4) limiting the collection of personal information without parental consent. The legal basis for the proposed rule is the COPPA.

Description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.

In general, the rule will apply to any commercial operator of an online service or Internet website directed to children or a commercial operator of an online service or Internet website who has actual knowledge that he or she is collecting personal information from a child. See proposed Rule § 312.3 (general requirements). The rule does not apply to nonprofit entities. See proposed Rule § 312.2 (defining "operator"). A precise estimate of the number of small entities that fall within the rule is not currently feasible because the definition of a website directed to children turns on a number of factors that will require a factual analysis on a case-by-case basis. The Commission seeks any information or comment on these issues, as noted below.

Description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

The statute and proposed rule do not directly impose any "reporting" or "recordkeeping" requirements within the meaning of the Paperwork Reduction Act, but would require that operators make certain third-party disclosures to the public, i.e., provide parents with notice of their privacy policies. *See* proposed rule §§ 312.3 (a) (notice on website or online service), 312.4(a), (b), and (c) (format and contents of notice), 312.5(c)(3) and (4) (parental notification to obtain consent), 312.6(a)(1) (parental notification of information being collected on children). The Commission is seeking clearance from the Office of Management and Budget (OMB) for these requirements and the Commission's Supporting Statement submitted as part of that process is being made available on the public record of this rulemaking.

The statute and proposed rule also contain a number of compliance requirements not subject to the Paperwork Reduction Act, including but not limited to obtaining verifiable parental consent to collect personal information from children, § 312.5(b); allowing parents to have the opportunity to review and make changes to information provided by their children, § 312.6; and developing and implementing methods for maintaining the confidentiality, security, and integrity of personal information collected from children, § 312.8. These statutorily mandated obligations do not require operators to file reports or maintain records within the meaning of the Paperwork Reduction Act, although the Commission recognizes that there are potential compliance costs associated with these requirements. As noted above, the only class of small entities that would be subject to the above-described compliance requirements would be commercial operators of websites or online services directed to children or those commercial operators who have actual knowledge that they are collecting information from children, as discussed earlier.

Since the rule does not directly mandate "reporting" or "recordkeeping" within the meaning of the Paperwork Reduction Act, the rule does not require professional skills for the preparation of "reports" or "records" under that Act. The statute and rule do require that certain third-party disclosures (i.e., privacy policy notices) may initially require professional attorney and computer programmer time to develop and post. For purposes of its Supporting Statement to OMB under the Paperwork Reduction Act, the Commission estimated approximately 60 hours per site (83 percent attorney hours, 17 percent programmer hours) in the first year and six hours per web site in subsequent years. However, the Commission, as noted below, seeks further comment on the actual costs or expenditures, if any, of developing and posting the required privacy policy notices, and the extent to which these costs may differ or vary for small entities. (See the Supporting Statement submitted by the Commission to OMB at

<http://www.ftc.gov/os/1999/9906/childprivsup>) It is important to note, however, that the Commission anticipates that any expenditures for professional attorney or programmer time may be significantly reduced or eliminated if websites avail themselves of software or other compliance tools or kits that make it easier and less costly to meet the rule's notice requirements. A number of industry groups have already developed privacy policy toolkits which are available online as part of their self-regulatory efforts in the privacy area. The Commission seeks further comment on this issue.

Certain of the statute's and rule's other non-Paperwork Reduction Act requirements may require some clerical or computer programmer time for compliance. For example, an employee may be required to review parental responses to the operator's requests for consent. Depending on the method chosen by the operator to seek parental consent, some employee training may be required, e.g., training an employee manning a toll-free telephone number to recognize whether a child or adult is on the line. Similar skills would be required of employees responsible for handling requests from parents who want to review the information provided by their children. Finally, computer programming and security expertise will be required to ensure that the operator maintains the confidentiality, security, and integrity of the data collected from children. Because the Commission currently has no basis on which to determine the number of hours required to conduct such tasks and as these requirements are not subject to the Paperwork Reduction Act, the Commission has not attempted here to provide an estimate in terms of burden hours, but is instead seeking reliable information and comment on costs and burdens for small entities.

Identification, to the extent practicable, of all relevant federal rules that may duplicate, overlap or conflict with the proposed rule.

The Commission is unaware of any duplicative, overlapping, or conflicting federal rules. As noted below, the Commission seeks comments and information about any such rules, as well as any other state, local, or industry rules or policies that require website operators and online services to implement business practices (e.g., notification, parental consent, security measures, etc.) that would comply with the requirements of the Commission's proposed rule.

Description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities, including alternatives considered, such as: (1) establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) use of performance rather than design standards; (4) any exemption from coverage of the rule, or any part thereof, for such small entities.

Under the proposed rule, subject operators will be free to choose one or more methods to achieve the goals of the rule based on their individual business models and needs. In many instances the proposed rule utilizes a performance standard to permit as much flexibility as possible for website operators to comply with the rule. For example, proposed Rule § 3.12.4(b) minimizes the burden on website operators and online service providers by permitting the notice to be posted by providing “links” to notices, rather than requiring complete texts of the notice, on each “page” or other location(s) where personal information is collected from children. Likewise, the requirements for parental notice (proposed Rule § 312.4(c)) are flexible and open-ended for all entities, not just small entities, requiring simply that the operator make “reasonable efforts, taking

into account available technology, to ensure" that notice reaches parents. See also proposed Rule § 312.5 regarding parental consent.

Although these rules impose some costs, it is important to recognize that the requirements of notice, consent, access and security are mandated by the COPPA itself. Although the Commission has sought to minimize the burden on all businesses, including small entities, by incorporating the statute's flexible "performance" standards, the Commission does not have the discretion to provide for exemptions from the COPPA based on size of the operator. Likewise, the proposed rule attempts to clarify, consolidate, and simplify the statutory requirements for all entities, including small entities, but the Commission has little discretion, if any, to mandate different compliance methods or schedules for small entities that might "take into account the resources available to small entities" but not comply with the statutory requirements. For example, the COPPA requires the posting of privacy policies by websites and online services before information is collected from children and a waiver for small entities of that prior notice requirement (e.g., by permitting notice after the fact) would be inconsistent with the statutory mandate. See COPPA, Pub. L. No. 105-277, § 1303(b)(1)(A)(i) and (ii).

Nevertheless, the Commission is seeking to address the variability of online businesses and to devise performance standards to allow for flexibility and innovation to achieve compliance with the mandated COPPA protections. Throughout the rulemaking proceeding, the Commission has made every effort to gather information regarding the economic impact of the COPPA's parental notice and consent requirements on all operators, including small entities. Thus, the *Federal Register* notice announcing the proposed rule included a number of questions for public comment regarding the costs and benefits associated with these key requirements with respect to small entities.

In addition, the agenda for the July 20th public workshop includes topics designed to elicit economic impact information, particularly as it would affect small businesses. The workshop will examine a wide range of mechanisms to implement parental consent so as to obtain a rich record of how operators, including small entities, can comply with the statutory requirement.

QUESTIONS FOR COMMENT TO ASSIST REGULATORY FLEXIBILITY ANALYSIS:

1. Please provide comment on any or all of the provisions in the proposed rule with regard to (a) the impact of the provision(s) (including any benefits and costs), if any, and (b) what alternatives, if any, the Commission should consider, as well as the costs and benefits of those alternatives, paying specific attention to the effect of the rule on small entities in light of the above analysis. In particular, please provide the above information with regard to the following sections of the proposed rule:

a. the requirement that notice be placed on the website, § 312.4(b);

b. the requirement that notice be provided to parents, § 312.4(c);

c. the requirement that operators obtain verifiable parental consent, § 312.5;

d. the requirement that parents be allowed to review and correct personal information provided by their children, § 312.6;

e. the requirement that operators take steps to ensure the confidentiality, safety, and integrity of the information provided to them, § 312.8; and

f. any other requirement not mentioned above.

Costs to "implement and comply" with the rule include expenditures of time and money for: any employee training; attorney, computer programmer, or other professional time; preparing relevant materials; processing materials, including, for example, processing parental consent materials or requests for access to information; and recordkeeping.

2. Please describe ways in which the rule could be modified to reduce any costs or burdens for small entities consistent with the COPPA's mandated requirements.

3. Please describe whether and how technological developments (such as the development and implementation of digital signatures) could reduce the costs of implementing and complying with the rule for small entities or other operators.

4. Please provide any information quantifying the economic benefits to website operators of collecting personal information from or about children, including any information showing: advertising revenues based in part upon the number of children registered at a site; revenue derived from the sale or rental of children's personal or aggregate information to others; efficiencies resulting from marketing to a targeted audience; or revenue resulting from designing a customized and appealing site.

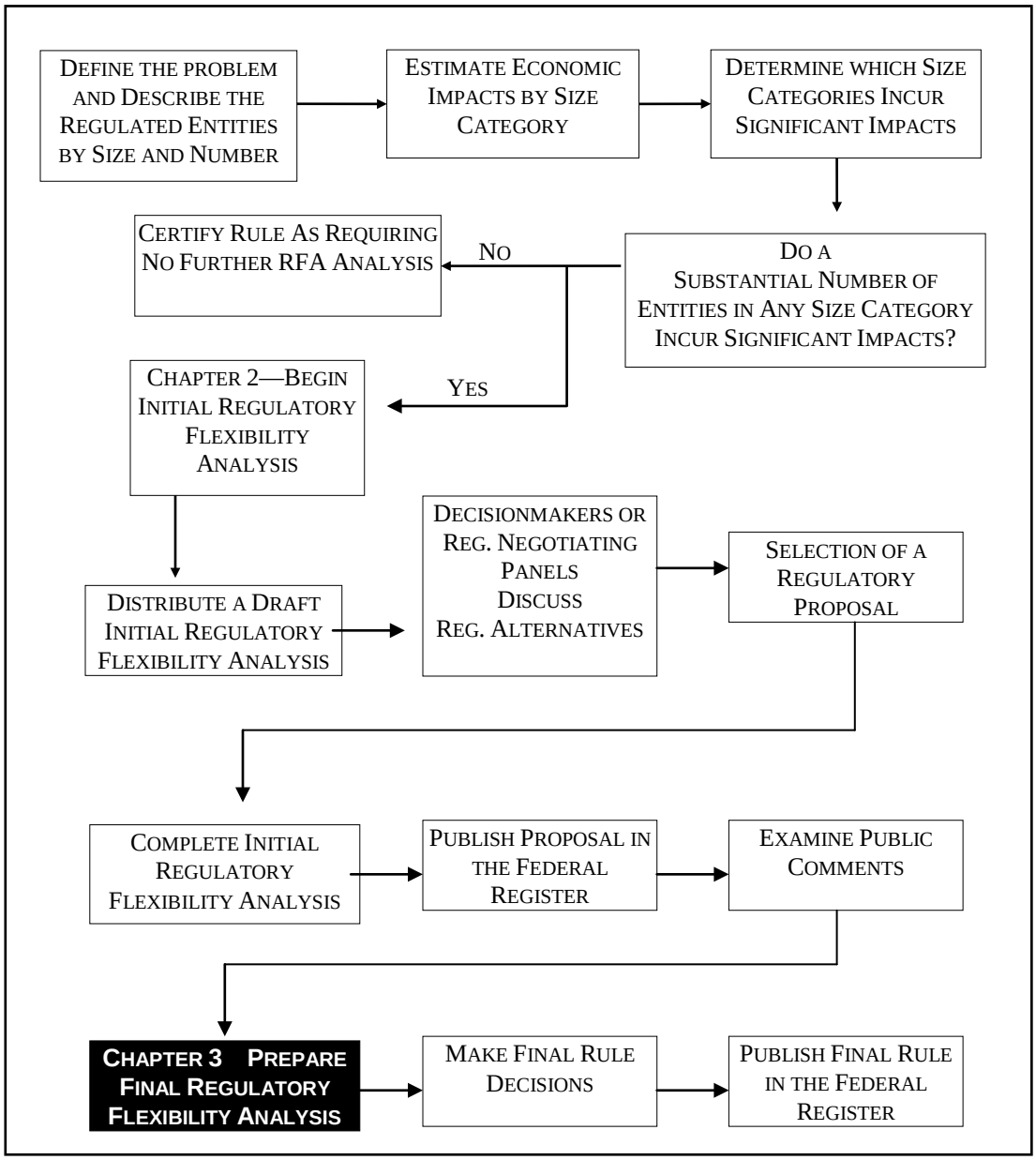
5. Please identify all relevant federal, state or local rules that may duplicate, overlap or conflict with the proposed rule. In addition, please identify any industry rules or policies that require website operators and online services to implement business practices (e.g., notification, parental consent, security measures, etc.) that would already comply with the requirements of the Commission's proposed rule.

By direction of the Commission.

Donald S. Clark
Secretary

CHAPTER 3 PREPARING A FINAL RULE: THE FINAL REGULATORY FLEXIBILITY ANALYSIS

The RFA decision process



When promulgating a final rule, agencies must prepare a final regulatory flexibility analysis (FRFA) unless the agency finds that the final rule will not have a significant economic impact on a substantial number of small entities or the final rule is issued under the APA provision allowing for good cause to forego notice and comment rulemaking.[118] When the agency publishes its final rule, it must also publish the FRFA, or a summary of the FRFA, in the *Federal Register*.[119] Draft final rules that are not certified must be submitted to Advocacy before publication in the *Federal Register.*[120] The agency must also make copies of the FRFA available to the public. These published FRFAs are then subject to judicial review.[121] If agencies are uncertain, they may obtain Advocacy input/comments on the FRFA prior to its publication in the *Federal Register*.

The RFA mandates that agencies revise their initial regulatory flexibility analysis based on the public comments received. Agencies routinely create a summary of the public's comments to be published along with the final rules. In developing this summary, the agency should specifically summarize comments from small entities even if the comments of the small entities do not relate to the RFA. This will help the agency prepare a more accurate FRFA or demonstrate support for a certification. Once the agency determines that it cannot certify the final rule under section 605(b), the agency must prepare a FRFA. If the agency determines that the rulemaking will not result in a significant economic impact on a substantial number of small entities, the head of the agency may so certify under section 605(b) of the RFA, and provide a copy of the certification to the Chief Counsel for Advocacy.[122]

Issues to be addressed in the analysis

Section 604(a) of the RFA outlines the central issues the agency must address in the FRFA. In short, agencies must evaluate the impact of a rule on small entities and describe their efforts to minimize the adverse impact. To the extent that the final regulation has significant beneficial economic impacts, the agency should describe efforts to ensure that the benefits of the final rule maximize benefits to small businesses and minimize adverse economic impacts.

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[118] 5 U.S.C. § 604 and 605(b). The APA provision is found in 5 U.S.C. § 553 (b)(B).

[119] *Id.* at § 604(b). Since the actual FRFA usually more accurately informs the public of the agency's efforts to analyze costs and alternatives, it is good practice to include the actual FRFA in the final rule as published in the *Federal Register*.

[120] Exec. Order No. 13,272, 67 Fed. Reg. 53,462 (Aug. 16, 2002).

[121] 5 U.S.C. § 611.

[122] As indicated earlier in the discussion concerning certifications, RFA § 605(b) requires that the certification appear in either the proposed or final rule. Although it is fairly clear that the certification must appear in the final rule if there is no certification in the proposed rule, it is not clear whether the certification must be duplicated in the final rule if it already appears in the proposed rule. The Office of Advocacy believes that, given the emphasis in the law on public notice, the certification should also appear in the final rule even though there may have already been a certification in the proposed rule. Doing so will help demonstrate the continued validity of the certification after receipt of public comments. For a more detailed discussion of certifications, see Chapter 1 of this guide.

The requirements for a FRFA are somewhat different than those for an IRFA. The requirements for the FRFA are very similar to the requirements that the courts impose on the development of a statement of basis and purpose for a final rule under section 553 of the APA.[123] The only additional requirements are those that relate to ensuring the items in the FRFA are easily identifiable to small entities without having to search the entire *Federal Register* notice. The agency should coordinate the preparation of the FRFA with development of the basis and purpose statement in the preamble. The preparation of a basis and purpose statement is not a substitute for a FRFA or for real agency consideration of significant alternatives that are more cost-effective to small entities but still achieve the objectives of the agency. The requirements, outlined in section 604(a)(1)–(5), are highlighted in italics below:

> 1) *A succinct statement of the need for, and objectives of, the rule.* The agency can cross-reference to a similar succinct statement in the supplementary information if the cross reference enables small entities to easily identify the need for and objectives of the rule.
>
> 2) *A summary of the significant issues raised by the public comments in response to the IRFA, 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.* Under the APA, agencies are required to respond to comments addressing relevant statutory considerations.[124] Since the RFA constitutes a relevant statutory consideration, the agency is obligated under the APA to respond to comments on the RFA and relate how it changed the proposal, if at all, in response to the comments.
>
> 3) *A description 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.*
>
> 4) *A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the types of professional skills necessary for preparation of the report or record.*
>
> 5) *A description of the steps the agency has taken to minimize the significant adverse 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 of the other significant alternatives to the rule considered by the agency was rejected.* Again

[123] *E.g.*, Troy Corp. v. Browner, 120 F.3d 277, 289 (D.C. Cir. 1997); Lloyd Noland Hosp. v. Heckler, 762 F.2d 1561, 1566-67 (11th Cir. 1985); United States v. Nova Scotia Foods, 568 F.2d 240, 252 (2d Cir. 1977); Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 393 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974); Automotive Parts & Accessories Ass'n v. Boyd, 4057 F.2d 330, 338 (D.C. Cir. 1968).
[124] *Id.*

this requirement already is mandated by the rational rulemaking requirements of the APA.[125]

Additional questions to be addressed in a FRFA

A number of important questions will assist the agency in preparing a FRFA:

Have all significant issues been assessed?

Have all significant issues raised in the public comments regarding the IRFA been summarized and assessed, and have any changes been made since the publication of the proposed rule as a result of those comments? The RFA does not require agencies to address every issue raised during the public comment period—only the significant ones. The RFA does require agencies to assess (and not just present) the significant issues raised by interested stakeholders. Agencies are also required to publish in the final rule the specific changes that were made to the proposed rule in response to the public comments. Although there is no requirement to do so, some agencies include in their FRFAs the number of times a particular comment was raised.

Has the number of small entities been estimated?

Is it possible to estimate the number of small entities to which the rule will apply? If not, why not? The RFA requires that during its IRFA preparation, the agency must estimate the number of small entities affected. An additional FRFA requirement is that if no estimates of the number of affected small entities are available, agencies must explain why. An agency must have a strong argument that it cannot estimate the number of small entities, as in the case of a regulation affecting an emerging industry about which little is known.

If an agency is uncertain about how to proceed in the absence of firm data, Advocacy advises agencies to construct public records that reflect aggressive and meaningful public outreach. Agencies should compile economic data on the industries/organizational sectors to be regulated and the economic impacts on small entities within those sectors. If such efforts produce inconclusive data or fail entirely, the agency may demonstrate its efforts to comply with the requirements of the RFA and explain why such data were not available. Moreover, this will demonstrate to the courts that the agency was conducting rational rulemaking by determining the universe of affected entities.

Has the adverse economic impact on small entities been minimized?

Agencies must consider, and may adopt, one or more significant alternatives to minimize the rule's burden on small entities.[126] Some of the traditional alternatives may include

[125] *See* American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 539-41 (1981).

[126] The outcome of a rulemaking would be superior if the agency adopted a standard that achieves its objectives but reduces burdens or increases benefits to small entities. Development of regulations that have

lengthening the time for compliance; tiering the compliance requirements based on the size of the business or degree to which small entities contribute to the problem; providing for exemptions for parts of the rule or the entire rule for small entities; timing compliance to correspond with other statutory deadlines with related requirements; allowing for increased flexibility in the methods used for achieving the agency's objectives (for example, using a performance standard instead of requiring a specific technology); making requirements less prescriptive; etc. Such alternatives also include providing regulatory relief to all regulated entities, such as lowering the overall stringency of a standard or changing the regulatory threshold. In the first instance, it remains the obligation of the agency to develop significant alternatives pursuant to the RFA. Otherwise the agency is transferring its statutory RFA mandate to those entities that can least afford or have the least expertise in rulemaking processes to craft alternatives—small entities. Even after the agency has crafted alternatives, it should, as a matter of course, in the proposed rule and IRFA, specifically request whether any other alternatives exist that the agency has not considered. Small entities may be able to provide additional alternatives based on the analysis already performed by the agency, i.e., it may spark ideas that small entities may not have thought of absent such analysis. Adoption of this procedure will ensure that agencies have met their obligation to consider alternatives to the final regulatory solution as mandated by the RFA.

Have all significant alternatives been reviewed?

Has the statement of factual, policy, and legal reasons for selecting the alternative adopted in the final rule, and the reasons for rejecting other significant alternatives, been included or appropriately cross-referenced for easy identification by small entities? The Small Business Regulatory Enforcement Fairness Act (SBREFA)[127] made significant changes to this section of the RFA with respect to compliance requirements. Prior to 1996, an agency needed only state the alternatives and the reason (or reasons) for rejecting a particular alternative. As a result of the amendments, an agency must now include a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule. This explanation already is required under the APA, and the FRFA will help the agency demonstrate compliance with the APA's rulemaking procedures through the clarification of the reasons for selecting or rejecting particular alternatives. In addition to educating the courts, the rationales might spur action by Congress to correct a flaw that the agency identified. Thus, the FRFA, if done correctly, can play a key role in the development of public policy. The agency must also detail for the public record why each of the other significant alternatives was rejected; again, this is a requirement of APA rulemaking requiring the agency to explain how it considered all

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small entity orientation will be beneficial in the long run to the agency. Since most regulated entities are small, rules that have a small entity orientation will likely garner greater support from that community, increased compliance, reduced penalties, and quicker achievement of the agency's statutory objective. A regulation that does not have such small entity orientation will face resistance from the regulated community, force the agency to increase enforcement, and delay accomplishment of whatever goal the agency was attempting to reach. For example, if the OSHA ergonomics rule had gone into effect, it is unlikely that many small entities could have complied. The Department of Labor would have expended scarce resources to obtain compliance without accomplishing the goal of increasing worker safety.

[127] 5 U.S.C. § 604(a)(5).

relevant statutory criteria including those mandated by the RFA. The changes indicate that agencies were not providing specific explanations of their final actions. There should be significant articulable and supportable reasons for rejecting alternatives. The development and consideration of alternatives is subject to judicial review.[128]

Permissible delays in publication

Section 608(b) of the RFA provides that an agency may delay, but not waive, the completion of a FRFA if the rule is being promulgated in response to an emergency that makes compliance with the RFA impracticable. Under this provision, the agency must publish its reasons for the delay upon publication in the *Federal Register*. The delay may not exceed 180 days after the final rule is published; otherwise the rule lapses and has no effect. The rule cannot be re-promulgated until a FRFA has been completed. This section is also subject to judicial review.

What a FRFA should look like: A real-life example

On the following pages is an example of a satisfactory FRFA released by the National Highway Traffic Safety Administration (NHTSA)**.** This FRFA contains each of the elements required by the RFA and presents a thorough analysis of the regulation's impact on small entities.[129]

[128] *See* National Ass'n of Psychiatric Health Sys. v. Shalala, 120 F. Supp. 2d 33 (D.D.C. 2000), in which the court ordered HHS to complete a FRFA that discussed less burdensome alternatives considered and rejected in order to comply with the RFA.

[129] For an additional example of a satisfactory FRFA, see the Environmental Protection Agency final rule for Effluent Guidelines and Standards for the Organic Chemicals, Plastics, and Synthetic Fibers Industry, 58 Fed. Reg. 36,872-01.

EXAMPLE OF A FINAL REGULATORY FLEXIBILITY ANALYSIS

FINAL ECONOMIC ASSESSMENT

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION

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Child Restraint Systems,

Child Restraint Anchorage Systems

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FINAL REGULATORY FLEXIBILITY ANALYSIS

The Regulatory Flexibility Act of 1980 (Public Law 96-354) requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations and small governmental jurisdictions.

Section 603 of the Act requires agencies to prepare and make available for public comment a final regulatory flexibility analysis (FRFA) describing the impact of final rules on small entities. Section 603(b) of the Act specifies the content of a FRFA. Each FRFA must contain:

- A description of the reasons why action by the agency is being considered;
- A succinct statement of the objectives of, and legal basis for, the final rule;
- A description of and, where feasible, an estimate of the number of small entities to which the final rule will apply;
- A description of the projected reporting, record keeping and other compliance requirements of the final 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;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the final rule.
- Each final regulatory flexibility analysis shall also contain a description of any significant alternatives to the final rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the final rule on small entities.

1. Description of the reasons why action by the agency is being considered

NHTSA is considering this action to improve compatibility between child restraints and vehicle safety belts and increase the correct installation of child restraints.

The correct use of child restraints is important because of the number of children killed and injured in vehicle accidents. Annually, about 600 children less than five years of age are killed and over 70,000 are injured as occupants in motor vehicle crashes.

While child restraints are highly effective in reducing the likelihood of death or serious injury in motor vehicle crashes, the degree of their effectiveness depends on how they are installed. NHTSA estimates that the potential effectiveness of child restraints, when correctly used, is 71 percent. However, it is estimated that imperfect securing of children in the child restraints and/or the child restraints in vehicles reduce that effectiveness from the potential 71 percent to an actual 59 percent.

Child restraint effectiveness is affected by limitations imposed by vehicle belt design, and by belt anchorage locations. Some belt systems can be used to secure a child restraint only when used with an accessory item that impedes movement of the belt or child restraint in a crash, such as a

locking clip or supplemental strap. Some belt systems, such as an automatic seat belt, may not be compatible with a child restraint at all.

The agency recognizes the difficulty of designing vehicle seat belts to restrain both child restraint systems and a wide range of weights and sizes of individuals. Some vehicle seats have the seat belt anchorage positioned far forward of the vehicle "seat bight" (the intersection of the seat cushion and the seat back). Forward-mounted anchor points may better protect an adult using the vehicle seat belt system by drawing the vehicle belt low across the pelvis where the body can best tolerate the forces in a crash. However, when used with a child restraint, the belt anchor is too far forward of the seat bight to adequately resist the initial forward motion of the child restraint, which can result in a greater likelihood of a head impact.

Child restraint effectiveness is also reduced by incorrect securing of children and child restraints due to the complexities of adapting vehicle belts to those purposes and due to failure to follow instructions. A four-state study done for NHTSA in 1996 examined people who use child restraint systems and found that approximately 80 percent of the persons made at least one significant error in using the systems. Observed misuse due to a locking clip being incorrectly used or not used when necessary was 72 percent, and misuse due to the vehicle safety belt incorrectly used with a child restraint (unbuckled, disconnected, misrouted, or untightened) or used with a child too small to fit the belts was 17 percent.

2. Objectives of, and legal basis for, the final rule

This document requires that motor vehicles and add-on child restraints be equipped with a means independent of vehicle safety belts for securing child restraints to vehicle seats.

The difficulty with using vehicle safety belts to attach child restraints arises from the fact that those belts are primarily designed to restrain and protect larger and older vehicle occupants. Given the inability to change vehicle belt design and anchorage location because of this purpose, the agency is seeking a means of securing a child restraint that is independent of the safety belt.

This final rule reduces allowable head excursion to effectively require child restraints to be equipped with an upper tether strap, and requires vehicles to have two factory-installed, user-ready anchor points for attaching the tether. It also requires vehicles to have two rear vehicle seating positions equipped with a specialized lower anchorage system, and requires child restraints to be equipped with means of attaching to that system.

NHTSA has issued this final rule under the authority of 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.50. The agency is authorized to issue Federal motor vehicle safety standards that meet the need for motor vehicle safety.

3. Description and estimate of the number of small entities to which the final rule will apply

The final rule affects motor vehicle manufacturers, almost all of which would not qualify as small businesses, and aftermarket child restraint manufacturers. NHTSA estimates there to be about 10 manufacturers of aftermarket child restraints, four of which could be small businesses.

Business entities are generally defined as small businesses by Standard Industrial Classification (SIC) code, for the purposes of receiving Small Business Administration assistance. One of the criteria for determining size, as stated in 13 CFR 121.601, is the number of employees in the firm. There is no separate SIC code for child restraints, or even a category that they fit into well.

However, in order to qualify as a small business in all of the SIC codes that the child restraint manufacturers currently are listed under, including those business ventures other than child restraints, in the Standard and Poor's Register of Corporations, Directors and Executives, 1995, the firm must have fewer than 500 employees. In addition, to qualify as a small business in the Motor Vehicle Parts and Accessories category (SIC 3714), the firm must have fewer than 500 employees. Thus, it is assumed that any child restraint manufacturer with fewer than 500 employees would be considered a small business. Several of the child restraint manufacturers (Table 19) are subsidiaries of larger corporations. In this case, the total number of employees of the corporation are considered in relation to the 500 employee limit to qualify as a small business.

4. Description of the projected reporting, record keeping and other compliance requirements for small entities

The final rule sets new performance requirements that would enhance the safety of child restraints. Child restraint manufacturers must certify that their products comply with the final rule. Manufacturers could use any means to determine that their products comply, so long as they exercise due care in making their certification. Manufacturers of child restraints should be familiar with the final test responsibilities because the test is almost identical to current test requirements.

The final rule will result in new designs for child restraints and an increase in the price of child restraints, which may have a significant economic impact on a substantial number of small businesses. If the price elasticity of demand for child restraints were somewhat elastic, an increase in the price of a child restraint could lead to a decrease in demand for the product, notwithstanding the restraint use laws. NHTSA does not know the specific elasticity of demand for child restraints, but believes it is highly inelastic. Based on comments submitted to the NPRM, it would appear that the elasticity of demand for child restraints might be inelastic. NHTSA believes that an increase in the price ($9.62) of a child restraint will not lead to any significant decrease in demand for the product.

An increase in child restraint prices may also affect loaner and giveaway programs. While such a program could have fewer seats available, comments submitted to the NPRM indicate that if the new seats perform as projected, there would be minor effect on the loaner programs.

There are no additional reporting or record keeping requirements in this final rule for child restraint manufacturers or small businesses.

5. Duplication with other Federal rules

There are no relevant Federal rules which may duplicate, overlap or conflict with the final rule.

6. Description of any significant alternatives to the Final rule

NHTSA tentatively believes that there are no alternatives to the final rule which would accomplish the stated objectives of 49 U.S.C. §30101 et seq. and which would minimize any significant economic impact of the final rule on small entities. As discussed in the preamble to this final rule, NHTSA considered a number of other approaches to minimize or eliminate compatibility problems between child restraints and vehicle seats.

Table 19
Employment of Child Restraint Manufacturers*
(less than 500 employees qualifies as a small business)

Manufacturer	Number of Employees
Babyhood Manufacturing Co.	10
Century	1,000
COSCO (Dorel Company)	1,000
Early Development Co. has less than 10 employees, However, it is partly owned and a joint venture with Takata of Japan	large company
Evenflo itself has 250 employees, but Evenflo is a division of Spalding & Evenflo Co. Inc.	2,600
Ferno-Washington, Inc.	515
Gerry is a product of Evenflo, which has 250 employees, But Evenflo is a subdivision of Spalding & Evenflo Co. Inc.	2,600
Kolcraft	500
Safeline Children's Products Co.	< 10
Little Cargo, Inc.	<10

* Source: Standard and Poor's Register of Corporations, Directors, and Executives, 1995.

SAE Recommended Practice J1819, "Securing Child Restraint Systems in Motor Vehicle Rear Seats," provides voluntary design guidelines that designers of both the vehicle and child restraint can evaluate each product for compatibility. However, J1819 alone has not solved the compatibility problems. It is a tool for evaluating compatibility problems, not a requirement that vehicle seats and child restraints must be compatible. NHTSA believes it is very difficult for a single system to optimize the safety protection for adults of all ranges and child restraints of different types.

Another alternative is the current "lockability" requirement, which requires vehicle lap belts or the lap belt portion of lap/shoulder belts to be capable of being used to tightly secure child restraints, without the need to attach a locking clip or any other device to the vehicle's seat belt webbing. NHTSA tentatively believes that the lockability requirement is insufficient alone in addressing compatibility problems. While the requirement ostensibly makes a locking clip obsolete, it still depends on the user knowing enough and making the effort to manipulate the belt system. Also, the vehicle belt must be routed correctly through the child restraint, which may not be an easy task in all cases. Further, the lockability requirement does not address compatibility problems arising from forward-mounted seat belt anchors. Thus, excessive forward movement of a child restraint can still occur, even if the feature is engaged and the belt is "locked."

Another alternative discussed in the preamble is the "Car Seat Only (CSO)" system suggested by Cosco. The CSO system consists of a simple lap belt installed for a vehicle seating position. No changes are needed to child restraint systems.

NHTSA is concerned that the CSO system might not make attaching a child restraint significantly easier than it is today. The CSO belt would have to be correctly routed through the child restraint, which is a problem occurring with present seats. In some cases, it appears that it might be difficult to cinch up the belt with the CSO system. Another concern relates to the potential that the CSO belt would be inadvertently used by an adult occupant as a restraint, particularly in a seating position equipped with a lap belt, even if the CSO belt were labeled.

As discussed and analyzed throughout this assessment, the agency considered requiring a rigid to rigid system or a nonrigid to nonrigid system. The agency finally decided to require a rigid 6 mm bar anchorage system in the vehicle, but allow the child restraint manufacturers to use any type of connector they wanted to connect to the rigid bars. Certainly for the small business child restraint manufacturers, the final rule provides the most flexibility possible of the alternatives considered.

CHAPTER 4 REGULATORY PANELS

In 1996, SBREFA amended the RFA to include a number of important provisions. One of those was section 609, which requires, among other things, that certain agencies conduct special outreach efforts to ensure that small entity views are carefully considered prior to the issuance of a proposed rule. This outreach is accomplished through the work of small business advocacy review panels, often referred to as SBREFA panels.

Who must hold SBREFA panels?

The statute requires that the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) evaluate their regulatory proposals to determine whether SBREFA panels should be convened. The requirement for SBREFA panels may appear to impose additional steps for EPA and OSHA in their rulemaking processes. However, the panel process only formalizes the outreach requirements and analyses that the Administrative Procedure Act and the RFA already mandate for all new rules that affect small businesses. Any additional work that may be needed in this special early outreach effort should be offset by time saved at the other end of the regulatory process. When problems are resolved before a proposed rule is published, objections from the public are reduced. Experience has shown that the panel process results in better rules, better compliance and reduced litigation. In at least one instance, EPA withdrew a regulatory proposal based on work performed in connection with the panel process.[130]

How is the decision to hold a SBREFA panel made?

For each proposed rule, the RFA requires that an agency either certify that the proposal has no significant economic impact on a substantial number of small entities, or prepare an initial regulatory flexibility analysis (IRFA) on the proposal.[131] Whenever EPA or OSHA determines that a regulatory proposal may have a significant economic impact on a substantial number of small entities, the law further requires that the agency convene a SBREFA panel. This SBREFA panel outreach must take place before the publication of the proposed rule. SBREFA panels are required for all EPA and OSHA rules for which an IRFA is required. However, the Chief Counsel for Advocacy may waive the panel requirement upon the request of EPA or OSHA under certain conditions. To waive the panel requirement, the Chief Counsel must find that convening a panel would not advance the effective participation of small entities in the rulemaking process. Section 609(e) of the RFA lays out several factors in making this determination, including consideration of whether small entities have already been consulted in the rulemaking process and whether special circumstances warrant the prompt issuance of a rule.

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[130] *See* EPA's Effluent Limitations Guidelines for Industrial Laundries; 64 Fed. Reg. 45071, withdrawn by EPA on August 18, 1997.

[131] See Chapter 1 for a detailed discussion of how to certify a proposed rule and Chapter 2 on how to prepare an initial regulatory flexibility analysis.

How does a SBREFA panel work?

A SBREFA panel consists of a representative or representatives from the rulemaking agency, the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) and the Chief Counsel for Advocacy.

The panel solicits information and advice from small entity representatives (SERs), who are individuals that represent small entities affected by the proposal. SERs help the panel better understand the ramifications of the proposed rule. Invariably, the participation of SERs provides extremely valuable information on the real-world impacts and compliance costs of agency proposals.

The law requires that a SBREFA panel be convened and complete its report with recommendations within a 60-day period. The formal panel process begins with the convening of the panel by the rulemaking agency. The date is normally fixed after consultation with both Advocacy and OIRA. Before convening, the three agencies usually work together to discuss regulatory alternatives and their advantages and disadvantages. The rulemaking agency usually has preliminary discussions with small entities about its draft proposal before the panel is formally convened. These preparations ensure that the panel process can be completed during the statutorily specified 60-day period.

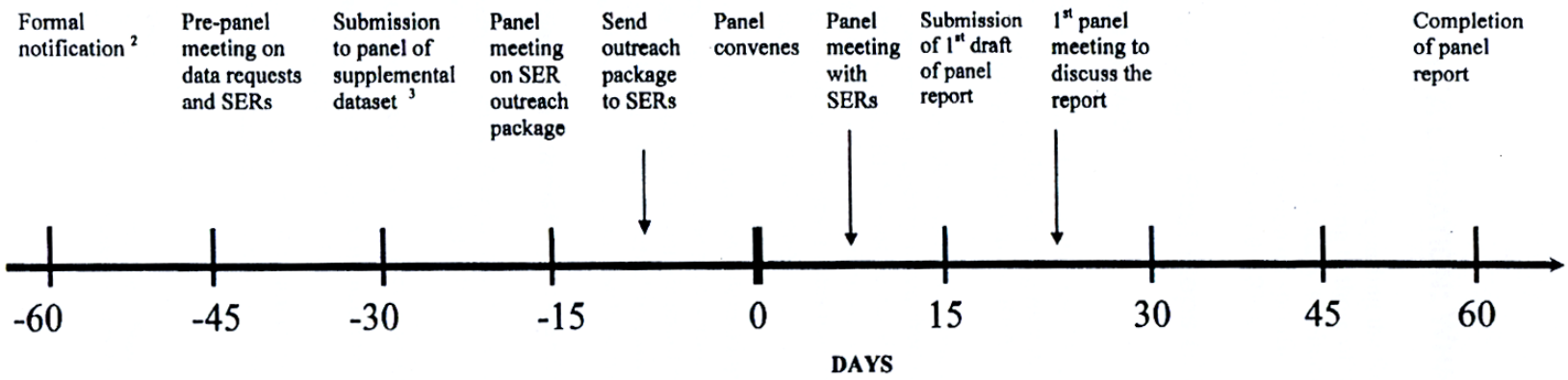
The product of a SBREFA panel's work is its panel report on the regulatory proposal under review. The panel completes its final report, including its recommendations, early in a rule's developmental stages, so that the agency has the benefit of the report's findings prior to publication of a proposed rule. The panel report also becomes part of the official docket for the proposed rule.

The purpose of the panel process is threefold. First, the panel process ensures that small entities that would be affected by a regulatory proposal are consulted about the pending action and offered an opportunity to provide information on its potential effects. Second, a panel can develop, consider, and recommend less burdensome alternatives to a regulatory proposal when warranted. Finally, the rulemaking agency has the benefit of input from both real-world small entities and the panel's report and analysis prior to publication.

Suggested SBREFA panel timeline

The RFA provides that the formal panel process must be concluded within 60 days from the formal convening of the panel to the completion of its report. Experience has shown that the panel process works best if agencies and panel members accomplish as much preliminary work as possible before the formal convening of the panel. A suggested timeline follows, although panel members have flexibility to adjust their pre-panel work schedules to ensure the best outcome for each individual rule.

SUGGESTED PANEL TIMELINE[1]



1. The suggested timeline for the panel process can be adjusted as necessary, except that the statute requires the panel's report to be completed within 60 days of the convening of the panel, Day 0 in this chart. Generally, as much preliminary work as possible should be done before Day -60.

2. The formal notifications by the convening agency to Advocacy and OIRA should include:

   - a description of the important components of the rule;
   - a description of the problem the rule is trying to solve and of the statutory obligations underlying the rule;
   - a quantitative or, if impracticable or unreliable, a qualitative description of the potential impacts;
   - a description of the types of entities likely to be affected by the proposed rule and of any small-entity stakeholder involvement in the process to date;
   - a description of any regulatory flexibility alternatives that are or have been under consideration;
   - a list of potential small entity representatives; and
   - a list of any other important documents or information that have already been developed to support the rulemaking.

3. The supplemental dataset should include a description of regulatory flexibility alternatives, information necessary to evaluate these alternatives or any other information that is reasonable to request, and the final list of SERs whom the Small Business Advocacy Review Panel Chairperson intends to select upon convening the panel.

CHAPTER 5 RFA LITIGATION: WHAT THE COURTS HAVE SAID

This chapter examines litigation regarding the Regulatory Flexibility Act and is organized in sections corresponding to those of the compliance guide overall. The section does not reflect the Office of Advocacy's opinion of the cases; rather, it is intended to provide the reader with information on specific case law and what the courts have held regarding agency compliance with the RFA.

Where do we begin? First steps of RFA rule analysis

Does the RFA apply?

An agency must first consider whether the RFA applies to the regulatory proposal at issue. An appropriate consideration begins with an examination of the Administrative Procedure Act (APA) as it relates to the RFA.

If, under the APA or any rule of general applicability governing federal grants to state and local governments, the agency is required to publish a general notice of proposed rulemaking (NPRM), the RFA must be considered.[132] Significantly, some agencies, such as the Rural Utilities Service, have their own administrative rules that require notice and comment even though the agency's rules may be exempt from the APA. If an NPRM is not required, the RFA does not apply.

Further, only actions that qualify as rulemaking under the APA that affect small entities or small entity concerns trigger the protections of the RFA.[133] Small entities whose concerns must be accounted for include small businesses, small not-for-profit organizations, and small governmental jurisdictions—cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.[134]

What qualifies as a rulemaking under the APA?

Rules are exempt from APA requirements, and therefore from the RFA requirements, when any of the following is involved:

1. Military or foreign affairs functions of the United States.
2. Matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.
3. Rates, wages, corporate or financial structures or reorganization thereof, prices, facilities, appliances, services or allowances.[135]

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[132] 5 U.S.C. § 604(a).
[133] Atlantic Fish Spotters Ass'n v. Evans, 206 F. Supp. 2F.d 81, 93 (D. Mass. 2002).
[134] 5 U.S.C. § 601(3)-(5). See also Chapter 1 of this guide for a discussion of what qualifies as a small entity.
[135] 5 U.S.C. § 553(a).

Also exempt from the APA requirement for notice and comment rulemaking are interpretative rules.[136] Interpretative rules generally require no judgments and little by the agency on implementation, but rather interpret the language or intent expressed by Congress. Legislative rules require judgments and great discretion; an example is setting a clean air standard for the nation.

Exemptions under the APA

The D.C. District Court has addressed exemptions under the APA in determining whether the action qualifies as a rulemaking requiring notice and comment. In the following cases the courts held that the RFA did not apply because the APA requirements for notice and comment are inapplicable:

Military or foreign affairs functions of the United States. In reviewing the early RFA case, *In re Sealed Case,*[137] the D.C. District Court held that regulations such as those delineating the products subject to the ban on importation into the United States of uranium ore, uranium oxide, textiles, and coal from South Africa, fell under the foreign affairs function of the United States; thus, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking and opportunity for public participation were inapplicable. Because a notice of proposed rulemaking is not required for this rule, the Regulatory Flexibility Act, 5 U.S.C. §601 *et seq*., did not apply.[138]

Interpretative rules. In the more recent case of *National Association for Home Care v. Shalala,*[139] the plaintiffs argued that the Department of Health and Human Services failed to consider alternatives to the proposed rule as required by the RFA. The agency, however, asserted that the Balanced Budget Act (BBA) did not grant the Secretary any discretion in implementing the Interim Payment System (IPS). The court agreed, holding that the BBA was an interpretative rather than substantive rule, given its high degree of specificity regarding the implementation of the IPS. As an interpretative rule, the BBA need not comply with the RFA. The court stated generally that the RFA does not apply to interpretative rules which merely clarify or explain existing laws or regulations.[140]

Publications not subject to the APA and rate exemptions. In *American Moving and Storage Association, Inc., v. DOD*, [141] the D.C. District Court examined a notice published in the *Federal Register* by the Department of Defense announcing a significant change in procurement policy regarding its source for distance calculations for payments and audits in its transportation programs from a previously used official mileage table to a new computer software program. The plaintiffs asserted that the change would have a significant economic impact on small carriers, requiring RFA compliance. DOD asserted that the policy change was not a "rule" as defined by the RFA, and therefore, it did not

[136] SBREFA amended the RFA to bring certain interpretative rulemakings of the Internal Revenue Service within coverage of the RFA. The law now applies to those IRS rules published in the *Federal Register* that would normally be exempt from the RFA as interpretative rules, but that impose a "collection of information" requirement on small entities. For a more detailed discussion, see Chapter 1.
[137] *In re Sealed Case*, 666 F. Supp. 231, 236 (D.D.C. 1987).
[138] *Id.*
[139] National Ass'n for Home Care v. Shalala, 135 F. Supp. 2d 161, 165 (D.D.C. 2001).
[140] *Id.*
[141] American Moving and Storage Ass'n v. DOD, 91 F. Supp. 2d 132, 136 (D.D.C. 2000).

have to comply with the RFA. The court agreed with the agency and held that the procurement policy change was not a "rule" for RFA purposes. The court further found that even if the RFA definition of a rule included some procurement policy changes, the calculations for payments and audits were exempt from the definition by the APA exception relating to rates.[142] As a result, the RFA did not apply.[143]

The certification statement

The decision process

An agency may certify that no regulatory flexibility analysis is necessary when it determines that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule. However, an agency must provide a factual basis for the certification. A mere statement that there will be no effect is not sufficient. The agency must conduct an analysis demonstrating that it has considered the potential effects of the regulation.[144]

Cases in which the certification violated the RFA. In a number of cases, the certification was found to have violated the RFA.

In *Northwest Mining Association v. Babbitt*, [145] the Bureau of Land Management (BLM) published a final rule in February 1997 that would impose a bonding requirement on hardrock mining. The rule was originally proposed in 1991. While the original proposal would have set a limit on bonding requirements, the final rule contained burdensome provisions not included in the proposal—provisions on which the public, therefore, had no opportunity to comment. The BLM certified that the rule would not have a significant economic impact on a substantial number of small entities. However, the agency failed to substantiate its conclusions. In remanding the rule, the court stated that the final rule's certification violated the RFA because the factual basis for the certification that the agency provided failed to incorporate the correct definition of small entity.[146]

In *North Carolina Fisheries Association v. Daley,*[147] the District Court for the Eastern District of Virginia found that NMFS violated the RFA when it certified that there would not be a significant economic impact on a substantial number of small entities, because the fishing quota would remain unchanged. The court remanded the matter to NMFS with instructions to perform a proper analysis because even though the quota was the same, the agency provided no data to show that the quota was still valid.

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[142] 5 U.S.C. § 553(b) (1996).
[143] *Id.* at 136.
[144] North Carolina Fisheries Ass'n v. Daley, 16 F. Supp. 2d 647, 652 (E.D. Va. 1997).
[145] Northwest Mining Ass'n v. Babbitt, 5 F. Supp. 2d 9, 14 (D.D.C. 1998).
[146] *Id.* at 652.
[147] North Carolina Fisheries Ass'n v. Daley, 16 F. Supp. 2d 647 (E.D. Va. 1997).

In *Harlan Land Co. v. United States Department of Agriculture*, [148] the District Court for the Eastern District of California found the certification analysis performed by the Animal and Plant Health Inspection Services (APHIS) of the U.S. Department of Agriculture (USDA) was inadequate. APHIS had published a final rule allowing the importation of lemons, grapefruit and oranges from various areas in Argentina. APHIS prepared an economic analysis of the rule and determined that the rule would not have a significant economic impact on a substantial number of small entities. Based on that determination, APHIS did not prepare an RFA analysis.[149] Citrus growers brought suit against the USDA and APHIS, arguing that the agency violated both the APA and the RFA in issuing the rule. The economic analysis in the final rule focused on the impact that the Argentine imports would have on the supply and prices of citrus fruit in the United States and the resulting costs and benefits to domestic growers, etc. The analysis failed to consider what the costs would be if Argentine plant pests were introduced into U.S. citrus orchards. The court found that APHIS' determination of a lack of significant economic impact on a substantial number of small entities was based on its conclusion that there was a negligible risk of pest introduction. The court considered the risk assessment to be flawed and thus remanded the final rule to the defendants for consideration of the economic impact that the importation of Argentine citrus will have on small businesses.

Where the court found that certification was appropriate. In *Associated Builders and Contractors, Inc., v. Herman*, the Department of Labor suspended a revised class of employees called "helpers" on federal construction sites in 1993 and reinstated former helper regulations pursuant to a congressional mandate.[150] Regarding the RFA, the Department of Labor certified that the rule would not have a significant economic impact on a substantial number of small entities. Although the agency did not prepare a final regulatory flexibility analysis (FRFA), the court held that the Department of Labor properly published a certification in the *Federal Register* along with a statement of reasons.[151]

Size standards

It is important that an agency use the size standard contained in the Small Business Administration's small business size standard regulations,[152] promulgated by the SBA under the Small Business Act, or follow the consultation procedures outlined in section 601(3) of the RFA.

Incorrect size standard. In *Northwest Mining Association v. Babbitt*, discussed above, the court held that BLM violated the RFA because the agency failed to use the appropriate size standard as defined by the Small Business Administration (SBA). The court noted that "the RFA requires agencies to use the Small Business Administration's

[148] Harlan Land Co. v. United States Dept. of Agric., 186 F. Supp. 2d 1076 (E.D. Cal. 2001).
[149] *Id.* at 1097.
[150] Associated Builders and Contractors, Inc., v. Herman, 976 F. Supp. 1 (D.D.C. 1997).
[151] *Id.*
[152] 13 C.F.R. § 121.201 (1996).

definition of small entity."[153] Continuing, the court stated that "section 601 of the RFA sets forth, in relevant part, '[f]or the purposes of this chapter ... the term 'small entity' shall have the same meaning as the term 'small business' ....'"[154] The term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act.[155] The SBA publishes these small business definitions in 13 C.F.R. § 121.201. Division B of section 121.201 provides, in pertinent part, that mining concerns must have 500 or fewer employees to be considered "small."[156] Therefore, the standard for "small miner" which the BLM must use when performing an initial or final regulatory flexibility analysis or when certifying "no significant impact" is a 500 or fewer employee standard. By using a definition other than the SBA's, the BLM violated the procedure of law mandated by the statute. The court found that the definitions section of the RFA uses phrases such as " 'small entity' *shall have* the same meaning ..." and "'small business' *has* the same meaning ..." [157] (emphasis added). The court concluded that words such as those do not leave room for alternate interpretations by the agency. The rule was remanded to the agency.

Use of Incorrect Size Standard Cured. In *Small Business in Telecommunications v. the Federal Communications Commission (FCC)*, [158] the FCC adopted its own definition of "small business" regarding its Lower Channel Report and Order concerning a regulatory scheme for specialized mobile radio (SMR) service in the 800 to 900 MHz range. The Court of Appeals for the District of Columbia Circuit held that although the FCC failed to seek approval from the SBA for its definition, the omission did not nullify the entire rulemaking, since SBA did ultimately approve the definition prior to commencement of the lower channel auction.[159] If the agency modifies a small business size standard in the implementation of a rule, it must seek approval from the SBA Administrator.[160]

The agency must conduct an adequate analysis before certifying

The landmark legal decision recognizing an agency's failure to adequately examine the impact on affected entities before certification is the 1998 case, *Southern Offshore Fishing Association v. Daley.*[161] In that matter, the National Marine Fisheries Service (NMFS) published a proposed rulemaking to institute a 50 percent reduction in the shark fishing industry. NMFS certified that the rule would not have a significant economic impact on a substantial number of small entities. Although the agency published a FRFA at the time it finalized the rule, the court found that the agency certified without making a "reasonable, good-faith effort," prior to issuance of the final rule, to inform the public about the potential adverse effects of its proposals and about less harmful alternatives.

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[153] *Northwest Mining Ass'n*, 5 F. Supp. 2d at 15. See chapter 1 for detail on exceptions to using SBA size standards.
[154] 5 U.S.C. § 601(6).
[155] 15 U.S.C. § 632; 5 U.S.C. § 601(3).
[156] *Id.*
[157] 5 U.S.C. § 601.
[158] *Id.* at § 605(b).
[159] Small Businesses in Telecomm. v. FCC, 251 F.3d 1015, 1025 (D.C. Cir. 2001).
[160] *Id.* at 1025.
[161] *Southern Offshore Fishing*, 995 F. Supp. at 1437.

The agency continued to deny that its proposal would likely have a significant impact on a substantial number of small entities after receiving public comments challenging the certification. The court concluded that the preparing of a FRFA constituted "an attempt to agreeably decorate a stubborn conclusion" that there was no significant impact on a substantial number of small entities. The court remanded the agency's certification determination, requiring it to "undertake a rational consideration of the economic effects and potential [regulatory] alternatives."[162]

North Carolina Fisheries. The *North Carolina Fisheries* cases provide further guidance on what constitutes adequate analysis prior to certification that there will be no significant economic impact on a substantial number of small entities.

The first case arose in 1997.[163] There, the National Marine Fisheries Service (NMFS) set the 1997 quota for flounder fishing by continuing the quota from the previous year. In doing so, NMFS did not perform a regulatory flexibility analysis. Instead, the agency certified that the rule would not have a significant impact on a substantial number of small businesses because the quota remained the same from 1996 to 1997. There was no record showing that the agency did any comparison between conditions in 1996 and 1997. The court stated that "a simple conclusory statement that, because the quota was the same in 1997 as it was in 1996, there would be no significant economic impact, is not an analysis."[164] The court remanded the issue to the agency with orders to "undertake enough analysis to determine whether the quota had a significant economic impact on the North Carolina Fishery."[165] The court further ordered the department to "include in [the] analysis whether the adjusted quota will have a significant economic impact on small entities in North Carolina."[166]

The issue returned to the court in 1998.[167] The issue before the court on remand was whether the Secretary of Commerce had discharged his responsibilities under the RFA and under National Standard 8 of the Magnuson Act to perform an economic analysis.[168] After review, the court concluded that "the Secretary of Commerce acted arbitrarily and capriciously in failing to give any meaningful consideration to the economic impact of the 1997 quota regulations on North Carolina fishing communities. Instead, the Secretary has produced a so-called economic report that obviously is designed to justify a prior determination."[169] The court further stated that as part of an adequate analysis before certification, the agency must consider alternatives less burdensome to small entities.[170] The court concluded that "Congress has not intended for administrative agencies to circumvent the fundamental purposes of the RFA by invocation of the certification provision." The court felt that Secretary Daley's certification in this instance amounted to

[162] *Id.*
[163] *North Carolina Fisheries*, 16 F. Supp. 2d at 647.
[164] *Id* at 653.
[165] *Id.*
[166] *Id.*
[167] North Carolina Fisheries Ass'n v. Daley, 27 F. Supp. 2d 650 (E.D. Va. 1998).
[168] *Id.* at 660.
[169] *Id.* at 668.
[170] *Id.* at 660.

an effort to avoid the requirements of the RFA, specifically the requirement to consider alternative ways to minimize economic impacts. Because the court found that the Secretary and the agency did not uphold their responsibilities under the law, it set aside the 1997 summer flounder quota and imposed a penalty against the NMFS.

Court cases have held that the agency must account for the public comments it received challenging the initial determination that no significant economic impact was likely.[171] In *Northwest Mining Association v. Babbitt*,[172] the court addressed the Bureau of Land Management (BLM) claims that the Northwest Mining Association (NWMA) did not have standing to object to its final rule under either the APA or the RFA because it did not submit comments during the notice and comment period. The NWMA asserted that it did not need to submit comments during the notice and comment period because the BLM's original rule proposal did not properly inform it that its interests were at stake. The court agreed with the NWMA, holding that because there was no way the NWMA could have submitted comments regarding issues on which it was not informed were at stake, the agency must consider even comments not submitted during the formal notice and comment period.[173]

Direct versus indirect impact on small entities

Must the agency consider the indirect effects of the proposed regulation? It was first held in *Mid-Tex Electric Cooperative, Inc., v. Federal Energy Regulatory Commission (FERC)* that a regulatory flexibility analysis is required when an agency determines that the rule will have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule.[174] In that case, FERC proposed a rule that allowed electric utilities to include in their rate bases amounts equal to 50 percent of their investments in construction work in progress. In response to an argument that FERC "should have considered the impact of the proposed rule on wholesale and retail customers of the jurisdictional entities subject to rate regulation by the Commission," FERC stated that "the RFA does not require the Commission to consider the effect of this rule, a federal rate standard, on nonjurisdictional entities whose rates are not subject to the rule."[175]

The court agreed, reasoning that "Congress did not intend to require that every agency consider every indirect effect that any regulation might have on small businesses in any stratum of the national economy."[176] The court concluded that "an agency may properly certify that no regulatory flexibility analysis is necessary when it determines that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule."[177]

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[171] *See generally*, National Truck Equip. Ass'n v. NHTSA, 919 F.2d 1148 (6th Cir. 1990); Northwest Mining Ass'n v. Babbitt, 5 F. Supp. 2d 9 (D.D.C. 1998).
[172] *Northwest Mining Ass'n*, 5 F. Supp. 2d 9.
[173] *Id* at 13.
[174] Mid-Tex Elec. Coop v. FERC, 773 F.2d 327, 342 (D.C. Cir. 1985).
[175] *Id.* at 341.
[176] *Id.*
[177] *Id.* at 343.

In viewing this decision, the same court later held in *United Distribution Companies. v. FERC*[178] that an agency is under no obligation to conduct a small entity impact analysis of effects on entities it does not regulate. Because in this case FERC had no jurisdiction to regulate the local distribution of natural gas, it could not be required to conduct a regulatory flexibility analysis for those entities engaged in the local distribution of the gas.[179]

Although *Mid-Tex* occurred prior to the passage of the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, post-SBREFA courts have upheld its reasoning. For example, in *Motor and Equipment Manufacturers Ass'n v. Nichols,*[180] the court found that because the deemed-to-comply rule did not subject any aftermarket businesses to regulation, EPA was not required to conduct a regulatory flexibility analysis as to small aftermarket businesses. It was only obliged to consider the impact of the rule on small automobile manufacturers subject to the rule, and it met that obligation. A number of other cases have held similarly.[181]

Likewise in *American Trucking Associations v. EPA,*[182] EPA established a primary national ambient air quality standard (NAAQS) for ozone and particulate matter. At the time of the rulemaking, EPA certified the rule pursuant to 5 USC § 605(b). The basis of the certification was that EPA had concluded that small entities were not subject to the rule because the NAAQS only regulated small entities indirectly through the state implementation plans.[183] Although the court remanded the rule to the agency for non-RFA reasons, the court found that EPA had complied with the requirements of the RFA.

Similarly, in *Michigan v. EPA,*[184] EPA certified that its revised NAAQS would not have a significant economic impact within the meaning of the RFA. According to the EPA, the NAAQS itself imposed no regulations upon small entities. Instead, several states regulate small entities through the state implementation plans they are required by the Clean Air Act to develop. Because the NAAQS regulated small entities only indirectly—that is, insofar as it affected the planning decisions of the states—the EPA concluded that small entities were not "subject to the proposed regulation." The court agreed, stating that states have broad discretion in determining the manner in which they will achieve compliance with the NAAQS. In conclusion, the court stated that "a State may, if it chooses, avoid imposing upon small entities any of the burdens of complying with a revised NAAQS."[185]

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[178] United Dist. Cos. v. FERC, 88 F.3d 1105, 1170 (D.C. Cir. 1996).
[179] *Id.*
[180] Motor and Equip. Mfrs. Ass'n v. Nichols, 142 F.3d 449,467 (D.C. Cir. 1998).
[181] *See* American Trucking Ass'ns. v. EPA, 175 F.3d at 1044; Michigan v. EPA, 213 F.3d 663, 689 (D.C. Cir. 2000); Cement Kiln Recycling Coalition v. EPA, 255 F.3d 855, 868 (D.C. Cir. 2001).
[182] *American Trucking,* 175 F.3d at 1027.
[183] *Id*.
[184] *Michigan v. EPA*, 213 F.3d at 689.
[185] *Id.*

The court in *Cement Kiln Recycling Coalition v. EPA*[186] further bolstered the notion that indirect impacts should be disregarded by noting that the RFA is not intended to apply to every entity that may be targeted by the proposed regulation. The fact that the rule will have economic impacts in many sectors of the economy does not change this. The court reasoned that "requiring an agency to assess the impact on all of the nation's small businesses possibly affected by a rule would be to convert every rulemaking process into a massive exercise in economic modeling, an approach we have already rejected."[187]

An entity can otherwise experience indirect impacts through its dealings with the entity that experiences direct impacts, such as through increased after-market prices or newly required modifications to necessary equipment. Some courts have stated that this impact would likewise not require a regulatory flexibility analysis.[188]

The initial regulatory flexibility analysis

Because an agency's initial regulatory flexibility analysis cannot be the subject of litigation,[189] case law provides a detailed discussion only for the final regulatory flexibility analysis. It is important to note that although the IRFA is not judicially reviewable, a proper IRFA is necessary to provide the foundation for a good FRFA. An agency cannot develop an adequate FRFA if the IRFA did not lay the proper foundation for eliciting public comments and seeking additional economic data and information on the regulated industry's profile and regulatory impacts. Further, without an adequate IRFA, small entities cannot provide informed comments on regulatory alternatives that are not adequately addressed in the IRFA.[190]

In *Allied Local and Regional Manufacturers Caucus v. EPA*, paint manufacturers and associations of manufacturers and distributors of architectural coatings petitioned for review of EPA's regulations limiting the content of volatile organic compounds (VOCs) in consumer and commercial products such as architectural coatings, including paints. Plaintiffs alleged that EPA failed to comply with the RFA by failing to discuss the economic impact of "stigmatic harm" arising from the agency's suggestion that it may impose more stringent VOCs in the future, and of asset devaluation, in that the coatings rule allegedly will render existing product formulas valueless. The court ruled that section 603 of the RFA, which discusses IRFAs, was not subject to judicial review pursuant to section 611(c). However, the court did have the jurisdiction to determine whether the agency had met the overall requirement that the decisionmaking not be arbitrary and capricious. The court found that the EPA examined alternatives to product reformulation when creating regulations limiting content of VOCs in consumer and

[186] *Cement Kiln*, 255 F.3d at 868.
[187] *Id.*
[188] *See, e.g., Nichols*, 142 F.3d at 467; *Cement Kiln*, 255 F.3d at 868.
[189] Because § 611 of the RFA does not mention § 603, the IRFA requirement, a court would consider a pre-promulgation challenge unripe.
[190] *Southern Offshore Fishing*, 995 F. Supp. at 1434 and 1436 ("the agency could not possibly have complied with § 604 by summarizing and considering comments on an IRFA that NMFS never prepared").

commercial products, and that its decisions were neither arbitrary nor capricious. The court, therefore, found that EPA had met its obligations under the RFA.[191]

Similarly, in *U.S. Cellular Corp. v. FCC*,[192] the court noted that an IRFA is not subject to judicial review. There, the FCC adopted an order requiring wireless carriers to bear financial responsibility for enhanced 911 implementation, rather than having local government guarantee costs. Plaintiffs argued that the FCC failed to issue an IRFA and that the FRFA did not contain a description of the steps the agency took to minimize the impact on small businesses, as required by the RFA. The court held that the RFA expressly prohibits courts from considering claims of noncompliance with RFA section 603's requirement to issue an IRFA.[193]

The final regulatory flexibility analysis

General content

Section 604 of the RFA prescribes the content of the FRFA. Courts have found that an agency can satisfy the requirements of section 604 "as long as it compiles a meaningful, easily understood analysis that covers each requisite component dictated by the statute and makes the end product readily available to the public."[194] For example, in *Associated Fisheries of Maine, Inc., v. Daley*, the court stated that the Secretary of Commerce had complied with FRFA requirements because the Secretary explicitly considered numerous alternatives, exhibited a fair degree of sensitivity concerning the need to alleviate the regulatory burden on small entities within the fishing industry, adopted some salutary measures designed to ease that burden, and satisfactorily explained reasons for adopting others. Similarly, in *Alenco Communications v. FCC*,[195] the court held that the regulatory analysis was compliant with the terms of the RFA where the agency provides a lengthy analysis of the economic impact of the proposed rule on small businesses and responds to comments submitted by the Office of Advocacy and other commenters.[196]

Is a FRFA always required?

A FRFA is required in every instance where an agency finalizes a rule after being required to publish a general notice of proposed rulemaking under section 553 of the APA or any other law. The exception is when the agency certifies the rule will not have a significant economic impact on the affected entities, as discussed above.

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[191] Allied Local and Reg'l Mfrs. Caucus v. EPA, 215 F.3d 61 (D.C. Cir. 2000).
[192] U.S. Cellular Corp. v. FCC, 254 F.3d 78, 89 (D.C. Cir. 2001).
[193] *Id.*
[194] Associated Fisheries of Maine, Inc., v. Daley, 127 F.3d 104, 115 (1st Cir. 1997); Grand Canyon Air Tour Coalition v. FAA, 154 F.3d 455, 470 (D.C. Cir. 1998); National Propane Gas Ass'n v. DOT, 43 F. Supp. 2d 665, 681 (N.D. Tex. 1999); Associated Builders and Contractors, Inc., v. Herman, 976 F. Supp. 1 (D.D.C. 1997).
[195] Alenco Communications v. FCC, 201 F.3d 608 (5th Cir. 2000).
[196] *Id.* at 625.

However, in the event that the publication of an NPRM is impossible due to the emergency nature of the rule, the requirements of the RFA may be satisfied by publishing a FRFA subsequent to the rulemaking.[197] In *National Propane Gas Ass'n v. DOT,*[198] the Department of Transportation's Research and Special Programs Administration (RSPA) instituted an emergency interim final rule to address concerns about the transportation of compressed gas on highways. RSPA later modified and adopted the interim final rule as the emergency discharge control regulation for loading or unloading of cargo tank motor vehicles. The regulation required vehicle operators to shut down immediately if they learned of a gas leakage.

Gas companies brought suit alleging various violations of the APA and RFA. Plaintiffs challenged the rule on the grounds that defendants failed to prepare a FRFA, as required by the RFA. RSPA argued that the rule was not subject to the RFA because the RFA applies only to the rules for which an agency is required to publish a notice of proposed rulemaking pursuant to section 553 of the APA. RSPA asserted that the APA did not require a notice of proposed rulemaking here because of the emergency nature of the rule. Nevertheless, RSPA claimed that in preparing preliminary and final regulatory evaluations under Executive Order 12866, the agency did analyze the impact of the interim final rule and the final rule on all affected parties, including small businesses. The court agreed, and found that although the agency did not prepare a FRFA, all of the elements of a FRFA were available throughout their summary of such analysis published in the *Federal Register*. The court thus found that RSPA complied with each of the requirements found in the RFA, including responding to comments and consideration of alternatives. The court asserted that a preliminary regulatory evaluation was available in the docket for the public to provide comment, and it also found that to require an additional analysis by the agency would be duplicative.

Considering alternatives to the final rule

Section 604 of the RFA requires the agency to consider alternatives that would achieve the statutory objectives while lessening the regulatory burden on affected small entities. This involves making a "reasonable, good-faith effort to canvass major options and weigh their probable effects."[199]

In *AML International, Inc., v. Daley***,**[200] the National Marine Fisheries Service implemented a management plan for the spiny dogfish industry that imposed quotas that effectively shut down the industry for the next five years. Plaintiffs asserted that NMFS failed to comply with the RFA because the NMFS failed to consider alternatives. The court found that NMFS' consideration of alternatives was sufficient. NMFS considered and rejected alternatives because they did not meet the mandate of the Magnuson-Stevens Act or provide long-term economic benefits greater than those of the proposed action.[201]

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[197] *National Propane Gas Ass'n*, 43 F. Supp. 2d at 681.
[198] *Id.*
[199] National Ass'n of Psychiatric Health Sys., v. Shalala, 120 F. Supp. 2d 33, 42 (D. D.C. 2000).
[200] AML Int'l v. Daley, 107 F. Supp. 2d 90 (D. Mass. 2000).
[201] *Id.* at 105.

Similarly, in *Ace Lobster Co. v. Evans*, [202] the Department of Commerce imposed limitations on the number of lobster traps that could be used in a particular area. Lobster fisherman and business owners alleged that the Department of Commerce implemented the regulations in violation of the APA, the Magnuson-Stevens Act, and the RFA. The basis for the assertion was that during the comment period, numerous commenters submitted information about an alternative plan for the lobster fishery, which was approved by the Lobster Conservation and Management Team and submitted for consideration as an alternative. The agency rejected the alternative because it would likely increase the number of lobster traps in offshore waters and increase the lobster mortality rate. Plaintiffs alleged that the defendant did not adequately analyze the selected alternative or consider the alternative that would mitigate the negative economic impacts on offshore fishing fleets, and that the agency's concern for verification of prior fishing fleets was unfounded.[203] The court stated that under the standard for judicial review of compliance with the RFA, the court reviews only whether the agency conducted a complete IRFA and FRFA in which it described steps to minimize the economic impact of its regulations on small entities and discussed alternatives, providing a reasonable explanation for rejections. The RFA permits the agency to select an alternative that is more economically burdensome if there is evidence that other alternatives would not accomplish the objectives of the statute. Because the agency examined the alternative and decided that, while less onerous, it did not achieve the conservation goals, it met its obligations under the RFA. The court further found that there was sufficient analysis and explanation of the other rejected alternatives.[204]

What kinds of alternatives must the agency consider? In *Associated Fisheries of Maine*, the court first held that section 604 does not require that a FRFA address every alternative, only significant ones.[205] The RFA does permit the agency to select an alternative that is more economically burdensome if there is evidence that other alternatives would not accomplish the stated objectives of the applicable statutes.[206]

What is a *significant* alternative? This question was recently clarified by the court in *Little Bay Lobster Co. v. Evans*.[207] There, the court stated that "significant alternatives" are those with potentially lesser impacts on small entities (versus large-scale entities) as a whole, and not those that may lessen the regulatory burden on some particular small entity. Further, the agency is not obligated under the RFA to address alternatives that might have had lesser impacts on some small entities *vis a vis* other similarly affected small entities.[208]

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[202] Ace Lobster Co. v. Evans, 165 F. Supp. 2d 148 (D. R.I. 2001).
[203] *Id.* at 185.
[204] *Id.*
[205] *Associated Fisheries of Maine*, 127 F.3d at 115; *see also Grand Canyon Air Tour Coalition*, 154 F.3d at 470 and Blue Water Fishermen's Ass'n v. Mineta, 122 F. Supp. 2d 150, 178 (D. D.C. 2000).
[206] *Associated Fisheries of Maine*, 127 F.3d at 114.
[207] Little Bay Lobster Co v. Evans, 2002 WL 1005105, Slip. Op. (D. N.H. May 16, 2002).
[208] *Id.* at 25.

In *Hall v. Evans*, [209] the Department of Commerce determined that the monkfish fishery was overfished. To address the problem, the agency implemented a fishery management plan to prescribe landing limits for vessels holding limited access monkfish permits. The limits allowed categories A and C vessels using trawl gear to land up to 1,500 pounds of monkfish tailweight per day at sea, while vessels using any gear other than trawl or "mobile" gear may land up to 300 pounds of monkfish tailweight per day at sea. The plaintiffs filed suit asserting that the regulations violated the Magnuson Act and the RFA. The plaintiffs asserted that the defendant's RFA analysis: (1) failed to recognize the costs of forcing closures of the directed monkfishing industry within 4 years, supposedly to allow the industry to receive positive revenue benefits after 20 years; (2) forced particularly harsh consequences on small businesses; and (3) failed to conduct an assessment of meaningful and more gradual restrictions in order to avoid severe costs to small businesses. Plaintiffs asserted that neither the IRFA nor the FRFA provided an assessment of the real economic impact on small entities in that the IRFA failed to assess the number and quality of vessels affected by the regulations and failed to address the disparity in landing allocations between different gear types. Although the regulations were set aside for violation of the Magnuson Act, the court found no violation of the RFA. With respect to the RFA allegations, the court found that there was enough evidence in the IRFA to show that the defendants considered both the economic effect of the fishery plan as a whole upon small entities and less onerous alternatives.[210]

What kind of description of the alternatives considered must the agency include in the FRFA? The RFA requires a statement of the factual, policy, and legal reasons for selecting the alternative adopted by the final rule and why each one of the other significant alternatives to the rule considered by the agency that affect the impact on small entities was rejected.

In *Ashley County Medical Center v. Thompson*, [211] the Department of Health and Human Services imposed upper payment limit (UPL) regulations that would reduce the upper limit on what states could reimburse locally owned public hospitals for services to Medicaid beneficiaries. The plaintiffs alleged that the FRFA failed to describe the steps the agency had taken to minimize the significant economic impact on hospitals, and failed to discuss any affirmative steps the agency had taken or intended to take to mitigate the injury that the 2002 UPL rule would cause to public hospitals. The court, noting that the RFA requires only that the agency describe steps taken and not that the agency take any particular steps, stated that if there were no steps that could have been taken to minimize the impact on small businesses, then the statutory requirement would have been met simply by reporting that information. The court noted that the agency had provided a description of the alternatives considered and rejected in the *Federal Register*, and thus all the requirements of the RFA were clearly satisfied.[212]

[209] Hall v. Evans, 165 F. Supp. 2d 114 (D.R.I. 2001).
[210] *Id.* at 147.
[211] Ashley County Med. Ctr. v. Thompson, 205 F. Supp. 2d 1026 (E.D. Ark. May 13, 2002).
[212] *Id.*

Conversely, in *Nat'l Assoc. of Psychiatric Health Sys. v. Shalala*,[213] the plaintiffs challenged an interim final rule promulgated by the Department of Health and Human Services (HHS) that required a face-to-face evaluation of patients within one hour after the patient has been placed in restraints or seclusion. The plaintiffs argued that the Secretary failed to conduct an adequate analysis before adopting the one-hour provision. The court agreed with the plaintiffs, stating that it could not find that the Secretary made a good-faith effort to canvass major alternatives and weigh their probable effects.[214] Specifically, the Secretary did not obtain data or analyze available data on the impact of the final rule on small entities, nor did she properly assess the impact the final rule would have on small entities. The court stated that by these omissions the Secretary totally failed to comply with section 5 of section 604(a) of the RFA.[215] The court thus remanded the matter to HHS for completion of a compliant FRFA.[216]

However, in *Southern Offshore Fishing Ass'n v. Daley*,[217] the court stated that the agency's consideration of alternatives was inadequate. Particularly troublesome to the court was the "agency's apparently superficial analysis of less restrictive alternatives to the quota reduction. After extensive discussion and summary of its statistical modeling, [the agency's] report devotes only four of fifty pages to considering potential alternatives."[218]

Exceptions to the requirement of considering alternatives

- Where uniform requirements are mandated by statute, a statement to that effect by the implementing agency obviates the need to solicit or consider proposals which include differing compliance standards.[219]

- Where the Secretary is not granted the authority to examine alternatives in implementing the regulation.[220]

Analysis of the economic impact

What type of analysis must the agency conduct? It is now well established that the RFA does not require an economic analysis, per se.[221] Rather, the RFA mandates only that the agency describe the steps it took "to minimize the economic impact on small entities consistent with the stated objectives of applicable statutes."[222] Neither cost-benefit analysis nor economic modeling is specifically required. However, such an

[213] National Ass'n of Psychiatric Health Sys. v. Shalala, 120 F. Supp. 2d 33 (D.D.C. 2000).
[214] *Id.* at 44.
[215] *Id.*
[216] *Id. at 42.*
[217] Southern Offshore Fishing Ass'n v. Daley, 995 F. Supp. 1411 (M.D. Fla. 1998).
[218] *Southern Offshore Fishing Ass'n.* at 1437.
[219] Greater Dallas Home Care Alliance v. United States, 10 F. Supp. 2d 638, 648 (N.D. Tex. 1998).
[220] Greater Dallas Home Care Alliance v. United States, 36 F. Supp. 2d 765, 769 (N.D. Tex. 1999).
[221] *Alenco Communications*, 201 F.3d at 625; *see also Ashley County Med. Ctr* 205 F. Supp. 2d at 1026; and *Ace Lobster*, 165 F. Supp. 2d at 184.
[222] *Alenco Communications*, 201 F.3d at 625.

examination may be required by the underlying statute or E.O. 12866, working in concert with the RFA.

An agency can satisfy the requirements of an economic impact analysis by providing 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.[223] Courts have stated that sufficient analysis and explanations for the rejection of alternatives are all that is necessary to satisfy this requirement.[224]

Where the majority of businesses likely to experience impacts are deemed small, it follows that any attempt to reduce the adverse economic impacts of a regulation aimed at them is necessarily an attempt to minimize the negative effects of the regulation on small business.[225]

What is the relevant economic impact that agencies should consider? For the purpose of flexibility analysis, the relevant economic "impact" is the impact of compliance.[226]

The RFA requires only that the agency consider the economic effect on the entity, and not the effect on specific revenue earned.[227] This means that the agency need not consider how one particular element of the affected entity's business is affected. Rather, the agency should evaluate the regulation's entire effect.

What type of information should the agency consider? The agency should consider economic data and information regarding the regulated industry's profile and the anticipated regulatory impacts. The agency needs to consider the scope of the problem and the small business contribution to that problem. If necessary, the agency should seek additional information of this type through public comments, outside research, stakeholder meetings, etc.

It is important that the agency appropriately consider all relevant information. It has been held that although an agency has considerable discretion to act on the basis of less than perfect information when performing the analysis of the rule's economic impact on small entities, it is not permissible to omit known information in order to skew the results.[228]

In *North Carolina Fisheries Ass'n v. Daley*,[229] the court examined the agency's economic analysis. In performing the analysis, the Secretary of Commerce utilized criteria employed internally by the National Marine Fisheries Service (NMFS) in evaluating the economic impacts of regulations under the RFA. Thus, the Secretary considered the

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[223] *Id.*
[224] *Ace Lobster*, 165 F. Supp. 2d at 185.
[225] *Associated Fisheries of Maine*, 127 F.3d at 115.
[226] *Mid-Tex*, 773 F.2d at 342.
[227] Washington v. Daley, 173 F.3d 1158, 1170 (9th Cir. 1999).
[228] *North Carolina Fisheries*, 27 F. Supp. 2d at 660.
[229] *Id.*

following criteria:[230]

Criterion 1: Does the action result in revenue loss of more than 5 percent for 20 percent or more of the participants?

Criterion 2: Does the action result in 2 percent of the entities ceasing operations?

Based on the NMFS's internal guidelines, the Secretary found that there would be no significant economic impact on a substantial number of small businesses arising from the 1997 summer flounder quota. In making this determination, the economic analysis used the total number of vessels to be issued moratorium permits as "the universe for the evaluation of impacts." The small entities or communities studied constituted the whole state of North Carolina. Examining the unadjusted 1997 quota first, the economic analysis stated that it was "possible" that criterion 1 would be triggered by reducing the income of more than 20 percent of the entire North Carolina fleet by more than 5 percent. The economic analysis next considered the NMFS's criterion under the initial 1997 quota adjustment. Under the adjustment, the economic analysis determined that 57 percent of the vessels with home ports in North Carolina are projected to have revenue reductions of greater than 5 percent. The economic analysis further maintained that an additional 43 percent of North Carolina's flounder fleet may have reduced revenues by 25 percent or more. Despite this assessment, the economic analysis concluded that there were no significant economic impacts and asserted that any adverse effects arising from the initial 1997 quota adjustment were offset by previous revenues the fishermen had earned from overfishing.[231] The court concluded that the Secretary prepared an economic analysis utterly lacking in compliance with the requirements of the RFA. In the first place, the Secretary did not consider a community any smaller than the entire state of North Carolina. In the second place, the Secretary completely ignored readily available data that would have shown the number of fishing vessels likely to experience the impacts of the agency's regulatory actions. The agency's economic analysis indicating that there would be no significant economic impact on a substantial number of small entities was the result of impermissibly considering too large a community and ignoring readily available data.[232]

Public comments

Ordinarily, an agency must seek public comments regarding each proposal and the basis for the agency's decision in each case. The agency must be responsive to the comments it receives, accounting for the dismissal of significant alternatives proposed in the IRFA or by the commenters. Failure to seek public comments or to be responsive frustrates important public participation and will result in a breach of the RFA. An agency might consider eliciting information such as additional economic data, or information regarding the regulated industry's profile and regulatory impacts through public comments.

[230] It should be noted that NMFS no longer uses these criteria for its RFA analyses.
[231] *North Carolina Fisheries*, 27 F. Supp. 2d at 660.
[232] *Id.*

Must an agency always seek public comment? An agency need not seek comment on information that is supplementary to the decision. That is to say, an agency is entitled to rely on information not exposed to comment only as long as it is not substantially related to the agency's rationale.[233] Any information relied on in the analytical process at all, however, must be included in the IRFA.

Judicial review

The 1996 SBREFA amendment provides, for the first time, for judicial review of agency action under the RFA and allows the Chief Counsel for Advocacy to file as *amicus curiae* (friend of the court) in regulatory appeals.

[233] National Mining Ass'n v. Chao, 160 F. Supp. 2d 47, 88 (D.D.C. 2001).

CHAPTER 6 ADDITIONAL RFA AND SBREFA REQUIREMENTS

This chapter addresses additional agency responsibilities beyond the rulemaking process. Under the RFA and SBREFA, agencies have ongoing responsibilities toward small entities with respect to (1) providing notice of rulemakings, (2) reviewing existing rules, (3) developing compliance guides, (4) establishing penalty reduction policies, and (5) offering compliance assistance. In addition, SBREFA created a process for small businesses to report excessive federal agency enforcement actions.

Semi-annual regulatory agenda

Section 602 of the RFA requires federal agencies to publish a regulatory flexibility agenda in the *Federal Register* during April and October of each year. Each agency is required to list all rules it expects to propose or promulgate that are likely to have a significant economic impact on a substantial number of small entities. To be useful to small entities, the regulatory flexibility agenda should include a realistic assessment of the regulations under consideration by the agency for development in the coming year. Agencies generally prepare and publish their regulatory flexibility agenda with the unified regulatory agenda required by Executive Order 12866.

The regulatory flexibility agenda must contain:

- A brief description of the subject area of any rule the agency expects to propose or promulgate that is likely to have a significant economic impact on a substantial number of small entities. (See Chapter 1 of this guide for a discussion of how to certify a rule.)

- A summary of the nature of each such rule under consideration, the objectives and the legal basis for issuing each rule, and an approximate schedule for completing action on any rule for which an agency has issued a general notice of proposed rulemaking (NPRM).

- The name and telephone number of an agency official knowledgeable about the rule.

The RFA requires agencies to endeavor to provide direct notification of the agenda to small entities or their representatives, or to publish the agenda in publications that small entities are likely to receive, and to invite comments in the agenda.[234]

The law also requires each agency to transmit its regulatory flexibility agenda to the Chief Counsel for Advocacy for comment, if any. The Office of Advocacy welcomes the

[234] See § 609 of the RFA regarding the outreach to small entities to obtain needed comment during agency rulemaking. An example of a useful outreach tool is the U.S. Department of Transportation's Docket Management System (DMS). DMS offers a service (listserv) to which a small entity can subscribe and tailor to receive notification when certain documents reach the DMS.

opportunity to provide an agency with input on a pre-publication draft of the agency's regulatory flexibility agenda. Advocacy will review the draft agenda and may provide comment on its completeness and the agency's assessment as to whether a given rule will or will not affect small entities. At a minimum, each agency must provide the Office of Advocacy with a copy of the regulatory flexibility agenda upon its publication. If the agenda is submitted upon publication, the Office of Advocacy will offer comments; however, the agency and the small entities reviewing the agenda will not receive the benefit of Advocacy's pre-publication review.

Periodic review of existing rules

Section 610 of the RFA requires agencies to review all regulations that have a significant economic impact on a substantial number of small entities within 10 years of their adoption as final rules.[235] The purpose of the review is to assess the impact of existing rules on small entities and to determine whether the rules should be continued without change, amended, or rescinded (consistent with the objectives of applicable statutes) to minimize impacts on small entities. Agency practices pursuant to section 610 vary.[236]

Each year, agencies must publish in the *Federal Register* and solicit public comments on a list of the rules the agency will review under section 610 over the succeeding 12 months. The list must briefly describe each rule, including the need and legal basis for it. At a minimum, agencies must review each individual rule that has a significant economic impact on a substantial number of small entities within 10 years of the rule's promulgation. Agencies should have reviewed all rules promulgated prior to 1980 by January 1, 1991. Agency compliance with section 610 of the RFA is subject to judicial review.

In advance of publishing the agency's section 610 list in the *Federal Register*, the Office of Advocacy recommends that each agency provide Advocacy with notice of the rules the agency is considering for review. The Office of Advocacy may, if practicable, provide feedback to the agency on the rules selected for section 610 review. Agencies are encouraged to contact Advocacy as early in the process as possible to enable Advocacy to assist in identifying rules for review.

Following publication of the *Federal Register* notice, Advocacy can assist with outreach to small entities subject to the regulations under review to obtain comment on the rules. For instance, the Office of Advocacy can help identify small entities to appear at agency hearings or stakeholder meetings on the rules under review. Through Advocacy's network of Regional Advocates, the Office of Advocacy can spread the word to small entities that do not otherwise have a Washington, D.C., presence.

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[235] In 2007, the Office of Advocacy issued a Best Practices document to assist agencies in their section 610 compliance. See Appendix J on p. 131

[236] *See generally Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary* (GAO/GGD-99-55, April 1999.)

In reviewing rules to minimize impacts on small entities, agencies must consider the following:

- The continued need for the rule.
- The nature of complaints or comments received concerning the rule from the public.
- The complexity of the rule.
- 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.
- The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed since adoption of the rule.

During the review process, the Office of Advocacy encourages each agency to contact trade associations that represent small entities affected by the rules under review. The Office of Advocacy can help agencies identify relevant trade associations and individual small entities affected by the rule. Small entities and their representatives can provide the agency with information on the rule's impacts, as well as recent industry developments to aid in the agency's analysis and valuable insights on the factors listed above.

Upon conclusion of the agency's review, it is beneficial to publish in the *Federal Register* the agency's determination of what, if any, action it will take pursuant to the review. Federal agencies may also find it helpful to coordinate the section 610 review process with its preparation for and publication of the agency's semi-annual regulatory flexibility agenda.

Small entity compliance guides

For each rule (or related series of rules) requiring a final regulatory flexibility analysis, section 212 of SBREFA requires the agency to publish one or more small entity compliance guides. Agency compliance with this requirement is varied.[237] In other words, unless the agency is going to certify that the rule will not have a significant economic impact on a substantial number of small entities, the agency must issue a small entity compliance guide, and designate it as such. As appropriate to the rule, Advocacy urges agencies to write the small entity compliance guide in plain and simple language. It should be readily understandable from the perspective of small entities subject to the rule. The guide is to inform a small entity of its obligations and responsibilities under the rule. It may be appropriate to prepare separate guides for different classes or groups of small entities. The guides may cover federal and state requirements affecting the small entities subject to the rule.[238]

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[237] *See generally Regulatory Reform: Compliance Guide Requirement Has Had Little Effect on Agency Practices* (GAO-02-172, December 2001).

[238] *See* § 215 of the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 857 (codified at 5 U.S.C. § 601 et seq.).

In preparing a small business compliance guide, agencies should look to the small entity comments in the rulemaking record as one indicator of the type of questions to answer or issues to clarify in the compliance guide. In addition, it would be beneficial for the agency to contact small entities subject to the rule (or their trade associations) to solicit input on topics to address in the compliance guide. Agencies may engage the assistance of outside consultants and/or trade associations in the drafting and dissemination process. Small entities and their trade associations can also provide recommendations on the best venue for distribution of the compliance guides, through the agency website and/or through small business associations and organizations.

Most important, to be helpful to small entities, the agency should issue the compliance guide shortly after issuance of the final rule and well before the deadline for small entity compliance. To accomplish this, an agency should include development of the compliance guide in the rule development timetable and planning process. As with the regulatory analyses required under the RFA, the agency should anticipate the need to allocate appropriate personnel and resources toward developing the compliance guide at the inception of the rule development process.

Although the compliance guide requirement under SBREFA is not specific in many regards as to what agencies are required to do, Advocacy has noted several instances in which agencies have failed to meet even the most basic requirements of the statute. For instance, the FAR Council[239] publishes a list of rules for which a FRFA was prepared. This is not a compliance guide.

Compliance guides issued pursuant to section 212 are not subject to judicial review under SBREFA; however, the content of the compliance guide may serve as evidence of the reasonableness or appropriateness of any proposed fines, penalties, or damages in a civil or administrative action against a small business for a violation.[240]

Informal compliance assistance

Section 213 of SBREFA acknowledges the importance of compliance assistance and directs agencies that regulate small entities to establish a practice of answering inquiries from small entities. Agencies are to provide information and advice about compliance, helping small entities interpret and apply the law to specific facts provided by the small entity making the inquiry. As with the content of the compliance guides, guidance given by agencies on how the law is to be applied to a specific factual situation provided by the

[239] The Federal Acquisition Regulation (FAR) Council prepares and issues revisions to the uniform policies and procedures for acquisition by all executive agencies. The FAR Council does this in conjunction with the Defense Acquisition Regulations (DAR) Council and the Civilian Agency Acquisition (CAA) Council. 48 C.F.R § 1 (2000).

[240] Sections 231–233 of SBREFA amended the Equal Access to Justice Act (EAJA). These provisions expanded the ability of parties in litigation with the government to recover attorney fees under that law. In administrative and judicial proceedings, if the government's demand to enforce a party's compliance with a statutory or regulatory requirement is unreasonable when compared with the judgment or decision, the party may be entitled to attorney fees and other expenses related to defending against the action. SBREFA increased the allowable attorney fees from $75 per hour to $125 per hour.

small entity may be considered evidence of the reasonableness or appropriateness of proposed fines, penalties, or damages imposed on the small entity. Under this section, and using existing resources as practicable, agencies are to institute a practice of providing informal compliance assistance. Agencies were required to establish a program to provide informal compliance assistance within one year of SBREFA's enactment in 1996 and to report to Congress on their programs no later than two years after enactment.[241]

Regulatory enforcement fairness

Section 222 of SBREFA establishes a process for small businesses to register complaints about excessive enforcement actions. Pursuant to the law, the Administrator of the U.S. Small Business Administration has designated a "Small Business and Agriculture Regulatory Enforcement Ombudsman" (the "Ombudsman") and established a Small Business Regulatory Fairness Board (the "Fairness Board") in each of the SBA's 10 regions.

Each small business regulatory fairness board advises the Ombudsman on small business matters relating to agency enforcement activities and assists the Ombudsman with the preparation of the annual report to Congress. The fairness boards have the authority to hold hearings. Fairness board members are small business owners and operators appointed by the SBA Administrator after consultation with the chairperson and ranking minority members of the House and Senate Committees on Small Business.

The Ombudsman has established a process to receive comments from small businesses on agency enforcement activities and, when appropriate, the Ombudsman passes such comments on to the agency for review and response. The Ombudsman is required to report annually to Congress on agency enforcement efforts based on comments received from small business concerns and from the regulatory fairness boards.

For more information on the Ombudsman, please visit *http://www.sba.gov/ombudsman/*.

Penalty reduction policies

Agencies regulating activities of small entities are required, under section 223 of SBREFA, to establish a policy or program to provide for the reduction (and, under appropriate circumstances, the waiver) of civil penalties for violations of a statutory or regulatory requirement by a small entity. SBREFA grants agencies broad discretion with respect to the scope of their penalty reduction and waiver policies.[242] Agencies were to implement their small entity penalty reduction and waiver programs within one year of

[241] The Committee on Small Business and the Committee on Governmental Affairs of the U.S. Senate and the Committee on Small Business and the Committee on the Judiciary of the U.S. House of Representatives were to receive agency reports required under sections 213 and 223 of SBREFA.

[242] *See generally Regulatory Reform: Implementation of Selected Agencies' Civil Penalty Relief Policies for Small Entities* (GAO-01-280, February 2001). The Office of Advocacy maintains that agencies should define small entities in accordance with section 601 of the RFA.

the enactment of SBREFA in 1996 and to report on their programs to Congress one year later.[243] Under appropriate circumstances, an agency may consider the ability to pay as a factor in determining penalty assessments on small entities.

Policies or programs established by agencies should contain conditions or exclusions that may include, but are not limited to:

- Requiring a small entity to correct the violation within a reasonable period of time.
- Limiting the applicability of the policy to violations discovered through participation by a small entity in a compliance assistance or audit program operated or supported by the agency or a state.
- Excluding small entities that have been subject to multiple enforcement actions by the agency.
- Excluding violations involving willful or criminal conduct.
- Excluding violations that pose serious health, safety or environmental threats.
- Requiring a good-faith effort to comply with the law.

Congressional review

Section 251 of SBREFA, also known as the Congressional Review Act, requires agencies to provide Congress with notice of final agency rulemaking actions and the opportunity to review a "major rule" before it becomes effective.[244] Before a final rule can become effective, the agency promulgating the rule must submit a report to the House of Representatives, the Senate, and the Comptroller General of the U.S. Government Accountability Office (GAO).[245] The report must contain the following information:

- A copy of the rule.
- A concise general statement about the purpose of the rule, including whether it is a "major rule."[246]
- The proposed effective date of the regulation.

In addition, the agency is required to include with its report to the Comptroller General, and make available to both houses of Congress, the following information:

- A copy of the cost-benefit analysis of the rule, if any.
- The agency's actions relevant to sections 603, 604, 605, 607, and 609 of the RFA.

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[243] Approximately 22 of the 77 agencies that assess penalties submitted a report pursuant to section 223 of SBREFA. House of Representatives Report 106-8, Part I, pp. 5-6.
[244] Codified at Chapter 8 of title 5, United States Code.
[245] 5 U.S.C. § 801. The GAO's website, *www.gao.gov*, includes information on major rules, including a form for submitting a rule under the Congressional Review Act.
[246] A "major rule" is a rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) finds has resulted or is likely to result in an annual impact on the economy of $100 million or more; have a major impact on an industry, government, or consumers; or have an effect on competition, productivity, or international trade. 5 U.S.C. § 804(2).

- The agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995.[247]

Major rules cannot take effect until the end of a 60-legislative-day period beginning on the latter of: (1) the date Congress receives the agency's report or (2) the date of the rule's publication in the *Federal Register*. Congress may disapprove or rescind a rule by a joint resolution of disapproval, subject to a presidential veto.[248]

[247] 2 U.S.C. § 1501.

[248] This congressional authority was first used in S. J. Res. 6, introduced in accordance with 5 U.S.C. § 802, passed the House and Senate, and was signed into law on March 20, 2001 to prevent an ergonomics regulation issued by the Occupational Safety and Health Administration from going into effect.

CONCLUSION

The RFA does not seek preferential treatment for small entities, does not require agencies to adopt regulations that impose the least burden on small entities, and does not mandate exemptions for small entities.

Rather, as this guide has illustrated, the RFA establishes an analytical process for determining how public policy issues can best be achieved without erecting barriers to competition, stifling innovation, or imposing undue burdens on small entities. In so doing, it seeks a level playing field for small entities, not an unfair advantage.

This guide is designed to help institutionalize these concepts so that they become part of a regulatory agency's analytical fiber. The SBA's Office of Advocacy hopes that this guide helps to achieve this objective.

APPENDIX A THE REGULATORY FLEXIBILITY ACT

The following text of the Regulatory Flexibility Act of 1980, as amended, is taken from Title 5 of the United States Code, sections 601–612. The Regulatory Flexibility Act was originally passed in 1980 (P.L. 96-354). The act was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121).

Congressional Findings and Declaration of Purpose

(a) The Congress finds and declares that —

(1) when adopting regulations to protect the health, safety and economic welfare of the Nation, Federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public;

(2) laws and regulations designed for application to large scale entities have been applied uniformly to small businesses, small organizations, and small governmental jurisdictions even through the problems that gave rise to government action may not have been caused by those smaller entities;

(3) uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands including legal, accounting and consulting costs upon small businesses, small organizations, and small governmental jurisdictions with limited resources;

(4) the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace, discouraged innovation and restricted improvements in productivity;

(5) unnecessary regulations create entry barriers in many industries and discourage potential entrepreneurs from introducing beneficial products and processes;

(6) the practice of treating all regulated businesses, organizations, and governmental jurisdictions 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;

(7) alternative regulatory approaches which do not conflict with the stated objectives of applicable statutes may be available which minimize the significant economic impact of rules on small businesses, small organizations, and small governmental jurisdictions;

(8) the process by which Federal regulations are developed and adopted should be reformed to require agencies to solicit the ideas and comments of small businesses, small organizations, and small governmental jurisdictions to examine the impact of proposed and existing rules on such entities, and to review the continued need for existing rules.

(b) It is the purpose of this Act [enacting this chapter and provisions set out as notes under this section] to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. 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.

Regulatory Flexibility Act

§ 601 Definitions
§ 602 Regulatory agenda
§ 603 Initial regulatory flexibility analysis
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§ 601 Definitions

For purposes of this chapter —

(1) the term "agency" means an agency as defined in section 551(1) of this title;
(2) the term "rule" means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title, or any other law, including any rule of general applicability governing Federal grants to State and local governments for which the agency provides an opportunity for notice and public comment, except that the term "rule" does not include a rule of particular applicability relating to rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services, or allowances therefor or to valuations, costs or accounting, or practices relating to such rates, wages, structures, prices, appliances, services, or allowances;
(3) the term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;
(4) the term "small organization" means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;
(5) the term "small governmental jurisdiction" means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the Federal Register;
(6) the term "small entity" shall have the same meaning as the terms "small business," "small organization" and "small governmental jurisdiction" defined in paragraphs (3), (4) and (5) of this section; and
(7) the term "collection of information" —

(A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either —

(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons, other than agencies, instrumentalities, or employees of the United States; or

(ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes; and

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

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

§ 602. Regulatory agenda

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

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

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

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

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

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

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

§ 603. Initial regulatory flexibility analysis

(a) Whenever an agency is required by section 553 of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretative rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities. The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule. The agency shall transmit a copy of the initial regulatory flexibility analysis to the Chief Counsel for Advocacy of the Small Business Administration. In the case of an interpretative rule involving the internal revenue laws of the United States, this chapter applies to interpretative rules published in the Federal Register for codification in the Code of Federal Regulations, but only to the extent that such interpretative rules impose on small entities a collection of information requirement.

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

(1) a description of the reasons why action by the agency is being considered;

(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;

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

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

(5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

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

(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

(3) the use of performance rather than design standards; and

(4) an exemption from coverage of the rule, or any part thereof, for such small entities.

§ 604. Final regulatory flexibility analysis

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

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

(2) a 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;

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

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

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

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

§ 605. Avoidance of duplicative or unnecessary analyses

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

(b) Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.
(c) In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.

§ 606. Effect on other law

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

§ 607. Preparation of analyses

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

§ 608. Procedure for waiver or delay of completion

(a) An agency head may waive or delay the completion of some or all of the requirements of section 603 of this title by publishing in the Federal Register, not later than the date of publication of the final rule, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the provisions of section 603 of this title impracticable.
(b) Except as provided in section 605(b), an agency head may not waive the requirements of section 604 of this title. An agency head may delay the completion of the requirements of section 604 of this title for a period of not more than one hundred and eighty days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 of this title impracticable. If the agency has not prepared a final regulatory analysis pursuant to section 604 of this title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency.

§ 609. Procedures for gathering comments

(a) When any rule is promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule or the official of the agency with statutory responsibility for the promulgation of the rule shall assure that small entities have been given an opportunity to participate in the rulemaking for the rule through the reasonable use of techniques such as—

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

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

(3) the direct notification of interested small entities;

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

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

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

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

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

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

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

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

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

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

(d) For purposes of this section, the term “covered agency” means the Environmental Protection Agency and the Occupational Safety and Health Administration of the Department of Labor.

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

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

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

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

§ 610. Periodic review of rules

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

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

(1) the continued need for the rule;

(2) the nature of complaints or comments received concerning the rule from the public;

(3) the complexity of the rule;

(4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

(5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

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

§ 611. Judicial review

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

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

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

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

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

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

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

(A) remanding the rule to the agency, and

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

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

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

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

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

§ 612. Reports and intervention rights

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

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

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

APPENDIX B SMALL BUSINESS BY THE NUMBERS

Frequently Asked Questions About Small Business

What is a small business?
The Office of Advocacy defines a small business for research purposes as an independent business having fewer than 500 employees. Firms wishing to be designated small businesses for government programs such as contracting must meet size standards specified by the U.S. Small Business Administration (SBA) Office of Size Standards. These standards vary by industry; see www.sba.gov/size.

How important are small businesses to the U.S. economy?
Small firms:

- Represent 99.7 percent of all employer firms.
- Employ just over half of all private sector employees.
- Pay 44 percent of total U.S. private payroll.
- Have generated 64 percent of net new jobs over the past 15 years.
- Create more than half of the nonfarm private gross domestic product (GDP).
- Hire 40 percent of high tech workers (such as scientists, engineers, and computer programmers).
- Are 52 percent home-based and 2 percent franchises.
- Made up 97.3 percent of all identified exporters and produced 30.2 percent of the known export value in FY 2007.
- Produce 13 times more patents per employee than large patenting firms; these patents are twice as likely as large firm patents to be among the one percent most cited.

Source: U.S. Dept. of Commerce, Bureau of the Census and International Trade Admin.; Advocacy-funded research by Kathryn Kobe, 2007 (**www.sba.gov/advo/research/rs299tot.pdf**) and CHI Research, 2003 (**www.sba.gov/advo/research/rs225tot.pdf**); U.S. Dept. of Labor, Bureau of Labor Statistics.

What share of net new jobs do small businesses create?
Firms with fewer than 500 employees accounted for 64 percent (or 14.5 million) of the 22.5 million net new jobs (gains minus losses) between 1993 and the third quarter of 2008. Continuing firms accounted for 68 percent of net new jobs, and the other 32 percent reflect net new jobs from firm births minus those lost in firm closures (1993 to 2007).

Source: U.S. Dept. of Labor, Bureau of Labor Statistics, Business Employment Dynamics. Note that the methodology used for the figures above counts job gains or losses in the actual class size where they occurred.

How many businesses open and close each year?
An estimated 627,200 new employer firms began operations in 2008, and 595,600 firms closed that year. This amounts to an annual turnover of about 10 percent for entry and 10 percent for exit. Nonemployer firms have turnover rates three times as high as those of employer firms, mostly because of easier entry and exit conditions.

Starts and Closures of Employer Firms, 2004–2008

Category	2004	2005	2006	2007	2008
Births	628,917	644,122	670,058	663,100e	627,200e
Closures	541,047	565,745	599,333	571,300e	595,600e
Bankruptcies	34,317	39,201	19,695	28,322	43,546

Notes: e = Advocacy estimate. Bankruptcies include nonemployer firms. For a discussion of methodology, see Brian Headd, 2005 (**www.sba.gov/advo/research/rs258tot.pdf**).
Source: U.S. Dept. of Commerce, Bureau of the Census; Administrative Office of the U.S. Courts; U.S. Dept. of Labor, Employment and Training Administration.

What is small firms' share of employment?

Small businesses employ just over half of U.S. workers. Of 119.9 million nonfarm private sector workers in 2006, small firms with fewer than 500 workers employed 60.2 million and large firms employed 59.7 million. Firms with fewer than 20 employees employed 21.6 million. While small firms create a majority of the net new jobs, their share of employment remains steady since some firms grow into large firms as they create new jobs. Small firms' share of part-time workers (21 percent) is similar to large firms' share (18 percent).

Source: U.S. Dept. of Commerce, Bureau of the Census: Statistics of U.S. Businesses, Current Population Survey.

How many small businesses are there?

In 2008, there were 29.6 million businesses in the United States, according to Office of Advocacy estimates. Census data show that there were 6.0 million firms with employees in 2006 and 21.7 million without employees in 2007 (the latest available data). Small firms with fewer than 500 employees represent 99.9 percent of the 29.6 million businesses (including both employers and nonemployers), as the most recent data show there were about 18,000 large businesses in 2006.

Source: Office of Advocacy estimates based on data from the U.S. Dept. of Commerce, Bureau of the Census, and U.S. Dept. of Labor, Employment and Training Administration.

What is the survival rate for new firms?

Seven out of ten new employer firms last at least two years, and about half survive five years. More specifically, according to new Census data, 69 percent of new employer establishments born to new firms in 2000 survived at least two years, and 51 percent survived five or more years. Firms born in 1990 had very similar survival rates. With most firms starting small, 99.8 percent of the new employer establishments were started by small firms. Survival rates were similar across states and major industries.

Source: U.S Dept. of Commerce, Bureau of the Census, Business Dynamics Statistics. Note that the figures could be skewed slightly by the rare occurrence of new firms opening multiple establishments in their first few years.

How are small businesses financed?

Commercial banks and other depository institutions are the largest lenders of debt capital to small businesses. They accounted for almost 65 percent of total traditional credit to small businesses in 2003. (This includes credit lines and loans for nonresidential mortgages, vehicles, equipment, and leases.) Credit cards account for much of the growth in small business lending over the past few years. For more information, see Advocacy's

annual publication, *Small Business Lending in the United States* (**www.sba.gov/advo/research/ lending.html**).

How do regulations affect small firms?

Very small firms with fewer than 20 employees annually spend 45 percent more per employee than larger firms to comply with federal regulations. These very small firms spend four and a half times as much per employee to comply with environmental regulations and 67 percent more per employee on tax compliance than their larger counterparts. For data broken out by industry, see **www.sba.gov/advo/ research/rs264tot.pdf**.

Annual Cost of Federal Regulations by Firm Size, All Business Sectors (Dollars)

Type of Regulation	Cost per Employee for Firms with:	
	<20 Employees	500+ Employees
All Federal Regulation	$7,647	$5,282
Environmental	3,296	710
Economic	2,127	2,952
Workplace	928	841
Tax Compliance	1,304	780

Source: *The Impact of Federal Regulations on Small Firms*, an Advocacy-funded study by W. Mark Crain, 2005 (**www.sba.gov/advo/research/rs264tot.pdf**).

Whom do I contact about regulations?

To submit comments on proposed regulations, send email to **advocacy@sba.gov** or visit Advocacy's regulatory alerts page at **www.sba.gov/advo/laws/law_regalerts.html**. To inquire about unfair regulatory enforcement, contact SBA's Office of the National Ombudsman at **ombudsman@sba.gov**.

What is the role of women, minority, and veteran entrepreneurs?

Of the 23 million nonfarm businesses in 2002, women owned 6.5 million businesses, generating $940.8 billion in revenues, employing 7.1 million workers, and paying $173.7 billion in payroll. Another 2.7 million firms were owned equally by both women and men. Also in 2002, minorities owned 4.1 million firms that generated $694 billion in revenues and employed 4.8 million people. Hispanic Americans owned 6.6 percent of all U.S. businesses; African Americans, 5 percent; Asian Americans, 4.6 percent; American Indians or Alaska Natives, 0.8 percent; and Native Hawaiian or other Pacific Islanders, 0.1 percent. Veterans made up 14 percent of all owners in 2002, and 7 percent of them were service-disabled.

In 2007, the overall rate of self-employment (unincorporated and incorporated) was 10 percent, and the rate was 7.1 percent for women, 7.4 percent for Hispanic Americans, 5.2 percent for African Americans, 10.1 percent for Asian Americans and Native Americans, and 14.4 percent for veterans. According to a recent study, service-disabled veterans were less likely than non-service-disabled veterans to be employed, and they had lower self-employment rates.

Source: U.S. Dept. of Commerce, Bureau of the Census, Survey of Business Owners; Office of Advocacy: *Women in Business* (**www.sba.gov/advo/research/rs280.pdf**) and *Minorities in Business* (www.sba.gov/advo/research/rs298.pdf); Open Blue Solutions, 2007 (**www.sba.gov/advo/research/rs291tot.pdf**), and Office of Advocacy: *The Small Business Economy, 2009* (Table A.13, **www.sba.gov/advo/research/sbe.html**).

What research exists on the cost and availability of health insurance?

For many years, the cost and availability of health insurance have been top small business concerns. These concerns are driven by premium increases and administrative costs. Advocacy research shows that: (1) insurers of small health plans have higher administrative expenses than those that insure larger group plans, and (2) employees at small firms are less likely to have coverage than the employees of larger entities.

A Kaiser Family Foundation study confirmed the connection between the size of a firm and whether it offers health insurance. The Kaiser survey shows that about half of businesses with fewer than 10 workers offer health benefits to their employees. The ratio grows to about three-fourths for firms with 10–24 employees, to almost 90 percent for firms with 25–49 employees, and to 98 percent for firms with 200 employees or more. Two-thirds of workers in firms of all sizes take health insurance coverage when offered. Overall in 2007, small firm employees were almost twice as likely as large firm employees to be uninsured (24.6 percent vs.12.6 percent, respectively).

Source: National Federation of Independent Business; Kaiser Family Foundation; Advocacy-funded research by Rose C. Chu and Gordon R. Trapnell, 2003 (**www.sba.gov/advo/research/rs224tot.pdf**); Joel Popkin and Company, 2005 (**www.sba.gov/advo/research/rs262tot.pdf**); and Econometrica, Inc., 2007 (**www.sba.gov/advo/research/rs295tot.pdf**); and Office of Advocacy: *The Small Business Economy, 2009* (**www.sba.gov/advo/research/sbe.html**)

How can I get more information?

For more information, visit Advocacy's website: **www.sba.gov/advo.** Specific points of interest include:

- Economic research: **www.sba.gov/advo/research.**
- Firm size data (U.S., state, and metropolitan static and dynamic data): **www.sba.gov/advo/research/data.html.**
- Small firm lending studies: **www.sba.gov/advo/research/lending.html.**
- Small business profiles by state and territory: **www.sba.gov/advo/research/profiles.**
- The Small Business Advocate newsletter: **www.sba.gov/advo/newsletter.html.**

For email delivery of Advocacy's newsletter, press, regulatory news, and research, sign up at http://web.sba.gov/list. For RSS feeds, visit www.sba.gov/advo/rsslibrary.html. Direct questions to (202) 205-6533 or **advocacy@sba.gov.**

The SBA's Office of Advocacy was created by Congress in 1976 to protect, strengthen, and effectively represent the nation's small businesses within the federal government. As part of this mandate, the Office conducts policy studies and economic research on issues of concern to small business and publishes data on small business characteristics and contributions. For small business resources, statistics, and research, visit the Office of Advocacy's home page at www.sba.gov/advo.

Is there a PDF version of the FAQ?

Yes. The pdf version is located at: **http://www.sba.gov/advo/stats/sbfaq.pdf**

Updated September 2009.

APPENDIX C SMALL BUSINESS STATISTICS FOR REGULATORY ANALYSIS

One of the most difficult tasks in preparing an analysis for the Regulatory Flexibility Act is locating statistics on small business. The information in this appendix should help federal agencies identify data sources appropriate for regulatory analyses.

The IRS received an estimated 24.4 million business tax returns in 1999. Of these, 72 percent were for sole proprietorships, 20 percent for corporations, and 8 percent for partnerships. About 23 percent of tax returns are filed by about 5.6 million firms with employees; the remainder represent the full- and part-time self-employed. By U.S. Small Business Administration size standards, about 99.7 percent of all firms are small and have fewer than 500 employees.

Ideally, the data used to analyze the costs and benefits of government regulation should be longitudinal micro-data for individual firms — that is, data that can be used to trace the performance of a collection of firms over several years. Unfortunately, virtually all publicly available data on individual firms are subject to confidentiality restrictions. Individual names and addresses not only cannot be disclosed, but data must also be presented so that individual firm performance cannot be identified or intuited, even by statistical manipulation. Therefore, most government agencies release summary information, grouping data by industry, size, and/or location. It is worthwhile noting that there also is a problem associated with using grouped data through time: the firms that make up the group change. Some firms start up while others go out of business. Some firms expand into a higher size cohort, while others decline into a smaller size category. It is difficult, if not impossible, to clearly separate changes to firms that remain in the group from changes in the composition of the group.

The data sources listed here generally cover statistics on industry employment, payroll, and receipts. Most databases available from government sources do not provide financial data—the balance sheet and income statement information needed for analyses of the cost of regulations. This is the most sensitive type of information and is rarely available even in aggregate form. Profit information also is usually unavailable. While data such as that reported by the Census Bureau will always lag by two to three years, new data on firm dynamics —especially on firm births and deaths—are now becoming more available from both public and private sources.

Definitions

Various terms are used in data collection. It is important for those who use the data to understand the variations and their subtle distinctions.

Establishment: an establishment is the smallest unit in which business activity is conducted and on which statistical information is collected. The establishment concept does not refer to either ownership or taxpaying status. Establishments may be branches of

larger firms and may therefore differ in purchasing power, advertising coverage, management and control systems, technical resources, and access to capital and credit from separately owned and operated businesses of similar size. (Most very small businesses are single establishments.)

Enterprise: the enterprise or firm concept refers to all establishments owned by a "parent" company. For instance, an enterprise may own subsidiaries, branches, and unrelated establishments. In most instances, it is necessary to use the enterprise concept to study the characteristics of small firms since the ownership issue is critical for assessing the impact of a given policy. About 15 percent of total employment can be found in small establishments (fewer than 100 employees) owned by larger firms (more than 100 employees).

The Office of Advocacy's Census-Based Small Business Database

Beginning in late 1991, the SBA's Office of Advocacy contracted with the Economic Surveys Division of the Bureau of the Census to produce linked longitudinal data files on an enterprise basis. The SBA's Small Business Database, an extension of the Census Bureau's Enterprise Statistics program, includes information gathered from 5.6 million enterprises and 7.0 million establishments (as of 1999). (To see these data, go to the Office of Advocacy's website at *www.sba.gov/ADVO/stats*. Click on "firm size data.") The Office of Advocacy's data files generally include the number of establishments, firms, payroll per firm, and receipts per firm for various size classes based on firm employment size. The data are also broken out by location and/or industry.

Data are generally available at the four-digit Standard Industrial Classification (SIC) code level of industrial detail for the United States overall, and at the two-digit level by state. The SIC system is being replaced by the North American Industry Classification System (NAICS), and data are increasingly available on a 6-digit NAICS. The 1999 industry data delineated for more than 1,200 industries can be downloaded from the Office of Advocacy's website.

Customized tabulations or copies of the database are available. Inquiries can be directed to Mr. Trey Cole, Bureau of the Census, at (301) 457-3320. Some of these data have already been published by a variety of sources, including the data tables compiled by the Office of Advocacy and published in the President's annual economic report, *The State of Small Business: A Report of the President*[249]. Other tables from this database have been published in the SBA's *Handbook of Small Business Data*[250] and in other reports.

[249] Executive Office of the President, *The State of Small Business: A Report of the President* (Washington, D.C.: U.S. Government Printing Office, annual)
[250] U.S. Small Business Administration, Office of Advocacy, *Handbook of Small Business Data*, 1994 ed. (Washington, D.C.: U.S. Government Printing Office, 1994).

Characteristics of Small Business Owners and Employees, 1997

A publication of the Office of Advocacy, *Characteristics of Small Business Owners and Employees, 1997,*[251] uses data from two sources: the Census Bureau's Current Population Survey (1993–1996) and the Characteristics of Business Owners 1992 (a survey that was co-funded by the Office of Advocacy). It uses these sources to describe the businesses' sources of capital, their profitability, employment, major industry, and home-based status of women and minority business owners. Because 85 percent of the firms covered by the Characteristics of Business Owners survey have no employees, this data source provides some information on potential regulatory impacts on very small firms, particularly their ability to absorb the burden of federal regulation.

Other Federal Agency Data on Small Firms

Federal Reserve Survey of Small Business Finances

Within the past 15 years (1987, 1993, and 1998), the Federal Reserve Board has conducted three major surveys of small firm finances. The first two were in conjunction with the Office of Advocacy. The National Survey of Small Business Finances (NSSBF), now the Survey of Small Business Finances (SSBF) has been the most detailed examination to date of the credit needs of small firms, as well as their sources and uses of funds. The survey collects information on small businesses (those with fewer than 500 employees) in the United States. Owner characteristics, firm size, use of financial services, and the income and balance sheets of the firm are some examples of the types of information collected. These data may be of use for regulatory analysis when capital costs associated with regulations are at issue.

Census Bureau's Characteristics of Business Owners Survey[252]

For the year 1987, and again for the 1992–1994 period, the Minority Business Development Agency of the U.S. Department of Commerce and the SBA's Office of Advocacy contracted with the Census Bureau to produce the Characteristics of Business Owners (CBO) Survey data. The CBO is a survey of 125,000 small firms. The CBO is the only nationally representative source of information about many of the subjects covered in the survey: demographic characteristics of the owner and economic characteristics of the firm such as sales, export status, franchise status, hours and weeks worked by the business owner, sources of debt and equity capital, etc.

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[251] U.S. Small Business Administration, Office of Advocacy, *Characteristics of Small Business Owners and Employees, 1997*, report no. PB98 – 127111 (Springfield, VA.: National Technical Information Service, 1998). Also available on the Office of Advocacy's Internet site*: http://www.sba.gov/advo/*

[252] U.S. Department of Commerce, Bureau of the Census, *Characteristics of Business Owners: 1992*, CBO-1 (Washington, D.C.: U.S. Government Printing Office, 1997).

IRS Statistics of Income

Each quarter, the Statistics of Income (SOI) division of the Internal Revenue Service publishes the *SOI Bulletin*. This publication contains data for both households and businesses and is an invaluable source of statistical information. Data on business firms are generally classified by receipt size class for proprietorships, partnerships, and corporations. Data on business profits from the IRS are elusive. For sole proprietorships and partnerships, only data on net income are available.

For small business corporations, more data are available. The IRS *Source Book for Corporations* contains data for corporations by asset size class. Balance sheet and income statement information is available for corporations in about 15 different asset classes. From these detailed data, it is possible to calculate rates of return on assets as well as the profits of small business (generally subchapter S) corporations.

Data on Self-Employed Persons

Each year, the March Current Population Survey of the Bureau of the Census asks a series of expanded questions about self-employment as part of its firm-size supplement. These questions include the hours and weeks spent working in the business during the previous year, the income earned, the demographics of the business owner, whether the firm (owner) has or provides benefits, and several related questions about the industry of the firm. These data are available from the Population Division of the Bureau of the Census at (301) 763-4100.

Private Data Sources

The Kauffman – Ernst and Young Data Base of Fast Growth Companies (KEYFGC) is a promising new database that relies on data from two sources: the accounting firm of Ernst and Young for employment and sales information, and the Dun & Bradstreet Corporation for financial data. The major promise of these data is the ability to understand where and how fast-growing companies develop over time, including details about their locations and industries. In addition, the KEYFGC data set is one of the only databases with actual financial data available on individual (but unidentified) companies.

Economic Research on Small Businesses

Over its history, the SBA's Office of Advocacy has both conducted and contracted for research on a variety of small business topics. The scope and breadth of the research conducted under the auspices of the Office of Advocacy can be found at *http://www.sba.gov/advo/research/*.

APPENDIX D MEMORANDUM OF UNDERSTANDING

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE OFFICE OF ADVOCACY, U.S. SMALL BUSINESS ADMINISTRATION

AND

THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS,
OFFICE OF MANAGEMENT AND BUDGET

I. BACKGROUND

The Office of Advocacy of the U.S. Small Business Administration (Advocacy) and the Office of Information and Regulatory Affairs of the Office of Management and Budget (OIRA) recognize that small entities (including small businesses, non-profit organizations and small governmental jurisdictions) as defined in 5 U.S.C. § 601, often face a disproportionate share of the Federal regulatory burden compared with their larger counterparts. Advocacy and OIRA further recognize that the best way to prevent unnecessary regulatory burden is to participate in the rulemaking process at the earliest stage possible and to coordinate both offices to identify draft regulations that likely will impact small entities.

Inasmuch as Advocacy and OIRA share similar goals, the two agencies intend to enhance their working relationship by establishing certain protocols for sharing information and providing training for regulatory agencies on compliance with the Regulatory Flexibility Act (RFA) and various other statutes and Executive orders that require an economic analysis of proposed regulations.

II. PURPOSE

The purpose of this Memorandum of Understanding (MOU) between Advocacy and OIRA is to achieve a reduction in unnecessary regulatory burden for small entities. This initiative also is intended to generate better agency compliance with the RFA and other statutes and Executive orders requiring an economic analysis of proposed regulations.

III. AUTHORITY

This agreement is under the authority of 15 U.S.C. § 634(a) et seq., 5 U.S.C. § 601 et seq.; Executive Order 12866, as amended, and other relevant provisions of law.

IV. OBJECTIVES

To the extent consistent with Advocacy and OIRA authority, Advocacy and OIRA agree to accomplish the following objectives:

a. Establish an information sharing process between Advocacy and OIRA when a draft rulemaking is likely to impact small entities.
b. Establish Advocacy guidance for Federal agencies on the requirements of the RFA.
c. Establish training for Federal agencies on compliance with the RFA.

V. SCOPE

Nothing in this MOU shall be construed to limit or otherwise affect the authority of the Office of Advocacy as established in 15 U.S.C. § 634a et seq. or the authority, management or policies of OIRA.

VI. RESPONSIBILITIES

a. Advocacy

1. During OIRA's prepublication review of an agency's rule under Executive Order 12866, OIRA may consult with Advocacy regarding whether an agency should have prepared a regulatory flexibility analysis. Advocacy will designate staff by issue and/or agency to facilitate such discussions. If OIRA is uncertain as to small business impact or RFA compliance, OIRA may send a copy of the draft rule to Advocacy for evaluation.

2. If Advocacy's discussions with an issuing agency do not result in an acceptable accommodation, Advocacy may seek the assistance of OIRA during the regulatory review process under Executive Order 12866 and may recommend that OIRA return the rule to the agency for further consideration.

3. Advocacy will monitor agency compliance with the RFA by reviewing the semi-annual regulatory agenda and the analyses that agencies publish in the *Federal Register*. Similarly, Advocacy will review the initial regulatory flexibility analyses that agencies provide directly to Advocacy. If Advocacy finds that a rule does not comply with the RFA, Advocacy will raise these concerns with OIRA.

4. Advocacy shall provide OIRA with a copy of any correspondence or formal comments that Advocacy files with an agency concerning RFA compliance.

5. Advocacy will develop guidance for agencies to follow on how to comply with the RFA.

6. Advocacy will organize training sessions for Federal agencies on how to comply with the analytical requirements of the RFA.

b. OIRA

Consistent with OIRA's responsibility to ensure adequate interagency coordination, OIRA shall endeavor to do the following:

1. During OIRA's prepublication review of an agency's rule pursuant to Executive Order 12866, OIRA will consider whether the agency should have prepared a regulatory flexibility analysis. If Advocacy has a concern in this regard, OIRA will provide a copy of the draft rule to Advocacy. In addition, upon request, OIRA may, as appropriate, provide Advocacy with draft proposals and accompanying regulatory analyses.

2. If, in the judgment of Advocacy or OIRA, an agency provides an inadequate regulatory flexibility analysis, or if an agency provides a rule with an inadequate certification pursuant to section 605 of the RFA, OIRA may discuss and resolve the matter with the agency in the context of the regulatory review process under Executive Order 12866. Where OIRA deems it appropriate, OIRA may return a rule to the agency for further consideration.

3. If Advocacy or OIRA are concerned about an information collection requirement contained in a rule which OIRA is reviewing under the Paperwork Reduction Act, OIRA may discuss and resolve the matter with the agency..

4. OIRA will endeavor to provide assistance, as appropriate, at the request of Advocacy in support of its development of guidance for agencies to follow in complying with the RFA and its training sessions on the analytical requirements of the RFA.

c. **Joint Advocacy-OIRA Responsibilities**

For rulemakings and information collection requests related to urgent health, safety, environmental, and homeland security matters, Advocacy and OIRA shall endeavor to cooperate and discuss their concerns in an expeditious manner.

VII. TERM

This MOU shall take effect on the date of signature of both parties, and will remain in effect for three years, at which time it may be renewed by mutual agreement of Advocacy and OIRA.

VIII. AMENDMENT

This MOU may be amended in writing and at any time by mutual agreement of Advocacy's Chief Counsel or his/her designee and the Administrator of OIRA or his/her designee.

IX. TERMINATION

Either Advocacy or OIRA may terminate this MOU upon 90 days advance written notice.

X. POINTS OF CONTACT

Points of contact for this MOU are as follows:

For **Advocacy**:

Thomas M. Sullivan
Chief Counsel
Office of Advocacy
U.S. Small Business Administration
409 Third Street, SW
Suite 7800
Washington, DC 20416
(202) 205-6533
(202) 205-6928 (fax)

For **OIRA**:

Dr. John D. Graham
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
262 Old Executive Office Building
Washington, DC 20503
(202) 395-4852
(202) 395-3047 (fax)

XI. ACCEPTANCE

The undersigned parties hereby accept the terms of this MOU:

FOR THE OFFICE OF ADVOCACY:

/s/

_____
Thomas M. Sullivan, Chief Counsel

FOR THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS

/s/

_____
John D. Graham, Administrator

APPENDIX E EXECUTIVE ORDER 13272

Title 3--
The President

Executive Order 13,272 of August 13, 2002

Proper Consideration of Small Entities in Agency Rulemaking

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. General Requirements. Each agency shall establish procedures and policies to promote compliance with the Regulatory Flexibility Act, as amended (5 U.S.C. 601 et seq.) (the ``Act''). Agencies shall thoroughly review draft rules to assess and take appropriate account of the potential impact on small businesses, small governmental jurisdictions, and small organizations, as provided by the Act. The Chief Counsel for Advocacy of the Small Business Administration (Advocacy) shall remain available to advise agencies in performing that review consistent with the provisions of the Act.

Sec. 2. Responsibilities of Advocacy. Consistent with the requirements of the Act, other applicable law, and Executive Order 12,866 of September 30, 1993, as amended, Advocacy:

(a) shall notify agency heads from time to time of the requirements of the Act, including by issuing notifications with respect to the basic requirements of the Act within 90 days of the date of this order;
(b) shall provide training to agencies on compliance with the Act; and
(c) may provide comment on draft rules to the agency that has proposed or intends to propose the rules and to the Office of Information and Regulatory Affairs of the Office of Management and Budget (OIRA).

Sec. 3. Responsibilities of Federal Agencies. Consistent with the requirements of the Act and applicable law, agencies shall:

(a) Within 180 days of the date of this order, issue written procedures and policies, consistent with the Act, to ensure that the potential impacts of agencies' draft rules on small businesses, small governmental jurisdictions, and small organizations are properly considered during the rulemaking process. Agency heads shall submit, no later than 90 days from the date of this order, their written procedures and policies to Advocacy for comment. Prior to issuing final procedures and policies, agencies shall consider any such comments received within 60 days from the date of the submission of the agencies' procedures and policies to Advocacy. Except to the extent otherwise specifically provided by statute or Executive Order, agencies shall make the final procedures and policies available to the public through the Internet or other easily accessible means;
(b) Notify Advocacy of any draft rules that may have a significant economic impact on a substantial number of small entities under the Act. Such notifications shall be made (i) when the agency submits a draft rule to OIRA under Executive Order 12,866

if that order requires such submission, or (ii) if no submission to OIRA is so required, at a reasonable time prior to publication of the rule by the agency; and

(c) Give every appropriate consideration to any comments provided by Advocacy regarding a draft rule. Consistent with applicable law and appropriate protection of executive deliberations and legal privileges, an agency shall include, in any explanation or discussion accompanying publication in the Federal Register of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule that preceded thefinal rule; provided, however, that inclusion is not required if the head of the agency certifies that the public interest is not served thereby.

Agencies and Advocacy may, to the extent permitted by law, engage in an exchange of data and research, as appropriate, to foster the purposes of the Act.

Sec. 4. Definitions. Terms defined in section 601 of title 5, United States Code, including the term ``agency,'' shall have the same meaning in this order.

Sec. 5. Preservation of Authority. Nothing in this order shall be construed to impair or affect the authority of the Administrator of the Small Business Administration to supervise the Small Business Administration as provided in the first sentence of section 2(b)(1) of Public Law 85-09536 (15 U.S.C. 633(b)(1)).

Sec. 6. Reporting. For the purpose of promoting compliance with this order, Advocacy shall submit a report not less than annually to the Director of the Office of Management and Budget on the extent of compliance with this order by agencies.

Sec. 7. Confidentiality. Consistent with existing law, Advocacy may publicly disclose information that it receives from the agencies in the course of carrying out this order only to the extent that such information already has been lawfully and publicly disclosed by OIRA or the relevant rulemaking agency.

Sec. 8. Judicial Review. This order is intended only to improve the internal management of the Federal Government. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person.

THE WHITE HOUSE,

August 13, 2002.

APPENDIX F EXECUTIVE ORDER 12866

Regulatory Planning and Review

Public Papers of the Presidents

September 30, 1993

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles. (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of cost and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) The Principles of Regulation. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entitles, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including

specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and government entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Sec. 2. Organization. An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people. (a) The Agencies. Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and assuring that the regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order.

(b) The Office of Management and Budget. Coordinated review of agency rulemaking is necessary to ensure that regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to agencies and assist the President, the Vice President, and other regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations, as provided by the this Executive order.

(c) The Vice President. The Vice President is the principal advisor to the President on, and shall coordinate the development and presentation of recommendations concerning, regulatory policy, planning, and review, as set forth in this Executive order. In fulfilling their responsibilities under this Executive order, the President and the Vice President shall be assisted by the regulatory

policy advisors within the Executive Office of the President and by such agency officials and personnel as the President and the Vice President may, from time to time, consult.

Sec. 3. Definitions. for purposes of this Executive order: (1) "Advisors" refers to such regulatory policy advisors to the President as the President and Vice President may from time to time consult, including, among the others: (1)the Director of OMB; (2) the Chair (or another member) of the Council of Economic Advisers; (3) the Assistant to the President for Economic Policy; (4) the Assistance to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Assistant to the President for Science and Technology; (7) the Assistant to the President for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Deputy Assistant to the President and Director of the White House Office of Environmental Policy; and (12) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" or "rule" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

(1) Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations or rules that are limited to agency organization, management, or personnel matters; or

(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the

promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

(f) "Significant regulatory action" means any regulatory action that is likely to result in a rule that may:

(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 Executive order.

Sec. 4. Planning Mechanism. In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law:

(a) Agencies' Policy Meeting. Early in each year's planning cycle, the Vice President shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming years.

(b) Unified Regulatory Agenda. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) The Regulatory Plan. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory

agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Plan shall be approved personally by the agency head and shall contain at a minimum:

(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits;

(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order;

(D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

(3) Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies, the Advisors, and the Vice President.

(4) An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency, the Advisors, and the Vice President.

(5) If the Administrator of OIRA believes that planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the effected agencies, the Advisors, and the Vice President.

(6) The Vice President, with the Advisors' assistance, may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.

(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(d) Regulatory Working Group. Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Regulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility, the Advisors, and the Vice President. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Vice President on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) Conferences. The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (1) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to

determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrative of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Vice President, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

Sec. 6. Centralized Review of Regulations. The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) Agency Responsibilities. (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(2) Within 60 days of the date of this Executive order, each agency head shall designate a Regulatory Policy Officer who shall report to the agency head. The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the

Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(l), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient

functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

(i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) OIRA Responsibilities. The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines: (i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did not attend, and telephone conversations between OIRA personnel and any such persons); and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Vice Presidential and Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

Sec. 7. Resolution of Conflicts. To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Vice Presidential and Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

Resolution of such conflicts shall be informed by recommendations developed by the Vice President, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

During the Vice Presidential and Presidential review period, communications with any person not employed by the Federal Government relating to the substance of the regulatory action under review and directed to the Advisors or their staffs or to

the staff of the Vice President shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

At the end of this review process, the President, or the Vice President acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

Sec. 8. Publication. Except to the extent required by law, an agency shall not publish in the Federal Register or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a regulatory action, the head of that agency may request Presidential consideration through the Vice President, as provided under section 7 of this order. Upon receipt of this request, the Vice President shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

Sec. 9. Agency Authority. Nothing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by law.

Sec. 10. Judicial Review. Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 11. Revocations. Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.

William J. Clinton

The White House, September 30, 1993.

Filed with the Office of the Federal Register, 12:12 pm., October 1, 1993

APPENDIX G ABBREVIATIONS USED IN THIS GUIDE

Advocacy	Office of Advocacy, U.S. Small Business Administration
ANPRM	advance notice of proposed rulemaking
APHIS	Animal and Plant Health Inspection Service
APA	Administrative Procedure Act
ATA	American Trucking Association
BBA	Balanced Budget Act
BLM	Bureau of Land Management
CAA	Civilian Acquisition Agency
C.F.R	*Code of Federal Regulations*
CMS	Centers for Medicare and Medicaid Services
COPPA	Children's Online Privacy Protection Act
DAR	Defense Acquisition Regulations
DOC	Department of Commerce
DOD	Department of Defense
DOI	Department of the Interior
DOL	Department of Labor
DOT	Department of Transportation
E.O.	Executive Order
EPA	Environmental Protection Agency
FAR	Federal Acquisition Regulation
FCC	Federal Communications Commission
FERC	Federal Energy Regulatory Commission
FmHA	Farmers Home Administration
FR	Federal Register
FRFA	final regulatory flexibility analysis
FTC	Federal Trade Commission
GAO	General Accounting Office, now Government Accountability Office
HHS	U.S. Department of Health and Human Services
IPS	Interim Payment System
IRFA	initial regulatory flexibility analysis
IRS	Internal Revenue Service
MMS	Minerals Management Service
NAAQS	national ambient air quality standard
NAICS	North American Industry Classification System
NEPA	National Environmental Policy Act
NHTSA	National Highway Traffic Safety Administration
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NPRM	notice of proposed rulemaking
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
P.L.	Public Law
PRA	Paperwork Reduction Act

RFA	Regulatory Flexibility Act
RSPA	Research and Special Programs Administration
SBA	Small Business Administration
SBIC	small business investment company
SBREFA	Small Business Regulatory Enforcement Fairness Act
SERS	small entity representatives
SIC	Standard Industrial Classification system
USDA	U.S. Department of Agriculture
U.S.C.	United States Code
UPL	upper payment limit
VOCs	volatile organic compounds

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APPENDIX J SECTION 610 OF THE REGULATORY FLEXIBILITY ACT: BEST PRACTICES FOR FEDERAL AGENCIES

Introduction

Section 610 of the Regulatory Flexibility Act (RFA)[253] requires federal agencies to review regulations that have a significant economic impact on a substantial number of small entities[254] within 10 years of their adoption as final rules. These periodic rule reviews are a mechanism for agencies to assess the impact of existing rules on small entities and to determine whether the rules should be continued without change, or should be amended or rescinded, consistent with the objectives of applicable statutes. Agency compliance with section 610's periodic review requirement has varied substantially from agency to agency since 1980.[255] While some agencies systematically review all of their existing rules, other agencies review few, if any, of their current rules. Agencies also vary considerably in the amount of public involvement they allow, and the amount of information they provide to the public about their reviews.

The Office of Advocacy, an independent office within the U.S. Small Business Administration (Advocacy), has previously given relatively little guidance to agencies on section 610. In 2003, pursuant to the requirements of Executive Order 13,272,[256] Advocacy issued a general guide on how to comply with the RFA, including section 610.[257] The 2003 guide did not, however, address commonly asked questions about section 610, such as the timing and scope of reviews, how the public can be involved, and how agencies should communicate with the public about their reviews. The 2003 guide also did not provide examples of retrospective reviews that were, in Advocacy's view, conducted properly.

This best practices document is intended to provide Advocacy's interpretation of section 610 of the RFA and answer common questions about conducting retrospective reviews of

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[253] 5 U.S.C. § 610 (2000).

[254] "Small entities" include small businesses that meet the Small Business Administration size standard for small business concerns at 13 C.F.R. § 121.201, small governmental jurisdictions with a population of less than 50,000, and small organizations that are independently owned not-for-profit enterprises and which are not dominant in their field. See 5 U.S.C. §§ 601(3)-(5).

[255] *See, for example,* Government Accountability Office, *Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews* (GAO-07-791), July 2007; General Accounting Office, *Regulatory Flexibility Act: Agencies' Interpretations Vary* (GAO/GGD-99-55) April 1999. *See also* Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement – and Current Proposals to Invigorate the Act,* 33 Fordham Urb. L.J. 1199-1255 (2006).

[256] Exec. Order No. 13,272 § 2(a), 67 Fed. Reg. 53,461 (Aug. 13, 2002) ("Advocacy . . . shall notify agency heads from time to time of the requirements of the [RFA], including by issuing notifications with respect to the basic requirements of the Act . . . .")

[257] Office of Advocacy, *How to Comply with the Regulatory Flexibility Act: A Guide for Government Agencies* (May 2003) available at http://www.sba.gov/advo/laws/rfaguide.pdf.

existing regulations in a transparent manner. Advocacy intends this document to supplement the 2003 RFA guide; like the 2003 guide, it was developed to meet Advocacy's continuing responsibility under Executive Order 13,272 to "notify agency heads from time to time of the requirements of the [RFA]."[258]

The statutory text of Section 610, 5 U.S.C. § 610

§ 610. Periodic review of rules

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

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

(1) the continued need for the rule;

(2) the nature of complaints or comments received concerning the rule from the public;

(3) the complexity of the rule;

(4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

(5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

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

[258] Exec. Order No. 13,272 § 2(a), 67 Fed. Reg. 53,461 (Aug. 13, 2002).

Legislative history of the RFA relating to section 610.

Statements made during the 1980 debate on the Regulatory Flexibility Act demonstrate that Congress intended for section 610 to be a mechanism that requires agencies to periodically re-examine the regulatory burden of their rules vis-à-vis small entities, considered in the light of changing circumstances.[259] This view was also reflected in Advocacy's initial 1982 guidance explaining the then-new RFA, which stated that

> The RFA requires agencies to review all existing regulations to determine whether maximum flexibility is being provided to accommodate the unique needs of small businesses and small entities. Because society is not static, changing environments and technology may necessitate modifications of existing, anachronistic regulations to assure that they do not unnecessarily impede the growth and development of small entities.[260]

Put simply, the objective of a section 610 review is like the goal of many other retrospective rule reviews:[261] to determine whether an existing rule is actually working as it was originally intended and whether revisions are needed. Has the problem the rule was designed to address been solved? Are regulated entities (particularly small entities) able to comply with the rule as anticipated by the agency? Are the costs of compliance in line with the agency's initial estimates? Are small businesses voicing continuing concerns about the difficulty they have complying with the rule? The section 610 review is an excellent way to address these questions.

Is a section 610 review necessary even if the current rule did not impose a significant economic impact on a substantial number of small entities at the time the rule was promulgated?

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[259] House Debate on the Regulatory Flexibility Act, 142 Cong. Rec. H24,575, H24,583-585 (daily ed. Sept. 8, 1980) ("At least once every 10 years, agencies must assess regulations currently on the books, with a view toward modification of those which unduly impact on small entities." (Statement of Rep. McDade)) ("[A]gencies must review all regulations currently on the books and determine the continued need for any rules which have a substantial impact on small business." (Statement of Rep. Ireland)). Similarly, the section-by-section analysis of the periodic review provision of S. 299, which became the RFA, notes that the required factors in a section 610 review mirror the evaluative factors in President Carter's Executive Order 12,044, *Improving Government Regulations.* Exec. Order 12,044, 43 Fed. Reg. 12,661 (March 24, 1978). Pursuant to that Executive Order, President Carter issued a Memorandum to the Heads of Executive Departments and Agencies in 1979, further instructing federal agencies: "As you review existing regulatory and reporting requirements, take particular care to determine where, within statutory limits, it is possible to tailor those requirements to fit the size and nature of the businesses and organizations subject to them." President Jimmy Carter, Memorandum to the Heads of Executive Departments and Agencies, November 16, 1979.

[260] Office of Advocacy, *The Regulatory Flexibility Act* (October 1982).

[261] Typical agency-initiated retrospective regulatory reviews include post-hoc validation studies, reviews conducted pursuant to petitions for rulemaking or reconsideration, paperwork burden reviews, and reviews undertaken to advance agency policies.

In some cases, yes. Even if an agency was originally able to certify properly under section 605 of the RFA that a rule would not have a significant economic impact on a substantial number of small entities,[262] changed conditions may mean that the rule now does have a significant impact and therefore should be reviewed under section 610. For example, there may be many more small businesses that are subject to the rule now than when the rule was promulgated. The cost of compliance with a current rule may have sharply increased because of a required new technology. If there is evidence (such as new cost or burden data) that a rule is now having a significant economic impact on a substantial number of small entities, including small communities or small non-profit organizations, Advocacy believes that the agency should conduct a section 610 review.

Advocacy is aware that some agencies interpret section 610 not to require the periodic review of rules that were originally certified when they were promulgated as having no significant economic impact on a substantial number of small entities. This narrow interpretation of the section 610 review requirements discounts several important considerations. First, evidence of significant current impacts to small entities from an existing rule may call into question the accuracy of the original determination that the rule would have no significant impact. Second, as time passes and the agency (along with regulated small entities) are better able to measure and understand the impacts of a regulation, it benefits the agency to use the periodic review process to update their rules and perform regulatory "housekeeping." Third, limiting section 610 reviews only to rules that were found to have a significant economic impact on a substantial number of small entities at the time of promulgation would severely undercut section 610. EPA and OSHA, for example – which between them determine that at most one or two rules each year will have such an impact – will exclude each of the hundreds of other rules promulgated annually which may now significantly impact small entities from section 610 review. Given the legislative history of section 610, it is very difficult to believe that Congress intended this outcome. Finally, a reading of the plain language of section 610 supports Advocacy's interpretation. If Congress meant to limit periodic reviews, it would have simply required agencies to review rules that <u>had</u> a significant impact, rather than rules which <u>have</u> a significant impact.

An agency may learn about the current impacts of an existing rule through complaints from small entities or petitions for a section 610 or other retrospective review of the rule. If these complaints and/or petitions are founded on reliable cost and impact data, the agency will have a clear indication that small entities are now being impacted by the rule.

Scope of the review: What should be included?

Once an agency has determined that an existing rule has a significant economic impact on a substantial number of small entities at the present time, the agency's section 610 review should, at a minimum, address each of the five factors listed in section 610(b)(1)-(5):

[262] *See* 5 U.S.C. § 605(b).

- Whether or not there a continuing need for this rule, consistent with the stated objectives of the applicable statutes;
- Whether the public has ever submitted comments or complaints about this rule;
- The degree of complexity of this rule;
- Whether some other federal or state requirement accomplishes the same regulatory objective as this rule; and
- The length of time since the agency has reviewed this rule, and/or the extent to which circumstances have changed which may affect regulated entities.

Particular attention should be paid to changes in technology, economic circumstances, competitive forces, and the cumulative burden faced by regulated entities. Has the impact of the rule on small entities remained the same?

Section 610(b) requires an agency to evaluate and minimize "any significant economic impact of a rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes." To accomplish this, agencies may want to use an economic analysis similar to the Initial Regulatory Flexibility Analysis (IRFA) under section 603 of the RFA, taking into account the limitations on data availability and limited agency resources.[263] Agencies have the discretion to place significant weight on other relevant factors, in addition to the types of economic data required by an IRFA. These other factors include an agency's experience in implementing the rule, as well as the views expressed over time by the public, regulated entities, and Congress. With the benefit of actual experience with a rule, the agency and other interested parties should be in a good position to evaluate potential improvements to the rule. Several factors deserve attention here such as the benefits achieved by the regulation, unintended market effects and market distortions, unusually high firm mortality rates in specific industry sub-sectors, and widespread noncompliance with reporting and other paperwork requirements. Thus, a useful review should go beyond obvious measures such as ensuring that regulatory requirements are expressed in plain language and that paperwork can be filed electronically. The analysis should be aimed at understanding and reducing burdens that unnecessarily impact small entities.

As a matter of good practice, the section 610 analysis should be based on relevant data, public comments, and agency experience. The agency should make use of available data and data supplied by the public, and indicate the sources of the data. To the extent that an agency relies on specific data to reach a conclusion about the continuing efficacy of a rule, the agency should be able to provide that data. The agency should explain its assumptions so that stakeholders can understand its analysis.

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[263] *See* 5 U.S.C. § 603. Indeed, the legislative history of S.299, which became the RFA, notes that "[i]n reviewing existing rules, agencies should follow the procedures described in sections 602-609 [of the RFA] to the extent appropriate." 142 Cong. Rec. H24,575, H24,583-585 (daily ed. Sept. 8, 1980). In the context of a section 610 review, the elements of an IRFA analysis that should be present include: a discussion of the number and types of small entities affected by the rule, a description of the compliance requirements of the rule and an estimate of their costs, identification of any duplicative or overlapping requirements, and a description of possible alternative regulatory approaches. *See also* Office of Advocacy, *How to Comply with the Regulatory Flexibility Act: A Guide for Government Agencies* (May 2003) at 29-40, available at http://www.sba.gov/advo/laws/rfaguide.pdf.

Timing of the review: When does the agency have to start and finish?

The language of section 610 specifies that the review should take place within 10 years after the date a rule is promulgated. While agencies need to gain some experience with a rule before undertaking a retrospective review, the review may take place prior to the 10-year mark. If an agency substantially revises a rule after its initial promulgation, it is arguable as to whether the 610 review may be delayed to correspond to the revision date. Advocacy would not likely object to a revision of the date, but agencies should seek input from Advocacy on this point.

Section 610 does not specifically set a limit on the amount of time for a rule review. Some agencies have reported that they spend more than a year on each section 610 review. It is within an agency's discretion to determine how much time it needs to spend on retrospective rule reviews. Advocacy recognizes that section 610 reviews may take more than a year in order to permit adequate time to gather and analyze data, to allow public comment, and to consider those comments in the review. Of course, some reviews could take less time, based on the complexity of the issues and the nature of the regulated industry.

Agencies may wish to take advantage of the opportunity afforded in section 605(c) of the RFA to consider a series of "closely related rules" as one rule for periodic review purposes. An agency can accomplish a comprehensive section 610 review of closely related rules, satisfying the requirements of the RFA while potentially reducing the agency resources required.

How should agencies communicate with interested entities about section 610 reviews they are conducting?

Section 610(c) of the RFA requires agencies to publish in the *Federal Register* a list of the rules they plan to review in the upcoming year. Agencies use the *Unified Regulatory Agenda* for this purpose.[264] This listing requirement is intended to give small entities early notice of the section 610 reviews so that they will be ready and able to provide the agency with comments about the rule under review. As a practical matter, however, agencies often give stakeholders no other information about the ongoing status of a section 610 review, what factors an agency is considering in conducting the review, how comments can be submitted to the agency, or, ultimately, the factual basis on which the agency made its section 610 review findings.

Agencies should communicate with interested entities about the status of ongoing section 610 reviews, as well as those they have completed, to enhance transparency. This information may be most efficiently communicated via an agency website or other electronic media, and should inform interested parties of their ability to submit comments, as well as the agency's commitment to consider those comments. Several agencies already utilize web-based communications as an outreach tool during section

[264] The *Unified Regulatory Agenda* can be accessed at www.reginfo.gov.

610 reviews.[265]

Insights about an existing regulation received from regulated entities and other interested parties should be a key component of a retrospective rule review. By making the review process transparent and accessible, agencies are more likely to identify improvements that will benefit all parties at the conclusion of the review. Advocacy can help agencies who wish to communicate with small entity stakeholders – by hosting roundtables, working through trade groups, and getting a specific message to a targeted audience. Advocacy is ready to assist agencies in their outreach efforts.

Can other agency retrospective rule reviews satisfy the requirements of section 610?

Yes. Agencies that undertake retrospective rule reviews to satisfy other agency objectives may also be able to satisfy the periodic review requirement of section 610, as long as the rule reviews are functionally equivalent. For example, agencies that evaluated a current regulation pursuant to the Office of Management and Budget's 2002 publicly-nominated rule reform process[266] or OMB's manufacturing rule reform process[267] could qualify as section 610 reviews, if they otherwise met the criteria for section 610 review. Similarly, agencies that undertook retrospective reviews of their regulatory programs because of complaints or petitions from regulated entities could qualify as section 610 reviews – as long as the review includes the minimum factors required by section 610. The best way for agencies to get "credit" for a section 610 review in these circumstances is to communicate adequately with stakeholders, and with Advocacy.

Examples: In Advocacy's view, what are some recent retrospective rule reviews (conducted pursuant to section 610 or otherwise) that have been successful?

Federal Railway Administration's Section 610 Review of Railroad Workplace Safety – On December 1, 2003, the Department of Transportation's Federal Railroad Administration completed a section 610 review of its railroad workplace safety regulations. After determining that the workplace safety regulations had a significant economic impact on a substantial number of small entities, the FRA examined the rules in light of section 610's review factors. Although the FRA did not recommend any regulatory change as a result of this review, they provided a good description of its analysis of the workplace safety regulations under each review factor and the agency's conclusions. See www.fra.dot.gov/downloads/safety/railroad_workplace_safety.pdf.

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[265] See, e.g., www.osha.gov, www.epa.gov, and www.dot.gov and search for "RFA section 610."

[266] *See* Table 9, "New Reforms Planned or Underway – Regulations" and Table 10, "New Reforms Planned or Underway – Guidance Documents" in *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (September 2003) at 26-34; available at www.whitehouse.gov/omb/inforeg/2003_cost_ben_final_rept.pdf.

[267] See Regulatory Reform of the U.S. Manufacturing Sector (2005).

EPA's RCRA Review - As a result of public nominations for reforms to the Environmental Protection Agency's hazardous waste management program under the Resource Conservation and Recovery Act (RCRA), EPA evaluated the program and identified duplicative requirements, such as forcing filers to submit reports to multiple locations when one location is adequate. By reducing or eliminating these procedures after public notice and comment, EPA enabled regulated entities to collectively save up to $3 million per year while preserving the protections of the RCRA program. The retrospective review was successful because it involved a detailed review of the program's requirements and their costs, based on years of practical experience. The agency considered technical changes such as computerization that have made some of the older paperwork requirements redundant, and found ways to modernize the program to reflect current realities. *See* 71 Fed. Reg. 16,862 (April 4, 2006).

OSHA Excavations Standard – In March 2007, the Occupational Safety and Health Administration (OSHA) completed a section 610 review of its rules governing excavations and trenches. These standards had been in place since 1989, and were designed to ensure that trenches do not collapse on workers and that excavated material does not fall back into a trench and bury workers. In the review, OSHA did a good job of seeking public input on how and whether the rule should be changed. While the agency ultimately decided that no regulatory changes to the standard were warranted, it did determine that additional outreach and worker training would help continue the downward trend of fewer deaths and injuries from trench and excavation work. OSHA concluded that its current Excavations standard has reduced deaths from approximately 90 per year to about 70 per year. *See* 72 Fed. Reg. 14,727 (March 29, 2007).

FCC Section 610 Review of 1993-1995 Rules – In May 2005, the Federal Communications Commission undertook a section 610 review of rules the Commission adopted in 1993, 1994, and 1995 which have, or might have, a significant economic impact on a substantial number of small entities. The FCC solicited public comment on the rules under review, explained the criteria it was using to review the rules, and gave instructions on where to file comments. This approach was transparent because the agency allowed adequate time for comments (three months) and gave interested parties sufficient information to prepare useful comments. *See* 70 Fed. Reg. 33,416 (June 8, 2005).

How can agencies get section 610 assistance from the Office of Advocacy?

The Office of Advocacy is ready to assist agencies that are planning a retrospective review of their regulations, to ensure that the review fully meets the requirements of section 610. Discussions with the Office of Advocacy are confidential interagency communications, and the Advocacy staff is ready to assist you. For more information about this guidance, or for other questions about compliance with section 610, please contact Advocacy at (202) 205-6533.

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