Chapter 5
SQUEEZING BACK: MAKING FEDERAL AGENCIES MEASURE THEIR ECONOMIC IMPACT ON SMALL ENTITIES

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Synopsis

§ 5.01 Introduction[1]

In 1980, Congress enacted the Regulatory Flexibility Act (RFA)[2] after determining that uniform federal regulations produced a disproportionate adverse economic hardship on small entities. In order to minimize the burden of regulations on small entities, the RFA mandates that federal agencies consider the potential economic impact of federal regulations on small entities.[3]

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[2] Pub. L. No. 96-354, 94 Stat. 1164 (1980), amended by Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 847, 857 (1996) (codified as amended at 5 U.S.C. §§ 601-612, 801-808 (elec. 2006)).

[3] The RFA defines a small entity as a small business, small organization, or small governmental jurisdiction. 5 U.S.C. § 601(6) (elec. 2006). A small business is defined by the Small Business Act unless an agency, after consultation with the Office of Advocacy and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency. 5 U.S.C. § 601(3) (elec. 2006). A 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. 5 U.S.C. § 601(4) (elec. 2006). The term small governmental jurisdiction means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000 unless an agency estab-

The RFA requires agencies to prepare and publish an initial regulatory flexibility analysis (IRFA) when proposing a regulation, and a final regulatory flexibility analysis (FRFA) when issuing a final rule for each rule that may have a significant economic impact on a substantial number of small entities. The purpose of the analysis is to ensure that the agency has considered the economic impact of the regulation on small entities and that the agency has considered all significant regulatory alternatives that would minimize the rule's economic impact on affected small entities. The RFA allows the head of an agency to certify a rule in lieu of preparing a regulatory flexibility analysis if the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Pursuant to the RFA, the agency must provide a factual basis for the certification.

Initially, agency compliance with the RFA was not judicially reviewable. As a result, many agencies ignored the RFA and did not conduct full regulatory flexibility analyses in conjunction with their rulemakings since they could not be held legally accountable for not complying with the statute. In response to the widespread agency indifference, Congress amended the RFA in 1996 by enacting the Small Business Regulatory Enforcement Fairness Act (SBREFA). SBREFA revamped some of the requirements of the RFA and provided for judicial review of agencies' final decisions under the RFA.

Judicial review and the additional requirements of SBREFA encouraged agencies to pay closer attention to their RFA obligations. Some agencies submit their draft regulations to the Office of Advocacy in the U.S. Small Business Administration early in the process to obtain feedback on their RFA compliance and small business impact. Early intervention and improved agency compliance with the RFA have led to less burdensome regulations.

The Office of Advocacy began collecting data on the economic impact of SBREFA in the late 1990s. For example, in FY 2001, involvement by the Office of Advocacy in agency rulemakings helped save small businesses an estimated $4.4 billion in new

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lishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency. 5 U.S.C. § 601(5) (elec. 2006).

regulatory compliance costs.[4] Similarly, in FY 2002, the Office of Advocacy's efforts to improve agency compliance with the RFA on behalf of small entities secured more than $21 billion in first-year cost savings, with an additional $10 billion in annually recurring cost savings.[5] In FY 2003, Advocacy achieved more than $6.3 billion in regulatory cost savings and more than $5.7 billion in recurring annual savings on behalf of small entities. Similarly, in 2004, Advocacy helped save small entities more than $17 billion.[6] Most recently, in 2005, Advocacy's involvement in rulemakings resulted in $6.62 billion in first-year savings and $965 million in recurring annual savings for small businesses.

This article will provide background on the RFA, explain the requirements of the RFA, explore the impact of judicial review on the RFA, and provide some guidance on how the RFA reduces regulatory burdens which results in cost savings for small entities.

[1] Background of the Office of Advocacy

In 1976, Congress enacted Public Law No. 94-305.[7] It established the Office of Advocacy as an independent voice for small businesses before Congress and the Administration. The primary functions of the Office of Advocacy were to examine the role of small businesses in the American economy and the contribution that small businesses can make in improving competition, encouraging economic growth, and stimulating entrepreneurship. It was also supposed to measure the direct costs and other effects of government regulation on small businesses and make legislative and nonlegislative proposals for eliminating excessive or unnecessary regulation of small businesses.

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[4] The annual reports on implementation of the RFA can be found on the Office of Advocacy's website at http://www.sba.gov/advo/laws/flex.

[5] It should be noted that revisions made by the Environmental Protection Agency (EPA) to the Cross-Media Electronic Reporting and Record-Keeping Rule produced an estimated savings of $18 billion.

[6] The withdrawal of the Department of Housing and Urban Development's rule implementing the Real Estate Settlement Procedures Act, 12 U.S.C. §§ 2601-2617 (elec. 2006), accounted for $10.3 billion of the $17 billion cost savings.

[7] Pub. L. No. 94-305, 90 Stat. 663 (1976).

At that time, Congress directed the Office of Advocacy to:

> (1) serve as a focal point for the receipt of complaints, criticisms, and suggestions concerning the policies and activities of the Administration and any other Federal agency which affects small businesses;
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> (2) counsel small businesses on how to resolve questions and problems concerning the relationship of small businesses to the Federal Government;
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> (3) develop proposals for changes in the policies and activities of any agency of the Federal Government which will better fulfill the purposes of the Small Business Act and communicate such proposals to the appropriate Federal agencies;
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> (4) represent the views and interests of small businesses before other Federal agencies whose policies and activities may affect small business; and
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> (5) enlist the cooperation and assistance of public and private agencies, businesses, and other organizations in disseminating information about the programs and services provided by the Federal Government which are of benefit to small businesses, and information on how small businesses can participate in or make use of such programs and services.[7.1]

§ 5.02 Regulatory Flexibility Act (RFA) Compliance

[1] Background of the RFA

In the 1970s, Congress debated implementing the RFA. At that time, many small businesses testified about the difficulties that they experienced trying to comply with complex federal regulations.[8] In 1979, President Jimmy Carter added the Small Business Administration to his Regulatory Council and issued a memorandum to the heads of executive departments and agencies directing them to apply regulations in a flexible manner, taking into account the size and nature of the regulated businesses.

By 1980, the cost of governmental regulations had increased dramatically.[9] Accordingly, when the first of three White House Conferences on Small Business occurred that year, the economic impact of governmental regulations was a priority. The conference report noted that the Office of Advocacy estimated that small

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[7.1] *Id*. § 203; 15 U.S.C. § 634c (elec. 2006).

[8] Doris S. Freedman, Barney Singer & Frank S. Swain, "The Regulatory Flexibility Act; Orienting Federal Regulation To Small Business," 93 *Dick. L. Rev*. 439, 440 (1989).

[9] Off. of Advoc., U.S. Small Bus. Admin., Report on the Regulatory Flexibility Act, FY 2005 at 3 (2006), *available at* http://www.sba.gov/advo/laws/flex/05regflx.pdf.

firms spent $12.7 billion annually on government paperwork. At the end of the conference, the conferees recommended a "sunset review" and economic impact analysis of regulations.[10]

During the same time period, the House and Senate Small Business Committees held hearings on the impact of federal regulations on small businesses. At the hearings small business owners stated that the uniform application of regulatory requirements made it difficult for small firms to compete. The congressional hearings and the White House Conference recommendations formed the impetus for the passage of Public Law No. 96-354, the RFA. In the Findings and Purposes section of the Act, Congress stated that:

> (a) (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;
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> (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 though the problems that gave rise to government action may not have been caused by those smaller entities;
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> (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;
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> (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;
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> (5) unnecessary regulations create entry barriers in many industries and discourage potential entrepreneurs from introducing beneficial products and processes;
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> (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;
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> (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;

[10] *Id.*

(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 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.*[11]

[2] Early Implementation Results/Effectiveness

Although the RFA was a relatively short statute, difficulties arose with its implementation. One problem with the RFA was that the statute did not provide for judicial review of agency compliance. Indeed, the express language of the RFA precluded judicial review and stated that the regulatory flexibility analysis should constitute part of the whole record of agency action in connection with the review.[12] One court[13] interpreted the language to mean that the reviewing court was to consider the contents of the preliminary or final regulatory flexibility analysis along with the rest of the record, not in assessing the agency's compliance with the RFA, but in assessing the validity of the rulemaking under other provisions of the law. Thus, if the data in the regulatory flexibility analysis or data anywhere else in the rulemaking record demonstrated that the rule constituted an unreasonable assessment of social costs and benefits, then the rule would be deemed to be arbitrary and capricious and the rule could not stand.

Other problems were related to the language of the statute. For example, pursuant to sections 603, 604, and 605(b) of the RFA, agencies are required to consider the economic impact of an agency action on small entities. The RFA does not define eco-

[11] Pub. L. No. 96-354, § 2, 94 Stat. 1164 (1980) (emphasis added).

[12] Pub. L. No. 96-354, § 611.

[13] Thompson v. Clark, 741 F.2d 401, 405 (D.C. 1984).

nomic impact, which left open to debate the question of whether agencies should consider the indirect impact of actions.

The primary case on direct versus indirect impacts for RFA purposes in promulgating regulations is *Mid-Tex Electric Co-op., Inc. v. F.E.R.C.*[14] *Mid-Tex* addressed a Federal Energy Regulatory Commission (FERC) rule which stated that electric utility companies could include in their rates amounts equal to 50% of their investments in construction work in progress (CWIP). In promulgating the rule, FERC certified that the rule would not have a significant economic impact on a substantial number of small entities. The basis of the certification was that virtually all of the utilities did not fall within the meaning of the term "small entities" as defined by the RFA. Plaintiffs argued that FERC's certification was insufficient because it should have considered the impact on wholesale customers of the utilities as well as the regulated utilities. The court dismissed the plaintiffs' argument. The court concluded that the agency did not have to consider the economic impact of the rule on small entities that did not have to comply directly with the requirements of the rule.[15]

Other problems arose simply due to agency indifference. Whatever the cause of the problem, several attempts were made to amend or reinforce the RFA. During the 101st and 102d Congresses, bills were introduced to address the RFA issues, but they died in committee. Judicial review provisions were also proposed unsuccessfully in the 103d Congress.[16]

In 1993, President Clinton signed Executive Order 12866[16.1] which required agencies to tailor regulations to impose the least burden on society, design regulations in the most cost effective manner to achieve the regulatory objective, and consider regulatory alternatives. The Clinton Administration's National Performance Review also recommended that agency compliance with the RFA be subject to judicial review and that the Office of Advocacy be authorized to draft government-wide guidance on compliance

[14] 773 F.2d 327 (D.C. 1985).

[15] *Id.* at 342.

[16] Off. of Advoc., U.S. Small Bus. Admin., A Guide to the Regulatory Flexibility Act 5 (1996).

[16.1] 58 Fed. Reg. 51,735 (Oct. 4, 1993).

with the RFA.[17] In 1995, the White House Conference on Small Business supported reform of the RFA.[18] Finally, in 1996, Congress passed the SBREFA, which among other things allowed for judicial review of agency compliance with the RFA, expanded the requirements for a regulatory flexibility analysis, and created a panel process for the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA).

[3] RFA Application and Requirements

The language of the statute sets forth a structure for agencies to utilize in meeting the stated purpose and objective of the law. As stated above, the RFA requires agencies to prepare and publish an initial regulatory flexibility analysis (IRFA) when proposing a regulation, and a final regulatory flexibility analysis (FRFA) when issuing a final rule for each rule that may have a significant economic impact on a substantial number of small entities. In theory, if the analysis is performed correctly, it will ensure that the agency has considered the economic impact of the regulation on small entities and that the agency has considered all significant regulatory alternatives that would minimize the rule's economic impact on affected small entities.

Not all agency actions are subject to the requirements of the RFA, however. Therefore, one of the first decisions to make is to determine whether the RFA applies to the particular regulation. In general, the RFA applies to rulemakings that are required to be published pursuant to notice and comment rulemaking under section 553(b) of the Administrative Procedure Act (APA) or any other law.[19] 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.[20]

It should be noted that in some instances permits and orders constitute legislative rules that are subject to the RFA. In *National Ass'n of Home Builders v. U.S. Army Corps of Engineers*,[21]

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[17] Off. of Advoc., U.S. Small Bus. Admin., A Guide to the Regulatory Flexibility Act 5 (1996).

[18] *Id.*

[19] 5 U.S.C. § 601(2) (elec. 2006).

[20] *Id.*

[21] 417 F.3d 1272, 1284 (D.C. Cir. 2005).

plaintiffs challenged nationwide permits issued by the Corps under the Clean Water Act as violating, *inter alia*, the RFA, because the Corps did not conduct a flexibility analysis as required by the RFA. The Army Corps of Engineers argued that its permitting action did not constitute a "rule." It was an "order" because "order" included a "licensing" disposition and a "license" included a "permit." The court considered the argument an "elaborate statutory construction" and rejected it for a more straightforward one. The court found that the permitting action fit within the APA's definition of "rule" because each permit was a legal prescription of general and prospective applicability which the Corps issued to implement permitting authority that Congress entrusted to it pursuant to the Clean Water Act. As such, the action constituted a rule because it was an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.

In addition, the court found that the Army Corps of Engineers' action was a legislative rule because the permits authorized the discharge of certain materials, granted rights, imposed obligations, and produced other significant effects on private interests. Accordingly, they were subject to the notice and comment requirements of the APA and to the requirements of the RFA.

Moreover, in *United States Telecom Ass'n v. Federal Communications Commission*,[22] the court granted a petition challenging an order known as the Intermodel Order by the Federal Communications Commission (FCC) for not following the procedures set forth in the RFA. The Intermodel Order set forth the conditions under which wireline telecommunications carriers must transfer telephone numbers to wireless carriers. Petitioners argued that the FCC's order was a legislative rule that required notice and comment under the APA and a regulatory flexibility analysis under the RFA. The court found that the order was a legislative rule and not an interpretive one because it constituted a substantive change in a prior rule known as the First Order which is subject to the requirements of the APA and RFA. While the FCC satisfied the requirements of the APA, the court agreed with the petitioners that the agency had failed to comply

[22] 400 F.3d 29 (D.C. Cir. 2005).

with the RFA's requirements to prepare a final regulatory flexibility analysis.[23] In its defense, the FCC argued that its failure was harmless and would not have affected the final order. The court rejected this argument, as it was impossible to determine whether or not the order was harmless without the final regulatory flexibility analysis, and remanded the order to the FCC to prepare a FRFA to correct its procedural errors under the RFA.[24]

[4] Exemptions

If a rule is exempt from APA notice and comment requirements, it is also exempt from the RFA requirements. Accordingly, rulemakings that involve a military or foreign affairs function of the United States, or are a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts, are exempt from the RFA. In addition, except where notice or hearing is required by statute, the APA does not apply to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or 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.[25] Under those circumstances, the RFA would 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.

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 reviewing the early RFA case, *In re Sealed Case*,[26] 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

[23] *Id.* at 35.

[24] *Id.* at 42.

[25] 5 U.S.C. § 553 (elec. 2006).

[26] 666 F. Supp. 231 (D.D.C. 1987).

were inapplicable. Because a notice of proposed rulemaking was not required for this rule, the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq*., did not apply.[27]

Moreover, in *National Ass'n for Home Care v. Shalala*,[28] 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 that merely clarify or explain existing laws or regulations.[29]

Furthermore, in *American Moving & Storage Ass'n, Inc., v. U.S. Department of Defense*,[30] the D.C. District Court examined a notice published in the *Federal Register* by the Department of Defense (DOD) 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 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. As a result, the RFA did not apply.[31]

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[27] *Id.* at 235.

[28] 135 F. Supp. 2d 161, 165 (D.D.C. 2001).

[29] *Id.*

[30] 91 F. Supp. 2d 132, 136 (D.D.C. 2000).

[31] *Id.*

Although, in general, interpretative rulemakings are exempt from the RFA, the one exception would be Internal Revenue Service (IRS) interpretative rulemakings. SBREFA amended the RFA to bring certain interpretative rulemakings of the IRS within the scope of the RFA.[32] 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. 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.[33]

[5] Requirements of an Initial Regulatory Flexibility Analysis (IRFA)

The RFA clearly states that an IRFA shall describe the impact of a rulemaking on small entities.[34] In doing so the agency needs to address the reasons that an agency is considering the action; the objectives and legal basis of the rule; the type and number of small entities to which the rule will apply; the projected reporting, record keeping, and other compliance requirements of the proposed rule; and all federal rules that may duplicate, overlap, or conflict with the proposed rule. The agency must also provide 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.[34.1]

Although SBREFA amended the RFA to allow for judicial review, judicial review is available only for final agency actions.[35] In *Allied Local & Regional Manufacturers Caucus v. EPA*,[36] paint manufacturers and associations of manufacturers and distributors of architectural coatings petitioned for review of EPA's regula-

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[32] 5 U.S.C. §§ 603(a), 604(a) (elec. 2006).

[33] 5 U.S.C. § 601(7) (elec. 2006).

[34] 5 U.S.C. § 603(a) (elec. 2006).

[34.1] 5 U.S.C. § 603(c) (elec. 2006).

[35] 5 U.S.C. § 611 (elec. 2006) makes no reference to § 603 in discussing which sections of the RFA are judicially reviewable.

[36] 215 F.3d 61 (D.C. Cir. 2000).

tions 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 decision making not be arbitrary and capricious. The court found that the EPA examined alternatives to product reformulation when creating regulations limiting VOCs' content in consumer and commercial products, and that its decisions were neither arbitrary nor capricious. The court therefore found that EPA had met its obligations under the RFA.[37]

Likewise, in *U.S. Cellular Corp. v. F.C.C.*,[38] the court also 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 whether an agency complied with the requirements of the RFA in issuing an IRFA.[39]

It is important to note that although an IRFA is not judicially reviewable, an agency cannot develop a FRFA if it has not prepared a proper IRFA. In *Southern Offshore Fisheries Ass'n v. Daley*,[40] the National Marine Fisheries Service (NMFS) prepared a certification for the proposed rulemaking. After reviewing public comments, NMFS prepared a FRFA for the final rulemaking.

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[37] *Id.* at 80.

[38] 254 F.3d 78 (D.C. Cir. 2001).

[39] *Id.* at 89.

[40] 995 F. Supp. 1411 (M.D. Fla. 1998).

The court found "NMFS could not possibly have complied with § 604 by summarizing and considering comments on an IRFA that NMFS never prepared." As such, NMFS's FRFA did not comply with the requirements of the RFA.[41]

[6] Requirements of a Final Regulatory Flexibility Analysis (FRFA)

Section 604 of the RFA sets forth the requirements of a FRFA.[42] It states:

> § 604. Final regulatory flexibility analysis
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> (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—
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> (1) a succinct statement of the need for, and objectives of, the rule;

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[41] *Id.* at 1436-37.

[42] 5 U.S.C. § 604 (elec. 2006). It should be noted that in the event that the publication of a notice of proposed rulemaking 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. In *National Propane Gas Ass'n v. U.S. Dep't of Transp.*, 43 F. Supp. 2d 665 (N.D. Tex. 1999), 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.

(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.

One of the most important provisions of SBREFA expanded the requirements of the FRFA to require the agencies to describe the steps that were taken to minimize the impact on small entities.

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."[43] For example, in *Associated Fisheries of Maine, Inc., v. Daley*,[43.1] 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 salu-

[43] Associated Fisheries of Maine, Inc., v. Daley, 127 F.3d 104, 115 (1st Cir. 1997); Grand Canyon Air Tour Coalition v. F.A.A., 154 F.3d 455, 470 (D.C. Cir. 1998); Nat'l Propane Gas Ass'n v. D.O.T., 43 F. Supp. 2d 665, 681 (N.D. Tex. 1999); Associated Builders & Contractors, Inc. v. Herman, 976 F. Supp. 1 (D.D.C. 1997).

[43.1] 127 F.3d 104 (1st Cir. 1997).

tary measures designed to ease that burden, and satisfactorily explained reasons for adopting others. Similarly, in *Alenco Communications, Inc. v. F.C.C.*,[44] the court held that the regulatory analysis was compliant with the terms of the RFA where the agency provided a lengthy analysis of the economic impact of the proposed rule on small businesses and responded to comments submitted by the Office of Advocacy and other commenters.

[7] Alternatives

Less burdensome alternatives to the regulatory action achieve cost savings for small entities. The RFA requires agencies to provide a statement of the factual, policy, and legal reasons for choosing the selected alternative and to explain why each of the significant alternatives that affect the impact on small entities was rejected. In considering alternatives, the agency should make a "reasonable, good-faith effort to canvass major options and weigh their probable effects" in order to achieve the statutory objectives while lessening the regulatory burden on affected small entities.[45] However, an agency is not required to address every possible alternative. The agency must only consider significant alternatives.[46] "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.[47]

For example, in *Ace Lobster Co. v. Evans*,[48] the Department of Commerce imposed limitations on the number of lobster traps that could be used in a particular area. Lobster fishermen and business owners alleged that the Department of Commerce implemented the regulations in violation of the APA, the Magnuson-Stevens Fishery Conservation and Management Act, and the RFA. The basis for the assertion was that during the comment period, numerous commenters submitted information about an

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[44] 201 F.3d 608 (5th Cir. 2000).

[45] Nat'l Ass'n of Psychiatric Health Sys. v. Shalala, 120 F. Supp. 2d 33, 42 (D.D.C. 2000) (quoting *Associated Fisheries*, 127 F.3d at 116).

[46] *Associated Fisheries*, 127 F.3d at 115; *see also Grand Canyon*, 154 F.3d at 470; Blue Water Fishermen's Ass'n v. Mineta, 122 F. Supp. 2d 150, 178 (D. D.C. 2000).

[47] Little Bay Lobster Co v. Evans, No. 00-007-M, 2002 WL 1005105 (D. N.H. May 16, 2002) (not for publication).

[48] 165 F. Supp. 2d 148 (D. R.I. 2001).

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.[49] 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.[50]

[8] Certification

SBREFA also expanded the requirements of a certification. When an agency issues a rulemaking proposal, the 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."[51] 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. Prior to SBREFA, agencies were required to provide a succinct statement explaining the reasons for the certification. SBREFA amended the requirement to provide that a certification must be supported by a factual basis. The Office of Advocacy

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[49] *Id.* at 185.

[50] *Id.*

[51] 5 U.S.C. § 603(a) (elec. 2006).

advises agencies that they must perform a threshold analysis in order to determine if a certification is appropriate.

Courts have reviewed the issue of whether a certification was adequate. The *North Carolina Fisheries Ass'n, Inc. v. Daley*[52] case provides 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 case first arose in 1997 when 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."[53] 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."[54] 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."[55]

After remand, the issue returned to the court in 1998.[56] The issue before the court was whether the Secretary of Commerce had discharged his responsibilities under the RFA and under National Standard 8 of the Magnuson-Stevens Act to perform an economic analysis. 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

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[52] 16 F. Supp. 2d 647 (E.D. Va. 1997).

[53] *Id.* at 653.

[54] *Id.*

[55] *Id.*

[56] N.C. Fisheries Ass'n, Inc. v. Daley, 27 F. Supp. 2d 650 (E.D. Va. 1998).

obviously is designed to justify a prior determination."[57] The court further stated that as part of an adequate analysis before certification, the agency must consider alternatives less burdensome to small entities.[58] 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."[59] The court felt that Secretary Daley's certification in this instance amounted to 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.[60]

Moreover, in *Harlan Land Co. v. U.S. Department of Agriculture*,[60.1] 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. 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 no economic impact on a substantial number of small entities was based on its conclusion that there was a negligible risk of

[57] *Id.* at 652.
[58] *Id.* at 661.
[59] *Id.*
[60] *Id.*
[60.1] 186 F. Supp. 2d 1076 (E.D. Cal. 2001).

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.

[9] Additional Requirements of the RFA

In addition to considering the economic impact of a rulemaking on small entities, the RFA and SBREFA require agencies to publish a semi-annual regulatory agenda and to periodically review rules.

[a] Semi-Annual Regulatory Agendas

The RFA requires agencies to publish in the *Federal Register* during April and October of each year a regulatory flexibility agenda, which must contain:

> (1) 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;
>
> (2) a summary of the nature of any such rule under consideration . . . , 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).[60.2]

If a regulatory flexibility agenda includes a realistic assessment of the regulations under consideration by the agency for development in the coming year, it can be very useful for small entities. The notice provides agencies with an opportunity to gather information for meaningful comments and to develop less costly alternatives that may be presented to an agency.

[b] Periodic Review of Existing Rules

Section 610 of the RFA requires agencies to review within 10 years of their adoption as final rules all regulations that have a significant economic impact on a substantial number of small entities. 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

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[60.2] 5 U.S.C. § 602 (elec. 2006).

(consistent with the objectives of applicable statutes) to minimize impacts on small entities.[61]

[10] Additional Major Changes to the RFA as a Result of the SBREFA That Have Yielded Cost Savings for Small Entities

[a] Panel Process

One of the key provisions in SBREFA is section 609,[61.1] 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.

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.[62] 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 RFA already mandates for all new rules that affect small entities. When problems are resolved before a proposed rule is published, objections from the public are reduced and stronger alternatives to reduce regulatory burdens are pro-

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[61] *See* 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 Urban L.J.* 1199 (2006).

[61.1] 5 U.S.C. § 609 (elec. 2006).

[62] In June 1995, Senator Pete V. Domenici introduced S. 917, the Small Business Advocacy Act, to facilitate small business involvement in the regulatory process. The Act established a small business review panel to facilitate small business involvement in the regulatory development process within the EPA and OSHA. In his floor statement, Senator Domenici stated that EPA and OSHA were chosen because they were repeatedly cited as the most onerous and costly agencies to small business. He also referred to the findings of the New Mexico Small Business Council and a June 1994 General Accounting Office report, "Workplace Regulation—Information on Selected Employer and Union Experiences." *See* http://www.sba.gov/advo/laws/dom_s8255.html.

His statement was consistent with the findings of the November 1995 Hopkins Report, *Profiles of Regulatory Costs*, which was sponsored by the Office of Advocacy. The Report found that tax and environmental compliance costs were the highest. It also cited OSHA as having rising compliance costs.

duced. Experience has shown that the panel process results in better rules.

[i] Timing of Panel Process

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. If 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.[63]

However, the Chief Counsel for the Office of 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 contains several factors to be considered in making this determination, including whether small entities have already been consulted in the rulemaking process and whether special circumstances warrant the prompt issuance of a rule.

[ii] Procedure for Panel Process

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 the Office of 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.

[63] 5 U.S.C. § 609(a) (elec. 2006).

The formal panel process begins with the convening of the panel by the rulemaking agency. The date is normally fixed after consultation with both the Office of Advocacy and the Office of Information and Regulatory Affairs. 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 panel process achieves several objectives. 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 develops and recommends less burdensome alternatives to a regulatory proposal when warranted. Finally, the panel provides the rulemaking agency with input from both real world small entities and the panel's report and analysis prior to publication.

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. The panel process has resulted in significant cost savings for small entities while allowing the agency to achieve its regulatory goals.

[b] Compliance Guides

SBREFA requires agencies to provide plain English compliance guides to clearly explain each final rule that has a significant economic impact on a substantial number of small enti-

ties.[63.1] The intent of section 212 of SBREFA was to ensure that small businesses had a way to understand complex and technical federal regulations. Unfortunately, this is not always being done and small businesses continue to be frustrated with rules that are published without adequate compliance information.

[c] Creation of Small Business Ombudsman and Fairness Boards to Address Regulatory Enforcement Problems

SBREFA also required each agency to establish a policy to provide for the reduction and, under appropriate circumstances, the waiver of civil penalties for violations of statutory or regulatory requirements by a small business.[63.2] It required the Administrator of the U.S. Small Business Administration to designate a Small Business and Agriculture Regulatory Enforcement Ombudsman and to establish a Small Business Regulatory Fairness Board in each SBA regional office.[63.3] Whereas the Chief Counsel of Advocacy reviews agency rulemaking activities to determine the impact on groups of small entities, the Small Business and Agriculture Regulatory Enforcement Ombudsman works with each agency to review complaints from small businesses concerning enforcement related activities conducted by agency personnel and to reduce unreasonable penalties.

The Ombudsman is required to report annually to Congress on agency enforcement efforts. Small Business Regulatory Fairness Boards are established regionally to advise the Ombudsman on regulatory issues and agency enforcement activities that affect small businesses. Board members are small business owners and operators appointed by the SBA Administrator after consultation with the leadership of the House and Senate Small Business Committees.

[11] Additional Notable Cases and Impact of Judicial Review

Judicial review has resulted in increased agency compliance with the RFA. Agencies are performing better economic analyses

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[63.1] SBREFA, § 212, 5 U.S.C. § 601 note (elec. 2006).

[63.2] SBREFA, § 223, 5 U.S.C. § 601 note (elec. 2006).

[63.3] 15 U.S.C. § 657 (elec. 2006).

and providing more detailed information about the economic impact of the proposed actions on small entities. In some instances, judicial review has resulted in the delay of implementation of rules and cost savings for small entities. In other cases, it has resulted in an increased understanding of the requirements of the RFA and has provided insight into the areas that still need to be addressed to further reduce the regulatory burden on small entities.[64]

[a] ***Northwest Mining Ass'n v. Babbitt***

The first case to garner a complete remand of a rule for violation of the RFA was *Northwest Mining Ass'n v. Babbitt.*[65] In that case, 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. The court found 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. In remanding the rule, the court stated that: "While recognizing the public interest in preserving the environment, the Court also recognizes the public interest in preserving the right of parties which are affected by government

[64] For a detailed discussion on early SBREFA case law, see the Off. of Advoc., U.S. Small Bus. Admin., A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act 63-80 (2003), *available at* http://www.sba.gov/advo.

[65] 5 F. Supp. 2d 9 (D.D.C. 1998). Although § 612(b) of the RFA gives the Chief Counsel for the Office of Advocacy the authority to intervene as amicus curiae in any action brought in a U.S. court to review a rule, that option is rarely exercised. However, the Chief Counsel for the Office of Advocacy filed as amicus curiae in support of a group of small businesses that brought suit against the Bureau of Land Management to enjoin enforcement of a new regulation that the businesses contend will have a detrimental effect on them. Specifically, the Office of Advocacy challenged the agency's use of a small business size standard that was not in compliance with the SBA standards published in the Code of Federal Regulations under the mandate of the Small Business Act, and the brief raised concerns about the substance of the economic analysis put on record by the BLM.

regulation to be adequately informed when their interests are at stake and to participate in the regulatory process as directed by Congress."[66]

[b] *Southern Offshore Fishing Ass'n v. Daley*

In *Southern Offshore Fishing Ass'n v. Daley*,[67] the plaintiffs questioned the National Marine Fisheries Service's (NMFS) decision to reduce the quota for the shark fishery by 50%. The plaintiffs alleged that the NMFS failed to comply with the requirements of the RFA by failing to prepare an IRFA, solicit comments on the IRFA, prepare a FRFA incorporating the public comments on the FRFA, and prepare a FRFA in compliance with 5 U.S.C. § 604.

In reviewing the NMFS's decision to reduce the quota by 50%, the court ruled that the Secretary of Commerce did not act in a manner that was arbitrary and capricious. However, in determining whether NMFS complied with the RFA, the court found that the Secretary's "no significant economic impact" certification and the FRFA failed to satisfy APA standards and RFA requirements. The court criticized the agency's economic analyses and failure to comply with the law. It stated:

> NMFS prepared a FRFA lacking procedural or rational compliance with the requirements of the RFA. Section 604 requires that any FRFA contain "a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments." 5 U.S.C. § 604(a)(2). NMFS could not possibly have complied with § 604 by summarizing and considering comments on an IRFA that NMFS never prepared. NMFS's refusal to recognize the economic impacts of its regulations on small businesses also raises serious question about its efforts to minimize those impacts through less drastic alternatives. . . . NMFS may not have rationally considered whether and how to minimize the 1997 quotas' economic impacts because the agency fundamentally misapprehended the unraveling economic effect of its regulations on small business.[68]

The court remanded the agency's RFA determinations to the Secretary with instructions to undertake a rational analysis of

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[66] *Id.* at 15.

[67] 995 F. Supp. 1411 (M.D. Fla. 1998).

[68] *Id.* at 1434-36.

the economic effects and potential alternatives. The court retained jurisdiction over the case to review the economic analysis. Because of the delicate status of the Atlantic sharks, the court ruled that the public interest requires maintenance of the 1997 Atlantic shark quotas pending remand and further review of the court.[69]

On remand, the court addressed the insufficiency of the court-ordered economic analysis of the effects of the reduction in the shark quota submitted by NMFS. The court found that "the 1997 quota visited on shark fishermen a tangible and significant economic hardship."[69.1] In making the determination, the court criticized NMFS for relying on a pool of more than 2,000 individuals who hold shark fishery permits to constitute the universe of fishermen potentially affected by the quotas, even though 3/4ths of the permittees are not expected to land one shark. It stated that relying on the more than 2,000 plus permit holders as the operative universe enabled NMFS to disperse arithmetically the statistical impact of the quotas on shark fishermen.[69.2]

The court also found that "NMFS inadequately considered, and perhaps overlooked altogether, feasible alternatives or adjustments to the 1997 quotas that may mitigate the quotas' pecuniary injury to the directed shark fisherman."[69.3] In doing so, the court stated that "the defendant affords minimal treatment to more realistic and constructive alternatives. . . ."[69.4] To assist the court in reviewing the issue of NMFS's consideration of alternatives, the court appointed a special master for the purpose of analyzing the bona fides of the defendant's remand submission with respect to the availability of workable alternatives, regulatory and otherwise, to the 1997 shark quota.[69.5]

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[69] *Id.* at 1437.

[69.1] S. Offshore Fishing Ass'n v. Daley, No. 8:97-cv-1134-T-23EAJ, at 4 (M.D. Fla. Oct. 17, 1998).

[69.2] *Id*.

[69.3] *Id*. at 7.

[69.4] *Id*. at 5.

[69.5] *Id*. at 7-8.

[c] Indirect Impacts

Even after SBREFA, the issue of foreseeable indirect impacts continues to create major problems for small entities. In *American Trucking Ass'n, Inc. v. EPA*,[70] the U.S. Court of Appeals for the District of Columbia applied the holding of the *Mid-Tex* case.[71] In the *American Trucking* case, EPA established primary national ambient air quality standards (NAAQS) for ozone and particulate matter. At the time of the rulemaking, EPA certified the rule pursuant to 5 U.S.C. § 605(b). The basis of the certification was that small entities were not subject to the rule because the NAAQS regulated small entities indirectly through state implementation plans (SIPs). Although the court remanded the rule to the agency, the court found that EPA had complied with the requirements of the RFA. Specifically, 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 directly impact small entities.[72] The court also found that since the states would have broad discretion in obtaining compliance with the NAAQS, small entities were only indirectly affected by the standards.[73]

In *Mid-Tex*, compliance with FERC's regulation by the utilities was expected to have a ripple effect on customers of the small utilities. There were several unknown factors in the decisionmaking process that were beyond FERC's control, such as whether utility companies had investments, the number of investments, costs of the investments, the decision of what would be recouped, and to whom the utilities would pass the investment costs on.

Unfortunately, the concept of the RFA not applying to indirect economic impacts is now being used by agencies in cases where the impact is reasonably foreseeable, which undermines the spirit of the RFA. The 2002 Immigration and Naturalization Service's (INS) rule on B-2 tourist visas illustrates the importance of having reasonably foreseeable indirect impacts analyzed under the RFA in the rulemaking process. On April 12, 2002, the INS published a proposed rule, Limiting the Period of Admission

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[70] 175 F.3d 1027 (D.C. Cir. 1999).

[71] *See supra* § 5.02[2].

[72] *Am. Trucking*, 175 F.3d. at 1045.

[73] *Id. See also* Motor & Equip. Mfrs. Ass'n v. Nichols, 140 F.3d 449 (D.C. 1998).

for B Nonimmigrant Aliens.[74] The proposal eliminated the minimum six-month admission period of B-2 visitors for pleasure and placed the onus of explaining the amount of time for the length of stay on the foreign visitor. If the length of stay could not be determined, the INS agent would issue a visa for only 30 days.[75] Although it was foreseeable that small businesses in the travel industry could lose approximately $2 billion as a result of the proposal, INS certified that the proposal would not have a significant economic impact on a substantial number of small entities. The basis for the certification was that the proposal applied only to nonimmigrant aliens visiting the United States as visitors for business or pleasure.[76]

Because the courts have interpreted the RFA as only requiring agencies to consider the economic impact of the proposal on the entities that the proposal will directly impact, the certification was not technically erroneous. The Office of Advocacy submitted public comments asserting that from the standpoint of good public policy, the agency had a duty to perform a regulatory flexibility analysis and to consider less burdensome alternatives for achieving its goal when the potential impact of a regulation was foreseeable and economically devastating to a particular industry.[77] The Office of Advocacy reiterated this position at a hearing before the House Committee on Small Business in June 2002.[78] Representatives from the travel industry also testified at that hearing about the potential economic impacts that their businesses would have experienced as a result of INS's actions. The rule was eventually withdrawn.

§ 5.03 Other Issues

[1] Executive Order 13272

Even with the additional requirements under SBREFA and the threat of judicial review, some agencies were not complying with

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[74] 67 Fed. Reg. 18,065 (Apr. 12, 2002).

[75] *Id.*

[76] *Id.*

[77] The Office of Advocacy's comment letter is *available at* http://www.sba.gov/advo/laws/comments/ins02_0513.html.

[78] The Office of Advocacy's testimony before the U.S. House of Representatives, Committee on Small Business, is *available at* http://www.sba.gov/advo/laws/test02_0619.html.

the requirements of the RFA. On March 19, 2002, President George W. Bush announced his Small Business Agenda, which included the goal of tearing down the regulatory barriers to job creation for small businesses and giving small business owners a voice in the complex and confusing federal regulatory process.[78.1] To accomplish this goal, the President sought to strengthen the Office of Advocacy by enhancing its relationship with the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA), and by creating an executive order that would direct agencies to work closely with the Office of Advocacy and properly consider the impact of their regulations on small entities. To further this goal, on August 13, 2002, the President signed Executive Order 13272, titled "Proper Consideration of Small Entities in Agency Rulemaking."[79]

Executive Order 13272 enhances the Office of Advocacy's RFA mandate by directing federal agencies to implement written procedures and policies for measuring the economic impact of their regulatory proposals on small entities. It also requires agencies to notify the Office of Advocacy of draft rules that are expected to have a significant economic impact on a substantial number of small entities and to give every appropriate consideration to any comments provided by the Office of Advocacy, including publishing a response to the Office of Advocacy's comments in the *Federal Register*.

Early intervention in the rulemaking process has assisted the Office of Advocacy in obtaining savings for small businesses. For example, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Act),[79.1] authorized the Food and Drug Administration (FDA) to promulgate rules in an expedited timeframe to protect the nation's food supply. In response to the Act, FDA published four final rules, each preceded by a notice of proposed rulemaking: (1) prior notice of imported food shipments, (2) registration of food facilities, (3) establishment and maintenance of records, and (4) administrative detention. The Act required FDA to publish the first three rules within 18 months

[78.1] *See* http://www.whitehouse.gov/news/releases/2002/03/20020319-2.html.

[79] Exec. Order No. 13,272 (Aug. 13, 2002), 67 Fed. Reg. 53,461 (Aug. 16, 2002).

[79.1] Pub. L. No. 107-188, 116 Stat. 594 (2002).

or by December 12, 2003. FDA contacted the Office of Advocacy about the rules' impact on small businesses well before the proposed rules were published in the *Federal Register*. This early intervention allowed the Office of Advocacy to work closely with the FDA to reduce the economic effects of the rules on small businesses. As a result of the involvement of the Office of Advocacy and interested small businesses, FDA made several adjustments to the final rules including the creation of the new automated commercial environment (ACE) database and a far less onerous notice requirement (24 hours notice was reduced to two hours if the food is arriving by road, four hours if the food is arriving by rail, and eight hours if the food is arriving by sea); extending the registration update requirement from 30 days to 60 days; allowing those importers subject to the rule to check a food category titled "most or all" rather than requiring them to individually list food product categories that had been previously identified in the registration form; and exempting the food packaging industry, which consists primarily of small businesses, from the registration and prior notice requirements. The FDA also gave small businesses more time to comply with the requirements. The type of flexiblity in the implementation of the rule is demonstrative of the types of alternatives that can be implemented to reduce costs for small entities.[80]

[2] Implementation of the RFA in the States

The need for flexibility is not limited to federal regulations. At least 92% of businesses in every state are small businesses.[81] Those businesses bear a disproportionate share of regulatory costs and burdens.[82] Recognizing that state and local governments can be a source of burdensome regulations on small business, the Office of Advocacy drafted model regulatory flexibility legislation for the states based on the federal Regulatory Flexibility Act.[83]

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[80] Improving the Regulatory Flexibility Act - H.R. 682: Hearing before the H. Comm. on Small Business, 109th Cong. 3 (2005) (testimony of Thomas M. Sullivan, Chief Counsel of Advocacy, U.S. Small Bus. Admin.). Testimony *available at* http://www.sba.gov/advo/laws/test05_0316.txt.

[81] Off. of Advoc., U.S. Small Bus. Admin., Report on the Regulatory Flexibility Act, FY 2005 at 47-48 (2006), *available at* http://www.sba.gov/advo/laws/flex/05regflx.pdf.

[82] *Id.*

[83] *See* http://www.sba.gov/advo/laws/law.modeleg.html#Model.

Many states have some form of regulatory flexibility laws on the books. However, many of the laws do not contain the five critical elements addressed in the Office of Advocacy's model legislation. The model legislation recommends that state-level regulatory flexibility laws contain the following: (1) a small business definition that is consistent with state practices and permitting authorities; (2) a requirement that state agencies perform an economic impact analysis on the effect of a rule on small businesses before they regulate; (3) a requirement that state agencies consider alternatives that are less burdensome for small businesses while still meeting the agency's regulatory goals; (4) a provision that requires state governments to review existing regulations periodically; and (5) judicial review to give the law "teeth." Since 2002, 14 states have enacted regulatory flexibility laws based on the Office of Advocacy's model legislation. Those states are Alaska, Colorado, Connecticut, Indiana, Kentucky, Missouri, New Mexico, North Dakota, Oregon, Rhode island, South Carolina, South Dakota, Virginia, and Wisconsin.[84]

[3] Conclusion

The provisions of SBREFA have enhanced the requirements of the RFA. SBREFA closed some major loopholes in the RFA, such as judicial review, and added important new provisions that require major regulatory agencies (EPA and OSHA) to seek early involvement by small entities in the rulemaking process. The SBREFA amendments and increased institutionalization of the RFA requirements have resulted in significant cost savings for small entities by requiring agencies to consider less burdensome alternatives to regulatory actions. Maximum cost savings are achieved through early intervention via the panel process, through agency compliance with Executive Order 13272, through agencies giving full consideration to small entity comments on an IRFA, and the additional alternatives that small entities may submit for consideration pursuant to the RFA. Additional cost savings could be achieved if the RFA is further amended to include foreseeable indirect impacts. Such an addition would allow small entities to fully utilize the tools of the RFA and SBREFA to reap less burdensome regulations.

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[84] *Id.*