U.S. Small Business Administration
Office of Advocacy

February 2002

Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act, Fiscal Year 2001

The Office of Advocacy of the U.S. Small Business Administration was established in 1976 by Congress under Public Law 94-305 to advocate the views of small business before federal agencies and the Congress. The Chief Counsel for Advocacy is charged with monitoring agency compliance with the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) and reporting annually to the President and Congress on its implementation. This report addresses regulatory flexibility activity in fiscal year 2001.

As background to this report, the Office of Advocacy's 1999 communications with federal agencies on their compliance with the Regulatory Flexibility Act can be viewed on the office's site on the Internet at *www.sba.gov/advo*.

Copies of this report, as well as a companion report, *The Regulatory Flexibility Act: An Implementation Guide for Federal Agencies*, can be obtained at the home page or by writing to the Office of Advocacy at 409 Third Street S.W., Washington, DC 20416.

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To the President and Congress of the United States:

The Office of Advocacy has just celebrated a milestone: 25 years since it was empowered by the Congress to be an independent voice for small business. Since the enactment of the Regulatory Flexibility Act (RFA) in 1980, the Office of Advocacy has had an oversight role in implementing the law. The RFA requires federal agencies to determine whether a proposed rule will have a disproportionate effect on small firms and other small entities and, if so, to explore alternative regulatory solutions. As the U.S. Small Business Administration's Chief Counsel for Advocacy charged with monitoring federal agency compliance with the act, I am pleased to send you this report, which offers a review of RFA achievements and ongoing concerns in fiscal year 2001.

The small business community saved an estimated $4.4 billion in compliance costs as the result of regulatory changes made in fiscal year 2001 in response to recommendations made by the Office of Advocacy and the small business community. Many agencies should be applauded for their willingness to change regulatory proposals after analyzing scientific and economic data about burdensome impacts and finding equally effective alternatives for accomplishing public policy objectives. The RFA was enacted by Congress to accomplish these very outcomes, and it continues to be a strong tool for working within the federal regulatory arena.

The implementation of the act became more effective with the 1996 passage of the Small Business Regulatory Enforcement Fairness Act (SBREFA). Among other things, SBREFA amended the RFA to allow a small business, appealing from an agency final ruling action, to seek judicial review of an agency's compliance with the RFA. Not surprisingly, this change has been accompanied by increased agency interest in avoiding challenges to their regulations.

One thing has not changed: the need for the Office of Advocacy's involvement is greater than ever. Small firms continue to rely on an advocate to monitor the obstacles to small business growth that emerge in an ever-changing, regulated, but dynamic marketplace. In one report, of course, there is no way to capture all the daily interactions between Advocacy staff and regulatory officials in other federal agencies. More and more of Advocacy's involvement occurs during the pre-proposal and regulatory development stages, and while this work is not fully reflected in official comment letters, it is key to RFA enforcement. Certainly, the earlier an agency can take small business concerns into consideration during the regulatory development process, the more effective it can be in fulfilling the law's intent.

To ensure that the RFA is implemented properly, the Office of Advocacy educates both federal agencies and small entities about the RFA through seminars, briefings, and publications. Information about these, as well as regulatory comments and testimony, appear on Advocacy's home page at *http://www.sba.gov/ADVO*. Advocacy's active outreach, along with other specific procedures in place for examining the effects of rules on small businesses, continues to be a key component in ensuring that the RFA is a tool for responsible government.

Thomas M. Sullivan
Chief Counsel for Advocacy

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EXECUTIVE SUMMARY

In recent years, the economy has been extremely dynamic, with technology changing industry structure at a very rapid pace and creating new challenges for analyses of regulatory impacts on small business. Small businesses are a major force in this changing economic landscape, contributing major technological innovations that are spurring growth in the economy and creating most of the new jobs. In order to maintain this trend of job development, the continued viability of small businesses must be ensured.

In 1980, the U. S. Congress enacted the Regulatory Flexibility Act (RFA) with a mandate to federal regulatory agencies to analyze the impact of their regulations on small entities and to consider alternatives that would be equally effective in achieving public policy goals without unduly burdening small businesses. The Chief Counsel for Advocacy's annual report to Congress and the President on implementation of the Regulatory Flexibility Act provides insight into whether federal agency regulations were disproportionately burdensome on small businesses and whether they interfered with small business growth and innovation.

The annual report on regulatory flexibility compliance provides Congress and the President an opportunity to review the effects agency actions may have on small entities and to determine whether the agencies are meeting both the intent and the letter of the law. This report is divided into several parts. The first provides an overview of the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA): its purpose, how it is to be implemented by agencies, and why it is important to the small business community. The second part describes the role of the Office of Advocacy in rulemaking and lists FY 2001 achievements, comment letters, and SBREFA panels. The third highlights agency achievements and how more than $4.4 billion in compliance cost savings were achieved in fiscal year 2001. The fourth looks at ongoing concerns with respect to agency RFA compliance.

For many years the view of the Office of Advocacy and many small business advocates was that the RFA needed more teeth to accomplish compliance and that noncompliance was caused, in large part, by the lack of enforcement provisions in the law. With the passage of SBREFA, a small entity adversely affected or aggrieved by a final rule may, on appeal from the rule, seek judicial review of an agency's failure to comply with the RFA. This revision in the law continues to have a beneficial effect on the regulatory process. To avoid judicial review, some agencies are more inclined to do the kind of analysis required by the RFA and select the regulatory options that will achieve the regulatory objectives without imposing an unduly heavy burden on small entities.

The law is working, but the need for continued attention to the effects of regulation on the regulated population is greater than ever.

OVERVIEW OF THE REGULATORY FLEXIBILITY ACT AND FEDERAL AGENCY COMPLIANCE WITH THE LAW

The Regulatory Flexibility Act[1] is an important statute that, at long last, largely because of the 1996 SBREFA amendments, is having an impact on the way the government views the role of small businesses in the economy. The RFA mandates an analytical process that agencies must follow in order to level the regulatory playing field for small businesses and to preserve competition in the marketplace without compromising public policy objectives. Agencies must undertake a thorough analysis of the economic impact of their proposed regulations and consider alternatives that will achieve the same public policy goals, but with more equitable impact on small entities.

History of the RFA

Before the RFA was enacted in 1980, federal agencies did not evaluate, nor did they see the need to evaluate the impact their rules would have on small businesses. More often than not, agencies failed to recognize or understand the dynamic role small businesses play and how important they are to the nation's economic growth.

It was not readily understood that small businesses would suffer disproportionately—compared with large businesses—from "one-size-fits-all" regulations and that this could harm competition. Direct costs involved in complying with a regulation are often approximately the same for a large company as for a small company. But because a large company is able to spread the compliance costs over larger output, it can maintain a competitive advantage over a small company subject to the same regulation. Because large businesses can afford to hire more people to monitor proposed agency regulations and have easier and more direct input into the regulatory process, small businesses are inherently at a disadvantage in influencing final decisions on regulations.

In 1980, at the first White House Conference on Small Business, the message the delegates sent to the President and the Congress was loud and clear: they wanted relief from the heavy burdens placed on them by federal government regulations. Small businesses argued that when a federal agency issued a regulation, the burden of the law often fell hardest on them, not through any intentional desire by the agency to harm them, but because "one-size-fits-all" regulations were easier to design and enforce. No thought was given to any disproportionate impact, nor to the possibility that alternatives might be equally effective in achieving public policy objectives. Recognizing both the different impacts of regulations on firms of different sizes and the disparity between large and small firms in the level of input in the regulatory process, the Congress enacted the RFA in 1980 to alter how agencies craft regulatory solutions to societal problems and to change the one-size-fits-all regulatory mindset.[2]

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[1] The Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (codified at 5 U.S.C. § 601 *et seq.*), became law on September 19, 1980. The full law as amended appears as Appendix A of this report.

[2] Congress agreed with small businesses when it specifically found in the preamble to the RFA that "laws and regulations designed for application to large scale entities have been applied uniformly to small [entities, . . .] even

The Analysis Required by the RFA

The RFA requires a federal agency to review its regulatory proposals and determine if any new rule is likely to have a "significant economic impact on a substantial number of small entities." If such impact is likely to occur, the agency must prepare and make available for public comment an "initial regulatory flexibility analysis," describing in detail the potential economic impact of the proposed rule on small entities.

An essential part of this analysis is identifying alternatives to the proposed rule that can accomplish the same regulatory objectives but with reduced economic impact on small entities. By mandating this analytical process, the RFA seeks to ensure that agencies understand not only the industries they are regulating, but also the potential effect of their regulations on small entities before it is too late to pursue alternative measures. To reach this level of understanding, it is crucial for the agencies to solicit meaningful input from the small business community as early as possible.

The RFA is built on the premise that when an agency undertakes a careful analysis of its proposed regulations—with sufficient small business input—the agency can and will identify any disproportionate economic impact on small businesses. Once an agency identifies the impact a rule will have on small businesses, it is expected to seek alternative measures to reduce or eliminate the disproportionate small business burden without compromising public policy objectives. The RFA does not require special treatment or regulatory exceptions for small business, but mandates an analytical process for determining how best to achieve public policy objectives without unduly burdening small businesses.

Federal Agencies' Response to the RFA

The general purpose of the RFA is clear. However, in monitoring agency compliance, the Office of Advocacy has found over the years, and has reported to the President and the Congress, that federal agencies often failed to conduct the proper analyses as required by the law. Some agencies ignored the RFA altogether, while others asserted that the RFA did not apply to them. Other agencies recognized the RFA's applicability to their regulations, yet failed to comply with its requirements.

Agencies often did not understand or accept the possibility that less burdensome regulatory alternatives mignt be equally effective in achieving the agency's public policy objectives. Thus, many agencies failed—or even refused—to consider valid alternatives to their proposals, even when such options were brought to their attention by small businesses during the rulemaking process.

An agency's failure to weigh alternatives properly not only defeats the core purpose of the RFA; it effectively excludes small businesses from meaningful opportunity to influence the regulatory development process as Congress intended. Until 1996, there was no way to force agencies to comply, nor did the small business community have a remedy to seek redress. And

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though the problems that gave rise to the government action may not have been caused by those small entities." FINDINGS AND PURPOSES, Pub. L. No. 96-354. As a result, Congress found that these regulations have "imposed unnecessary and disproportionately burdensome demands" upon small businesses with limited resources, which, in turn, has "adversely affected competition." *Id*.

although the RFA authorized the Chief Counsel for Advocacy of the U.S. Small Business Administration (SBA) to file *amicus curiae* briefs in court cases involving agency regulation, prior to SBREFA, Advocacy could not successfully raise the issue of agency noncompliance because the courts did not have jurisdiction over the question.

The 1996 SBREFA Amendments to the RFA

The 1995 White House Conference on Small Business provided small business owners another opportunity to seek an amendment to the RFA authorizing judicial review of agency compliance with the RFA. They urged Congress to pass amendments that would add "teeth" to the law.

In 1996, the Congress enacted the Small Business Regulatory Enforcement Fairness Act, which amended the RFA in several critical respects. The SBREFA amendments to the RFA were specifically designed to ensure meaningful small business input during the earliest stages of the regulatory development process.

Most significantly, SBREFA authorized judicial review of agency compliance with the RFA, and reaffirmed the authority of the Chief Counsel for Advocacy to file *amicus curiae* briefs in regulatory appeals brought by small entities.

The SBREFA amendments also added a new provision to the RFA, namely, a requirement that small business advocacy review panels be convened to review Environmental Protection Agency (EPA) and Occupational Safety and Health Administration (OSHA) rules that might affect small entities. The purpose of the panels is to elicit comments from small entities on a rule's impact and alternatives that should be considered, and to develop a report on the panel's findings for the head of the agency within 60 days.

THE ROLE OF THE OFFICE OF ADVOCACY

The statutory responsibilities of the Office of Advocacy include representing the interests of small business before policymaking bodies within the federal government, conducting research on small businesses' contribution to the economy, and monitoring federal agency compliance with the Regulatory Flexibility Act.

The Office of Advocacy works with small businesses, federal agencies, trade associations, and the Congress to promote compliance with the RFA through several avenues. In FY 2001, the office responded to congressional inquiries on issues such as procurement reform, universal telephone service, bonding for mine operations, and recordkeeping for occupational injury and illnesses.

Advocacy staff members review thousands of pages of proposed regulations and work closely with small business owners and regulatory contacts within the federal agencies to focus agency attention on RFA requirements. In FY 2001, there was a noticeable increase in the number of agency inquiries requesting information on how to comply with the RFA and how to address RFA issues in the context of specific rules. These inquiries provided unique opportunities for one-on-one guidance, as well as opportunities to address the concerns of small entities before a rule was proposed. The Office of Advocacy attributes this increase in pre-proposal consultation in part to the SBREFA amendments.

Early intervention by the Office of Advocacy has helped federal agencies develop a greater appreciation of the role small businesses play in the economy and the rationale for ensuring that regulations do not erect barriers to competition. In particular, the Office of Advocacy has provided economic statistics on which industries or industrial sectors are dominated by small firms. These data show regulators why rules should be written to fit the economics of small businesses if public policy objectives will not otherwise be compromised. The Office of Advocacy gives federal agencies ready access to the statistics for use in the federal rulemaking process by making them available on its Internet home page. Advocacy also maintains a database of information on trade associations that can be helpful to federal agencies seeking input from small businesses.

Another avenue used by the Office of Advocacy to promote agency compliance is the network of small business representatives who can inform their members about changes in the law and how small businesses can more effectively participate in the rulemaking process. The Office of Advocacy conducts workshops for small business representatives on federal regulatory agency responsibilities under the law, factors to be addressed in economic analyses performed by agencies as they assess the impact of regulatory proposals, and the new judicial review provision enacted in the SBREFA amendments. Roundtable meetings are routinely held with small businesses and trade associations on specific issues such as procurement reform, environmental regulations, and industrial safety. Advocacy also plays a key role as a participant in the small business advocacy review panels convened to review Environmental Protection Agency and Occupational Safety and Health Administration rules (Table 1).

As regulatory proposals are developed, the Office of Advocacy may become involved through formal comment letters to the agency, congressional testimony if requested, or, where warranted, "friend of the court" briefs. In FY 2001, the Office of Advocacy submitted several dozen formal comment letters on proposed rules, critiquing agency noncompliance with the RFA and suggesting regulatory alternatives for consideration by the agency (Table 2).

One measure of the RFA's effectiveness is an estimate of the compliance costs that small firms will not have to incur as the result of regulatory changes made in response to Advocacy's recommendations and those of the small business community. These cost savings as a result of FY 2001 actions amounted to approximately $4.4 billion (Table 3). The savings are the direct result of agencies' analyses of economic and scientific data urged by Advocacy and the small business community.

Despite Advocacy's efforts, many agencies still fail to comply with the RFA. Some still use "boilerplate" language to certify that rules will not have a significant impact on a substantial number of small businesses without providing the factual justification required by the RFA. Many agencies continue to define "small business" and "small entity" incorrectly. Others fail to provide meaningful evaluations of regulatory alternatives or to perform adequate economic impact analyses. The culture change that finds some agencies welcoming the participation of small businesses and the Office of Advocacy in regulatory development is sometimes the result of litigation brought by small businesses against federal agencies.

The Office of Advocacy continues to work through the RFA and SBREFA processes to bring about better rulemaking at federal agencies up front. The changing culture at the Internal Revenue Service (IRS), whose rules affect every small business, is one example. The IRS once escaped the requirements of the RFA because it categorized most of its rules as "interpretive," meaning the rules simply carried out the intent of Congress and did not impose any additional requirements within the agency's discretion. Since the passage of SBREFA and the addition of some interpretive rules to the scope of the RFA, the IRS has been working with the Office of Advocacy to learn more about RFA compliance. In 2001, the IRS was more likely to request suggestions from small businesses about the most troublesome regulatory requirements and the best approach to solving such problems before the rules were published. That is exactly how the RFA intends the regulatory process to work.

TABLE 1: SBREFA PANELS THROUGH FISCAL YEAR 2001

Rule Subject	Date Convened	Report Completed	NPRM[1]	Final Rule Published
Environmental Protection Agency				
Non-Road Diesel Engines	03/25/97	05/23/97	09/24/97	10/23/98
Industrial Laundries Effluent Guideline	06/06/97	08/08/97	12/12/97	Withdrawn
Stormwater Phase 2	06/19/97	08/07/97	01/09/98	12/08/99
Transport Equipment Cleaning Effluent Guideline	07/16/97	09/23/97	06/25/98	08/14/00
Centralized Waste Treatment Effluent Guideline	11/06/97	01/23/98	01/13/99	12/22/00
Underground Injection Control Class V Wells	02/17/98	04/17/98	07/29/98	12/07/99
Ground Water	04/10/98	06/09/98	05/10/00	
Federal Implementation Plan for Regional Nitrogen Oxides Reductions	06/23/98	08/21/98	09/30/98	
Section 126 Petitions	06/23/98	08/21/98	09/30/98	05/25/99
Radon in Drinking Water	07/09/98	09/18/98	11/02/99	
Long Term 1 Enhanced Surface Water Treatment	08/21/98	10/19/98	04/10/00	
Filter Backwash Recycling	08/21/98	10/19/98	04/10/00	
Light Duty Vehicles/Light Duty Trucks Emissions and Sulfur in Gasoline	08/27/98	10/26/98	05/13/99	02/10/00
Arsenic in Drinking Water	03/30/99	06/04/99	06/22/00	01/22/01
Recreational Marine Engines	06/07/99	08/25/99	In process	
Diesel Fuel Sulfur Control Requirements	11/12/99	03/24/00	06/02/00	01/18/01
Lead Renovation and Remodeling Rule	11/23/99	03/03/00	In process	
Metals Products and Machinery	12/09/99	03/03/00	01/03/01	
Concentrated Animal Feedlots	12/16/99	04/07/00	01/12/01	
Reinforced Plastics Composites	04/06/00	06/02/00	In process	
Stage 2 Disinfection Byproducts	04/25/00	06/23/00	In process	
Recreational Rule – Air Pollution	05/03/01	07/17/01	In process	
Construction and Development Effluent Guideline	07/16/01	10/12/01	In process	
Occupational Safety and Health Administration				
Tuberculosis	09/10/96	11/12/96	10/17/97	
Safety and Health Program Rule	10/20/98	12/19/98	In process	
Ergonomics Program Standard	03/02/99	04/30/99	11/23/99	11/14/00[2]

[1]NPRM= Notice of proposed rulemaking.
[2]President Bush signed Senate J. Res. 6 on 03/20/01, which eliminates this final rule under the Congressional Review Act.

TABLE 2: REGULATORY COMMENTS FILED BY THE OFFICE OF ADVOCACY, FISCAL YEAR 2001

Date	Agency	Comment Subject
10/05/00	FCC	Eligibility Requirements for the Personal Communications Services (PCS) Frequency Blocks C and F Auction
10/12/00	DOT	Regarding H.R. 5164, the Transportation Recall Enhancement, Accountability, and Documentation Act
10/13/00	DOI	Final Regulatory Flexibility Analysis for the Department of the Interior's Rulemaking on Subpart 3809 Surface Management
11/09/00	EPA	Notice of Proposed Rulemaking, Cooling Water Intake Structures for New Facilities Pursuant to 316(b) of the Clean Water Act (65 *Fed. Reg*. 49,060 Aug 10, 2000)
11/20/00	DOJ	Regulation Concerning Commercial Mail Receiving Agencies.
12/12/00	FCC	Regarding Amendment of the Commission's Rules with regard to the 3650-3700 MHz Government Transfer Band (ET Dkt. No 98-237)
12/14/00	FCC	Amendment of the Rules with Regard to the 3650-3700 MHz and 4.9 GHz Band Transfer from the Federal Government.
12/15/00	DOT	Hours of Service of Drivers; Rest and Sleep for Safe Operation (65 *Fed. Reg*. 25540)
01/05/01	FCC	Automatic and Manual Roaming Obligations pertaining to Commercial Mobile Radio Services (WT Dkt. No. 00-193)
01/09/01	FCC	Regarding Children's Television; Obligation of Digital Television Broadcasters; (MM Dkt. No. 00-167)
01/16/01	FCC	In the Matter of Amendment of the Commission's Rules for Community Wireless Telecommunication Networks RM-10024
01/31/01	HHS	Interim Final Rule on the Use of Restraint and Seclulsion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals under 21 Years of Age.
02/08/01	FCC	Promoting Efficient Use of Spectrum through Elimination of Barriers to the Development of Secondary Markets (WT Dkt. No. 00-230)

Date	Agency	Comment Subject
03/17/01	FDA	Ruling that will have a Direct Impact on Ongoing FDA Rulemakings that could be Detrimental to Small Business Interests
03/22/01	DOL	Employment Standards Administration Application of the Fair Labor Standards Act to Domestic Service (66 *Fed. Reg*. 5481 Jan 19, 2001)
03/27/01	EPA	Review of Arsenic Safe Drinking Water Standard.
03/30/01	HHS	Final Rule on Standards for Privacy of Individually Indentifiable Health Information
03/30/01	FCC	Final Regulatory Flexibility Analysis and Initial Regulatory Flexibility Analysis for Numbering Resources Optimization
04/09/01	EPA	Control of Emissions from Nonroad Large Spark Ignition Engines, Recreational Engines (Marine and Land-based), and Highway Motorcycles; SBREFA Small Business Advocacy Panel
04/09/01	EPA	Review of Lead Toxic Release Inventory Reporting Rule.
04/13/01	FCC	Regulatory Review Spectrum Aggregation Limits for Commercial mobile Radio Services.
04/16/01	DOI	The National Park Service's Final Rule Phasing Out Snowmobiles in Yellowstone National Park, on the John D. Rockefeller Jr.Parkway; and with Some Exceptions in Grand Teton National Park (66 *Fed. Reg*. 7259)
04/19/01	FCC	Final Regulartory Flexibility Analysis for Revision of the Commission's Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Systems
05/03/01	FCC	Final Regulatory Flexibility Analysis for Implemetation of the Subscriber Carrier Selection Change Provisions of the Telecommunications Act of 1996 and Policies and Rules Concerning Unauthorized Changes of Consumers' Long Distance Carriers
05/04/01	DOE	Energy Effiiciency Standards for Air Conditioners and Heat Pumps
05/07/01	BLM	Proposed Suspension of the Mining Claims Under the General Mining Laws Rule

Date	Agency	Comment Subject
05/09/01	USDA	Department Side Management and Renewable Energy Systems
05/14/01	FWS	Notice of Availabiltiy of Interim Strategy on Section 7 Consultations Under the Endangered Species Act for Watercraft Access Projects in Florida that may Indirectly Affect the West Indian Manatee.
05/16/01	NAS	Comment on the Provisional Appointments to the NAS Subcommittee to Update the 1999 Arsenic in Drinking Water Report Tasked by the EPA to Review the Standard, Project No. BEST-01-01-A
05/21/01	NAS	Testimony before the National Research Counsil's Subcommittee to Update the 1999 Arsenic Drinking Water Report
05/21/01	DOT	Pipeline Safety: Hazardous Liquid Pipline Accident Reporting Revisions
05/25/01	DOT	Pipeline Integrity Management In Height Consequence Areas (Hazardous Liquid Operators with Less Than 500 Miles of Pipeline)
05/31/01	EPA	Effuent Elimination Guidelines and Standards for the Construction and Development Category; Small Entity Representative Recommendations
06/07/01	DOT	Participation by Disadvantaged Business Enterprises (DBEs) in Department of Transportation Financial Assistance Programs (66 *Fed. Reg*. 23208 May 8, 2001)
06/19/01	NAS	National Research Council Conflict of Interest/Bias Disclosure Regarding Arsenic Update Subcommittee.
06/25/01	EPA	Notice of Data Availability for the Proposal to Regulate Cooling Water Intake Structures for New Facilities (66 *Fed. Reg*. 28853 May 25, 2001)
07/06/01	GSA	Support for Revoking the Proposed Rule, Contractor Responsibility, Labor Relations Costs, and Costs Relating to Legal and Other Proceedings (66 *Fed. Reg.* 17758 April 3, 2001)
07/09/01	FCC	Regarding Streamlining Contributions to the Universal Service Fund (CC Dkt. No. 96-45, et al.)

Date	Agency	Comment Subject
07/09/01	FCC	Federal-State Joint Board Univeral Service. Streamlined Contributor Reporting Requirements Associated with Administration of Telecommunications Relay Service. Telecommunications Services for Individuals with Hearing and Speech Disabilities, and the Americans with Disabilities Act. Administration of the North American Numbering Plan. Number Resource Optimization. Telephone Number Portability
07/12/01	NAS	National Research Council Scientific Integrity Procedures and the Arsenic Update Subcommittee
07/16/01	GSA	Electronic Commerce in Federal Procurement (66 *Fed. Reg.* 27407 May 16, 2001
07/20/01	DOL	Employment Standards Administration; Supplemental Comments Regarding the Application of the Fair Labor Standards Act to Domestic Service (66 *Fed. Reg.* 5481 May 8, 2001)
08/01/01	DOA	Proposed Changes to the Livestock Mandatory Price Reporting Program.
08/03/01	EPA	Proposed Additional Regulation of Concentrated Animal Feeding Operations (66 *Fed. Reg.* 2960 January 12, 2001)
08/14/01	USPS	Proposed Rule on Delivery of Mail to a Commercial Mail Receiving Agency (66 *Fed. Reg*. 36224 July 11, 2001)
08/14/01	FRS	Board of Governors of the Federal Reserve System; Transactions Between Banks and their Affiliates (66 *Fed. Reg*. 24185 May 11, 2000)
08/16/01	DOA	Food Safety and Inspection Service Labeling of Natural or Regenerated Collagen Sausage Casing

TABLE 3: REGULATORY COST SAVINGS, FISCAL YEAR 2001

The following details rulemaking activities the Office of Advocacy was involved in during fiscal year 2001 that resulted in cost savings to small businesses. The combination of yearly savings and one-time savings during this period totals more than $4.4 billion.

Regulatory Cost Savings for Fiscal Year 2001

Agency	Subject Description	Cost Savings
BLM	*3809 Hardrock Mining Reclamation Bond Rule.* This rule requires hardrock miners to provide reclamation bonds for mining on federal lands. The rule was the subject of the *Northwest Mining v. Babbitt* case, in which the court remanded the rule to BLM for its failure to comply with the RFA. Advocacy criticized BLM throughout subsequent rulemaking procedures for failing to comply with the RFA. BLM finalized the rule on January 20, 2001. In March 2001, BLM proposed suspending the January 20 regulation and reinstating the rule that was in effect prior to January 20, 2001. In October 2001, BLM announced it would be issuing a final rule overturning all but the bonding provision of the 3809 hardrock mining regulation. Although the bonding provisions are a part of the final rule, the costly "mine veto" provision and other costly sections are not. BLM said the mine veto provision was more costly than all other sections combined.	**$877 million in annual savings** Source: The Office of Advocacy, based on BLM estimation of economic impact.
EPA	*Final Rule to Modify Reporting of Lead and Lead Compounds – Toxic Release Inventory Reporting - Section 313 of the Emergency Planning and Community Right-to-Know Act of 1996.* This rule changed the reporting threshold for facilities from the current 10,000 pounds to 100 pounds of lead throughput per year. Based on Advocacy's input, EPA changed the threshold from its proposal of 10 pounds to 100 pounds in the January 2001 final rule.	**$41 million in annual savings in the 2002; $20 million in annual savings in subsequent years**. Source: The Office of Advocacy, based on EPA's economic analysis in the rulemaking record.
EPA	*Control of Sulfur in Highway Diesel Fuel.* This rule limits the level of sulfur in highway diesel fuel.	**$35 million in annual savings** Source: The Office of Advocacy, based on EPA's economic analysis in the rulemaking record.
EPA	*Control of Air Toxics from Mobile Sources.* This rule sets standards for air pollution from cars, trucks, etc.	**$190 million in annual savings** Source: The Office of Advocacy, based on Turner, Mason analysis of cost to reduce benzene for 1994 reformulated gasoline rule.
FAR	*Contractor Responsibility, Labor Relations Cost, and Costs Relating to Legal and other Proceedings.* This rule provides federal government contracting officers	**$28 million in annual savings** Source: The FAR Council

	with additional clarification on the expansion of the categories of what constitutes a satisfactory record of integrity and business ethics in making contractor responsibility determinations for contract awards. The rule requires federal contractors to make certain certifications regarding compliance with laws and regulations promulgated by the federal government. It is based on the principle that the federal government should not enter into contracts with contractors who do not comply with the law. This rule was finalized, but the FAR Council stayed its implementation.	
FS	*Roadless Conservation Rule.* This Forest Service rule prohibits the construction and reconstruction of roads on 58.5 million acres of national forest lands. Throughout the rulemaking process, Advocacy argued that the rule would have a significant economic impact on small businesses and communities. The Forest Service finalized the rule on January 12, 2001. Subsequently, FS was sued in Idaho. The District Court of Idaho issued an injunction against the implementation of the rule. In July 2001, the Bush administration reopened the issue and published an advance notice of proposed rulemaking in July 2001 to solicit additional public input on the nation's future forest road policy. Advocacy contends that its vehement opposition to the rule throughout, and subsequent to, the rulemaking process may have played a role in the court's decision to issue an injunction and the FS decision to revisit the rule.	**$231.3 million in annual savings.** Source: The Office of Advocacy, based on FS' analysis in the rulemaking record.
OSHA	*Ergonomics Standard.* With this rule, the Occupational Safety and Health Administration required every business owner to have a plan in place to address musculoskeletal disorders as a result of repetitive stress injuries that occurred in or out of the workplace. OSHA's ergonomics program standard was issued November 14, 2000, and took effect January 16, 2001. However, on March 20, 2001, President Bush signed a joint resolution of Congress disapproving OSHA's ergonomics standard. Congress acted under authority of the Congressional Review Act of 1996. As a result, the standard is no longer in effect, and employers and workers are not bound by its requirements. The Office of Advocacy believes that both the SBREFA panel report and subsequent SBA cost analysis played a significant role in Congress' decision to prevent the rule's promulgation.	**$3 billion in one-time savings** Source: OSHA's estimate of the entire cost of the rule at the time of proposal.
	Subtotals:	**$1,402,300 in annual savings, and $3 billion in one-time savings**
	Total Cost Savings:	**$4,402,300 ($4.4 billion)**

RFA ACHIEVEMENTS IN FISCAL YEAR 2001

U.S. Department of Agriculture

Agricultural Marketing Service

Issue: Organic Food Production, Handling, and Labeling

The Office of Advocacy has worked with AMS and OMB on various versions of a regulation intended to provide a single national standard for organic food production, handling, and labeling. Congress ordered the agency to develop uniform standards because the label "organic" fell under a hodgepodge of state, regional, and private certifier standards, giving rise to confusion about the meaning of the label designation. After the rule was first proposed in 1997, AMS pulled it back after receiving about 300,000 mostly negative comments on issues ranging from economic impact to the controversial use of sewer-sludge fertilizer and irradiation. This rule marked the first time that AMS consulted with Advocacy proactively. The rule was re-proposed in March 2000 without the controversial elements and with a more transparent cost analysis, and a final rule was issued December 21, 2000. Overall, the final standard and its implementation included several changes to benefit organic producers, most of which are small:

- The market incentives for organic products are enhanced by a mandate that product content requirements be stricter before the term "organic" can be used.
- Simplified requirements for composting of manure and new options for dairy operations converting a whole herd to organic production provide greater flexibility for organic farmers.
- Industry standards for organic wine production were incorporated to minimize impact.
- The agency announced its intention to publish compliance guides for each regulated group.
- The Secretary of Agriculture announced that USDA would provide financial assistance to farmers in designated states to help pay their costs for organic certification.

Food Safety Inspection Service

Issue: Performance Standards for the Production of Ready-to-Eat Meat

The Food Safety Inspection Service (FSIS) published a proposed rule on the production of ready-to-eat (RTE) meat on February 27, 2001. The rule establishes food safety performance standards for all RTE and partially heat-treated meat and poultry products. The proposed standards set forth levels of pathogen reduction and limits on pathogen growth that official meat and poultry establishments must achieve in order to produce unadulterated products. The rule also contemplates environmental testing requirements intended to reduce the incidence of listeria monocytogenes in RTE meat and poultry products. This is a costly rule, with USDA's own estimates topping $68 million over a 10-year period. Advocacy expressed concern to OMB that the rule was highly assumption-based and needed additional vetting. It also contained a non-SBA-approved small business size standard. Advocacy requested an extension of the comment period. When the proposal was published in February 2001, the comment period was extended and the agency pledged to hold technical conferences to acquire more scientific information. The agency is working with SBA to develop an appropriate size standard for a "small processor."

Issue: FSIS Labeling of Natural or Regenerated Collagen Sausage Casings

In its rulemaking concerning labeling of natural or regenerated collagen sausage casings, the Food Safety Inspection Service (FSIS) failed to comply with RFA requirements to determine whether the rule would have adverse effects on small entities or to provide significant alternatives or exemptions that would minimize such effects, according to the Office of Advocacy's August 16, 2001, comment letter. FSIS admitted that it "did not currently have all the data necessary for a comprehensive analysis of the effects of this rule on small entities," but said "associated labeling costs would be low because manufacturers would be able to defer the development of new labels until their existing stocks of labels were exhausted."

Forest Service

Issue: Limitation on Road Construction in National Forests

Before fiscal year 2000, Advocacy's interaction with FS was limited. However, Advocacy became active in the Forest Service regulatory process when FS began its rulemaking concerning limiting road construction in national forests. The rule prohibited road construction and reconstruction in approximately 54 million acres of inventoried roadless areas. Advocacy's primary role in the interagency effort was to advise the agency on RFA compliance. Initially, FS held that an RFA analysis was not necessary because the initiative would not have a significant impact on a substantial number of small entities. Advocacy believed that the proposal could have an adverse impact on several small entities, including members of the timber industry, small natural-resource-dependent communities, members of the mining industry, recreation providers such as companies that rent snowmobiles and outfitters, and construction companies. As a result of Advocacy's involvement, Public Law 106-387, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2001 (October 28, 2000) contained a provision funding the review of rules and regulations to determine FS's consideration of small entities and the RFA. In 2001, the District Court of Idaho issued an injunction against the rule's implementation. FS has indicated a willingness to work with Advocacy towards RFA compliance. It is hoped that the congressional mandate and court action will be incentives for FS to consider the impacts of its regulations on small entities and alternatives to its actions in the future. Cost savings amounted to $231.3 million annually.

U.S. Department of Health and Human Services

Issue: Health Care Information Privacy

A final rule imposing strict requirements on all health care providers and their business partners with respect to the handling of confidential, individually identifiable patient information was issued on December 28, 2000.[3] The rule was promulgated in response to requirements outlined in

[3] See also *20 Years of the Regulatory Flexibility Act: Rulemaking in a Dynamic Economy*, the Office of Advocacy's FY 2000 RFA report.

the Health Insurance Portability and Accountability Act of 1996. The rule requires 1) patients to give written consent before their medical information can be given out; 2) health care providers to provide only the "minimum necessary" information when information is requested; 3) health care providers to ensure that their business partners (e.g., billing companies) do not release confidential patient information; etc. These rules apply to all types of records—electronic, paper and oral—even though the authorizing statute pertained only to electronic records. It was Advocacy's opinion that the rules were overly cumbersome and onerous. The final rule reflected much higher— and more accurate—cost estimates than those originally proposed by the agency (up from $613 million in the proposed rule to $3.54 billion in the final rule). The final rule also reflected greater emphasis on working with industry to provide sample forms and guidance. On March 30, 2001, Advocacy submitted formal comments to the agency expressing continued concerns about a number of issues. The primary concern was that small offices and clinics of doctors and dentists would bear 47.5 percent (almost $1 billion) of the cost in the first year, and 49 percent (about $5.6 billion) of the cost over 10 years. The comments urged the agency to reassess the small business burden, especially in light of the fact that, in spite of the rule's cost and complexity, patient privacy is still not assured. The final rule was placed on hold when the new administration took office in January 2001. The comment period for the rule was reopened and, in addition to Advocacy's comments, about 6,000 new comments were received. Congress also reviewed the regulation.

Centers for Medicare and Medicaid Services / Health Care Financing Administration

Issue: One-Hour Rule

The Health Care Financing Administration, recently renamed the Centers for Medicare and Medicaid Services (CMS) proposed a regulation intended to reduce the incidence of possible injury associated with restraining or secluding individuals under the age of 21 in psychiatric residential treatment facilities. The rule would require that face-to-face assessments be made within one hour of initiating restraint or seclusion. Advocacy commented formally in January 2001, raising concerns about the burden associated with the one-hour requirement, recommended alternatives such as video/audio monitoring and suggested that the biannual staff training requirements for CPR and other techniques were excessive. On May 21, 2001, HCFA released an amended interim final rule to address comments received in response to the January 2001 interim final rule:

- One of the new provisions clarified which institutions would be subject to the rulemaking. Those that receive Medicaid compensation on a service-by-service basis and do not receive Medicaid payment for the individual's room and board are not required to comply.
- The new rule also clarifies that CMS's definition of personal restraint does not include "briefly holding without undue force a resident for the purpose of comforting him or her, or holding a resident's hand or arm to safely escort him or her from one area to another…"
- Most important, the agency acknowledged staffing challenges (such as registered nurse shortages) faced by the affected entities and broadened the types of personnel allowed to seclude and restrain residents. Now, in a covered Medicaid psychiatric facility, these

activities can be performed only on order and under the supervision of a physician, a registered nurse, or other licensed practitioner permitted by the state to issue orders.

Food and Drug Administration

Issue: Juice HACCP

On April 24, 1998, the Food and Drug Administration published a proposed rule to establish requirements relating to the processing of juice and juice products under a hazard analysis and critical control points (HACCP) system. The proposal required the application of HACCP principles by processors and importers to ensure juice safety to the maximum extent practicable. The rule was proposed in response to reported food hazards and illnesses associated with unpasteurized juice products. Advocacy commented on the companion rule to require warning labels on juice that is not pasteurized.[4] Advocacy also worked with OMB during the final rule stage to ensure that small business concerns were addressed to the greatest degree possible. In the final rule published on January 19, 2001, FDA made a number of significant changes to benefit small businesses, among them the following:

- The requirements for testing for allergens and pesticides were eliminated. Instead, a processing business would be required only to identify hazards that are reasonably likely to occur and to include those hazards in their HACCP plans.
- The requirement for a five-log reduction in pathogens was altered for citrus fruit producers who can begin counting the reduction at the washing stage rather than the crushing stage—making it easier to achieve the reduction.
- An exemption was developed for processors that produce shelf-stable products.

U.S. Department of the Interior

Bureau of Land Management

Issue: Hardrock Mining

The Bureau of Land Management's (BLM) section 3809 hardrock mining regulation requires miners to obtain a reclamation bond when mining on government lands. The court remanded the regulation to the agency in 1998 after finding that BLM failed to comply with the RFA (see the *Northwest Mining v. Babbitt* case). The Office of Advocacy has submitted comments at various phases of the regulatory process. On January 20, 2001, the Bureau of Land Management implemented the final rule, which contained a new "mine veto" provision, and did not provide an opportunity for notice and comment. On March 23, 2001, after four lawsuits were filed alleging that the final rule violates not only the RFA, but also the Administrative Procedure Act (APA), the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act, and the General Mining Law, BLM published a proposal to suspend the final regulations to amend the section 3809 rules. In lieu of the new rules, BLM proposed reinstating the rules that

[4] See Advocacy's 1998 RFA report for details.

were in effect on January 19, 2001. The estimated economic impact of the final rule with the new provision was $305-$877 million. In October 2001, BLM published another final rule. It removed the costly "mine veto" provision, but did not implement the less costly alternatives that were suggested by the NRC report. Concurrently, BLM published a new proposed rule for public comment on 3809 hardrock mining reclamation.

National Park Service

Issue: Snowmobiles

On January 22, 2001, the U.S. Department of the Interior, through the National Park Service (NPS), published a final rule in the *Federal Register* phasing out snowmobile use in Yellowstone National Park, on the John D. Rockefeller, Jr. Parkway, and, with some exceptions, in Grand Teton National Park.[5] Only snow coaches (minivans on tracks) would be allowed under the new rule. On April 16, 2001, the Office of Advocacy submitted comments on the rule to be implemented in Yellowstone and recommended that the NPS reopen the rulemaking. The NPS's economic analysis suggested that some 70 small businesses depended on snowmobile rental revenue in the areas covered. Advocacy's view was that it was not clear what would be lost in environmental benefits if the NPS banned just the dirtiest and noisiest snowmobiles. The industry had already taken reasonable steps toward addressing problems caused by snowmobiles, like the recent introduction of the four-stroke snowmobile engine. The NPS's claim that it must immediately enforce the law also lacked credibility because the NPS had overlooked its legal obligation for 30 years. Advocacy did not believe that the NPS had the statutory authority to ban snowmobiles whenever and wherever it wishes, but even if it did, the NPS failed to justify taking such an action. Despite the comments filed by Advocacy and others, the rule became final on April 22, 2001. Suit was then filed by snowmobile manufacturers, enthusiasts, and the State of Wyoming against the U.S. National Park Service. A settlement agreement was reached in which the NPS committed to reexamine its closure in light of new, environmentally friendly snowmobile technology and other information provided by Advocacy and the public. As part of the settlement agreement, the NPS must issue a proposed new rule, incorporating all content from a supplemental environmental impact by March 15, 2002. The final decision and new rule is to be published by November 15, 2002.

U.S. Department of Labor

Occupational Safety and Health Administration

Because of the potential regulatory burden, Congress mandated that the Occupational Safety and Health Administration (OSHA) follow special requirements under SBREFA when it considers regulations that will have a significant impact on small entities. The small business advocacy review panel process requires OSHA and the Environmental Protection Agency to convene special panels whenever the agencies cannot certify under the RFA that a regulatory proposal will not have a significant economic impact on a substantial number of small entities. To date,

[5] 66 *Fed. Reg.* 7259.

OSHA has convened three such panels. Advocacy's experience in working with OSHA small business advocacy review panels has demonstrated that small business input early in the regulatory process improves the rule. None of the OSHA rules subjected to a SBREFA panel has been finalized. However, the SBREFA panel process itself (and the reports developed as a result of the process) has added to the knowledge of the agency and its understanding of the realistic impact these rules may have on small entities.

Issue: Ergonomics Standard

The purpose of the ergonomics standard was to reduce the number of repetitive stress disorders and other musculoskeletal injuries employees receive as a result of their regular work activity. The proposal covered every industry and business in the United States except those in construction, maritime industries, and agriculture. Twenty small entity representatives were chosen to advise the panel and provide input on the draft standard. The group included 13 owners or operators recommended by the Office of Advocacy to represent the interests of the many small businesses concerned about the potential impact of this rule. OSHA's ergonomics program standard was issued November 14, 2000, and took effect January 16, 2001. Small businesses continued to have grave concerns about the standard, especially with respect to the cost estimates. Most small businesses and their representatives previously indicated their disbelief in OSHA's estimation of the time and money the rule would require for businesses to comply. An economic study of the cost impacts of the pre-proposed ergonomics regulation commissioned by the Office of Advocacy showed that OSHA had grossly underestimated the cost of the proposal to small business. After OSHA revised its cost estimates and provided some relief to small businesses in the final rule, Advocacy continued to work with interested businesses, trade associations, OSHA, and OMB to ensure that these and many other concerns of small businesses were heard and taken into consideration. The Congress, acting under authority of the Congressional Review Act of 1996, heard the concerns of businesses and passed a joint resolution of disapproval of OSHA's ergonomics standard. On March 20, 2001, President George W. Bush signed the resolution. As a result, the standard is no longer in effect, and employers and workers are not bound by its requirements. Businesses have saved more than $3 billion as a result.

U.S. Department of the Treasury

Employee Benefits Working Group

The Employee Benefits Working Group of the Department of the Treasury has made a special effort to respond to the small business community. During fiscal year 2001, the Office of Advocacy worked with the group to resolve major initiatives including comparability testing for defined contribution plans' contributions and benefits.

Issue: New Comparability Testing

Comparability testing allows the age and service of employees to be considered in a formula that sets benefit levels. Because abuses had been reported, the IRS and Treasury intended to strengthen regulations to prevent abuse. As they began to consider drafting such regulations, questions arose: How far should they go? What was the scope of the problem, if any? In a breakthrough based on a good working relationship, Treasury and the IRS alerted the Office of Advocacy's pension group that Treasury was preparing a rule in the area of comparability testing. The Office of Advocacy set up a meeting for them to gauge the attitudes of small business plan organizers and practitioners. Throughout FY 2000, the pension working group met with Treasury officials to provide additional background and information about what standards should be set for the controversial plans. Treasury followed the advice of the pension group and stated that any rule promulgated would not take effect before 2002. This calmed the pension and small business community, assuring them of the chance to adjust their markets to the regulations. The proposed regulation, incorporating the changes recommended by the working group, was published October 6, 2000.

Internal Revenue Service

Since passage of the SBREFA, the IRS has worked with the Office of Advocacy to learn more about complying with the RFA. The IRS is performing more certifications and has done IRFAs with more frequency. In FY 2001, the IRS was responsive to the Office of Advocacy's questions, and arranged meetings when requested with concerned small business groups to discuss controversial rules. The IRS Taxpayer Advocate has done an excellent job of gathering information on trouble spots, and her annual report is very useful for the small business community. The new Small Business / Self-Employed Division (SB/SE) contains a research unit that should provide regulation writers with solid data to assess regulatory choices. On very sensitive issues this year, such as electronic filing or the offer-in-compromise program, the IRS's awareness of the RFA has resulted in creating an outreach effort that has elements of the panel process the RFA requires of OSHA and EPA. The result is better rulemaking.

Issue: Overseeing the Implementation of the IRS Restructuring and Reform Act that Requires the IRS to Reduce Regulatory Burdens on Small Business

With the passage of the IRS Restructuring and Reform Act of 1998, the IRS has undertaken a massive project to reshape the agency. The IRS is composed of four divisions, one of which is the Small Business and Self-Employed Operating (SB/SE) division, designed to serve the millions of small business taxpayers. The IRS recognizes that these taxpayers often face complicated tax issues, but may lack the financial resources to understand and address them. A primary focus of the SB/SE will be to educate small businesses and work with them to develop less burdensome and more practical means of compliance. The new SB/SE division is in place and working well. The Office of Advocacy and countless other small business stakeholders have been involved in a continuing process of briefings and comments on the proposed structure and guidelines. The IRS has sought Advocacy's opinions and those of small business groups recruited by Advocacy to help analyze IRS plans. Although effort expended on this is not a

regulatory activity *per se*, the restructuring involves changes in the culture of the IRS that will make it more sensitive to the needs of small businesses. The IRS has welcomed and implemented recommendations made by Advocacy, such as the following:

- The act states that the IRS should create a customer-friendly attitude and a division for small business that Advocacy has long advocated and supported. The IRS has taken steps to implement this goal.

- The act creates an oversight board for the IRS that includes someone experienced in running a small business. The board has moved to review the ongoing operations of the IRS. Policies should begin to reflect more input from the small business community.

- In consultation with Advocacy, the SB/SE established a size standard suitable for determining which firms will receive the specialized attention of the small business division.

- The IRS consulted with Advocacy on the manner of referrals between taxpayer education divisions, compliance divisions, and other outreach elements such as the Taxpayer Advocate.
- The Office of Advocacy has recommended small business participants for IRS forums, advisory committees, and training events and has included IRS in regular small business briefings and conferences.

- The IRS and SB/SE have asked Advocacy to participate regularly in its compliance and education training programs for IRS personnel.

Issue: *Simplified Tax and Wage Reporting System*

Advocacy continues to work with the IRS to establish one simple form that would satisfy the wage and tax reporting obligations of the very smallest businesses under both federal and state tax law. The overall program is called the Simplified Tax and Wage Reporting System (STAWRS). This major multi-agency effort involving the IRS, the Labor Department, the Social Security Administration, and the SBA aims at burden reduction for small businesses. STAWRS could significantly reduce the paperwork and compliance costs for business owners using the following tools:

- *Single Point Filing.* Advocacy's research established that tax and wage reporting is a costly burden for small businesses, which spend proportionally more than their large competitors on regulatory compliance than their large competitors. Regulations put them at a severe disadvantage.[6] A simple, multi-purpose form would eliminate duplicative information requested by federal, state, and local agencies regarding tax and wage reporting. A pilot program in Montana has successfully provided "one-form treatment" for participating small businesses. A follow-on project in Iowa has led to breakthroughs in electronic filing.

[6] See U.S. Small Business Administration, Office of Advocacy, *The Impact of Regulatory Costs on Small Firms* (Springfield, Va.: National Technical Information Service, 2001) and *idem*. *The Changing Burden of Regulation, Paperwork and Tax Compliance on Small Business: A Report to Congress,* (Springfield, Va.,: National Technical Information Service, 1995).

- *Commercial Off-the-Shelf Single Point Electronic Filing (COTS SPEF*). During 2001, the STAWRS program has moved forward to establish the rules and framework for the electronic filing of multiple employer-related documents. Advocacy has worked with the executive board to help decide the standards to be used and to oversee the project to make sure that the small business point of view is not lost. The pilot project in Iowa went well and the IRS is now well along toward the goal of bringing the program on line nationally.

- *Cash versus Accrual Accounting.* The Office of Advocacy had been working since 1999 to encourage the IRS to liberalize the rules to allow small firms to use the cash method of accounting. The law requires large firms to use accrual accounting (the recognition of income and expenses when the obligation for them occurs) rather than cash accounting (the reporting of income or expenses when the cash is actually received or distributed). However, where even a small business has an inventory, the law requires accrual accounting. The IRS agreed to review the policy and issue guidance that would make it clear that raw materials that were not a substantial part of the business would not qualify as inventory and that accrual accounting would therefore not be imposed in those instances. Working with the IRS and a number of other small business groups, the IRS and Treasury were willing to issue guidance that created a $1 million gross receipts threshold. Businesses below that level could simply choose cash or accrual accounting. Above that level, the agency believed that only Congress could change the standard. However, subsequent action raised the gross receipts threshold.[7]

Environmental Protection Agency

Issue: Toxic Release Inventory Reporting – Revision of Reporting Threshold for Lead and Lead Compounds

The Environmental Protection Agency (EPA) issued a proposed rule in August 1999 to reduce the reporting threshold for lead from 10,000 pounds to 10 pounds, which would dramatically increase the number of small businesses required to report the use of lead at their manufacturing facilities. This rule is part of the community-right-to-know requirements to inform the public about releases of chemicals into the environment. The reduction in the threshold was justified by the agency's designation of lead as a "persistent bioaccumulative toxic" (PBT) chemical. However, the Office of Advocacy pointed out that the agency could not identify any new reporting facility in the country at which any risk reductions would likely occur. In other words, the new information, in Advocacy's view, was unlikely to contribute to the community's right to

[7]This report deals with fiscal year 2001. However, in December of the new fiscal year, the IRS relented on the cash vs. accrual accounting issue and has drafted a revenue ruling that sets the mandatory accrual accounting threshold at $10 million. For many businesses (particularly businesses that do not have large or churning inventories), the IRS estimates that as many as 500,000 additional small businesses will be able to benefit from the revenue ruling by choosing to use simplified cash accounting methods.

know, since there were not significant releases of lead at those sites, and thus no risks needed to be addressed. Also, EPA's designation of lead as a PBT did not appear to be based on sound science, nor had the agency followed its own required agency peer review procedures. The Office of Advocacy recommended that the agency set the threshold instead at 1,000 pounds, based on the relative toxicity of lead compared with other reportable TRI chemicals. Based on the criticism of its previous scientific determination, in January 2001, the agency promulgated the standard at 100 pounds instead of 10 pounds, eliminating about one-half of the small businesses from the new reporting scheme, for an estimated savings of about $20 million annually. The first report is due in July 2002, and EPA is planning to review the scientific basis of the lead PBT determination during the early part of 2002.

Issue: Concentrated Animal Feeding Operations Proposal

Concentrated animal feeding operations (CAFOs) are operations that confine and feed in a limited area a large number of animals over a certain period of time. Among the more controversial elements of EPA's proposal is a provision that would regulate pollution from crops and groundwater and one that would require that "co-permits" be issued to both the livestock owner and livestock grower that raises the livestock for the owner, although typically, the two businesses are separate and the grower is responsible for disposal of the manure. This billion-dollar rule also prohibits any pollution from production areas without sound science to support this prohibition, removes a permit exemption for operations that do not pollute except during unusually large storms, and makes it easier to regulate the smallest farms, although EPA previously agreed not to do this. The Office of Advocacy was successful in preserving several significant alternatives in this proposal and has since submitted comments on the proposal to reinforce arguments in favor of appropriate small-entity flexibility. Since then, the EPA has moved in a positive direction by publishing a supplemental notice, providing additional data, and describing and soliciting comment on additional approaches to provide regulatory flexibility, consistent with the Clean Water Act. The EPA has until December 2002 under a court order to take final action on this rule, and Advocacy will continue to work with EPA on this issue.

Issue: Diesel Final Rule

EPA's rule to control sulfur in highway diesel fuel is one of several regulations with which the small businesses in the petroleum refining industry will have to comply in virtually the same timeframe. The rule limits air pollution from trucks and restricts the level of sulfur in highway diesel fuel to enable pollution reduction. EPA was able to offer only additional lead time for the small refiners. While this would allow a small refiner to delay compliance with one of two rules (the sulfur in gasoline rule or the sulfur in diesel fuel rule), it is not clear that many small refiners will be able to afford the rules that can't be delayed. Therefore, Advocacy has recommended that Congress provide tax relief to help defray the costs of compliance and restore the competitive imbalance created by this rule. Without this help, Advocacy believes that the loss of competition in this industry could ultimately be more expensive. If this tax relief is provided, Advocacy believes that most of the small refiners will be able to take advantage of the flexibility in the diesel rule, and the annual savings would be $35 million.

Issue: Mobile Source Air Toxics Rule

This EPA rule set standards for air toxic pollution from trucks and cars. The initial approach under consideration would have imposed millions of dollars in compliance costs on small businesses in the petroleum refining sector, which is already required to comply with several EPA rules virtually in the same timeframe. After additional analysis and discussion with Advocacy, EPA decided in principle to propose a "no-cost" approach requiring only that refiners maintain current levels of benzene in gasoline. To ensure that the rule would impose no costs, EPA agreed to finalize an even more flexible approach, which allows refiners to increase their fuel's benzene content if the increase is offset by decreases in other air toxics, maintaining current average levels of "air toxics" such as benzene, formaldehyde, etc. Advocacy estimates that these modifications to the rule will save small refiners $190 million annually.

Federal Acquisition Regulation Council

Issue: Regulation on Contractor Responsibility

On December 20, 2000, the Federal Acquisition Regulation Council issued its final rule on contractor responsibility, labor relations costs, and costs relating to legal and other proceedings, FAR case 1999-010. This issue started in 1999 with the FAR Council proposing to provide the contracting officer with authority to reject an apparent successful bid if the contractor has been the subject of a specified conviction, judgment, or adverse decision in the previous three years. In spite of continuing concerns expressed by the Office of Advocacy, small businesses, and procuring agency officials, the FAR Council on December 20, 2000, published its final rule with an implementation date of January 19, 2001. This final rule was so controversial that some agencies issued "class deviations." The Federal Acquisition Regulation controls the standards for "class deviations." Subpart 1.401(a) states that a deviation is the issuance or use of a policy, procedure, solicitation provision, contact clause, method, or practice of conducting acquisition actions of any kind at any stage of the acquisition process inconsistent with the FAR. FAR Subpart 1.402 states, "that unless precluded by law, executive order, or regulation, deviations from the FAR may be granted." This action delayed the implementation date. The Civilian Agency Acquisition Council (CAAC) a component of the FAR Council, also delayed the implementation of the rule until July 19, 2001. Subsequently, the FAR Council published FAR case 2001-014 on April 3, 2001, a rule to revoke the final rule in FAR case 1999-010. This action by the FAR Council stopped the implementation of the final contractor responsibility rule, for annual savings of $28 million.

ONGOING RFA COMPLIANCE CONCERNS

Department of Agriculture

Agricultural Marketing Service

Issue: USDA's Proposed Changes to the Livestock Mandatory Price Reporting Program

In August 2001, Advocacy commented to the USDA about proposed changes to the livestock mandatory reporting program that would move away from the 3/60 guidelines for mandatory price reporting to a 3/70/20 reporting system. The change means that larger firms would possess confidential and proprietary information that would allow them to discover the quantity of meat being sold by a small business and undercut the small business's prices. This possibility is particularly likely in the live market where the larger companies may have access to regional reports—and it is exactly the type of situation the RFA is designed to prevent. The proposed change is in direct conflict with the legislative intent of the mandatory price reporting statute, which protects the confidentiality of the program participants. The Office of Advocacy had participated in interagency meetings with OMB before the rule's release in late 2001. At that time, Advocacy expressed the view that the untested program was burdensome for small businesses that would be required to report thousands of prices daily, and that there was no evidence the rule would remedy the alleged problems with the voluntary system of reporting.

Food Safety Inspection Service

Issue: FSIS Proposed Rule for Increases in Fees for Meat, Poultry and Egg Products Inspection Services in FY 2000 and FY 2001

On August 31, 2000, Advocacy submitted comments to FSIS on a final rule seeking to increase the fees for the inspection of meat, poultry, and egg products for FY 2000.[8] FSIS acknowledged that the rate increase is significant and did not dispute that the increased fees will cost egg producers an additional $13,700 annually. However, the agency would not consider a phase-in approach so that firms could more easily cover the increased costs. The Office of Advocacy was concerned that the increased fees would likely have an adverse effect on egg producers' profitability since FSIS also published a proposed rule seeking to increase the fees for overtime and holiday inspection of meat, poultry, and egg products for fiscal year 2001. If implemented, the proposed increase was to become effective on October 8, 2000, essentially the same timeframe within which egg-producing firms would be required to pay increased overtime fees. Despite FSIS certifications, Advocacy was concerned that the rules would have a significant impact on a substantial number of small businesses, especially if they were made effective simultaneously. The Office of Advocacy recommended that FSIS republish the final and proposed regulations with a fact-based certification. To date the agency has not complied.

[8] This rule was inadvertently left out of Advocacy's FY 2000 report, so is reported here.

U.S. Department of Health and Human Services

Food and Drug Administration

Issue: Proposed Rule for Current Good Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

On July 16, 2001, the Office of Advocacy filed comments on the Food and Drug Administration's (FDA) proposed rule for current good manufacturing practices (CGMP), packing, or holding of dietary ingredients and dietary supplements.[9] The largest cost associated with the rule is for production and processing of dietary supplements; the second largest cost is for paperwork. The FDA acknowledged that the rule would result in the highest costs for small establishments. Further, the average burden on small businesses was expected to be at least 14 percent of annual revenue (around $71,000 annually). The simulated mean total costs were about $238 million for the first year and $178 million for later years. The FDA estimated that the benefit of the rule is $230 million the first year and $180 million thereafter. While the proposed rule identified potential alternatives, including a small business exemption and a phase-in of the rule for small businesses, the FDA dismissed the alternatives primarily because consumers will not be able to distinguish non-CGMP products from products that were produced using CGMP. As a result, the FDA concluded that affected small businesses have the option of incurring the cost of complying with the rule, changing product lines, or going out of business. In outreach meetings held by the FDA, small business representatives expressed concern about the cost and time involved in complying: the requirements contained in the rule, coupled with the anticipated hiring requirements necessary to comply, would cripple small businesses that manufacture dietary supplements. Advocacy's view was that the FDA should allow small businesses flexibility in maintaining and complying with CGMP as long as the individual business's manufacturing process is validated. FDA should take steps to reduce the overwhelming burden this rule imposes on small businesses.

U.S. Department of the Interior

The U.S. Department of the Interior's RFA compliance historically has been problematic. In the past, DOI's regulatory flexibility analyses consisted of either a single sentence stating "no significant impact on a substantial number of small entities" or a recitation of the RFA compliance requirements. Although the agencies within the DOI are now less likely to make such unqualified assertions, the analyses provided do not necessarily indicate an understanding of the potential impact the actions may have on small entities.

9 Docket No. 96N-0417.

Fish and Wildlife Service

The Fish and Wildlife Service (FWS) of DOI is charged to conserve, protect, and enhance fish and wildlife and their habitats. FWS implements provisions of the Endangered Species Act (ESA). The Office of Advocacy continues to be concerned about FWS' failure to provide the required RFA and ESA economic analysis at the time of proposed rulemakings. Although FWS showed some improvement in FY 2001 and is starting to provide more information at the time of proposal, its performance is inconsistent.

Issue: Interim Strategy for Watercraft Access Projects that May Impact the West Indian Manatee

The West Indian manatee has been listed as an endangered species since 1967. In Florida, watercraft-related manatee mortalities have increased since the collection of manatee mortality data began in 1974. More than 1 million watercraft vessels use Florida's waterways each year. The ability of a manatee to elude oncoming watercraft is largely determined by the speed of the oncoming watercraft. Although Florida has watercraft speed zones, studies indicate that compliance rates range from 50.9 percent to 78.7 percent and that the low level of compliance is attributable to low levels of law enforcement, poor signage, lack of law enforcement officers on the water, and few citations issued. From the information available, FWS concluded that the addition of new watercraft in Florida's waters has the potential to adversely affect manatees. In March 2001, FWS published a *Notice of Availability of Interim Strategy on Section 7 Consultations Under the Endangered Species Act for the Watercraft Access Projects in Florida that may Indirectly Affect the West Indian Manatee.* The strategy required applicants to provide conservation measures in project descriptions when applying for a permit to build a new facility. In addition, the strategy required applicants to make a financial contribution to an entity that funds manatee conservation. Although the strategy was not a rulemaking and was not subject to the RFA, Advocacy submitted comments on May 14, 2001, arguing that while the strategy would have little effect on the mortality rate of the manatee, it would have a negative impact on the construction of docks and on small dock builders. Advocacy asserted that FWS needed to consider other alternatives, such as increasing fines, requiring a special permit to operate in certain waterways, and requiring that watercraft operators read handouts on the danger of watercraft to the manatee.

U.S. Department of Labor

Employment Standards Administration

The Employment Standards Administration administers and directs employment standards programs with minimum wage and overtime standards; registers farm labor contractors; determines prevailing wage rates to be paid on government contracts and subcontracts; implements nondiscrimination and affirmative action programs for minorities, women, veterans, and handicapped government contract and subcontract workers; and carries out workers' compensation programs for federal and certain private employers and employees.

Issue: Application of the Fair Labor Standards Act to Domestic Service

On January 19, 2001, the Employment Standards Administration published a proposed rule on the application of the Fair Labor Standards Act (FLSA) to domestic service designed to amend the existing regulations on the exemption for companionship services. Under current law, domestic companions are exempt from FLSA minimum wage and overtime requirements. The proposed rule amended the regulations to revise the definition of companionship services; clarified the criteria used to judge whether employees qualify as trained personnel; and amended the regulations to require third-party providers of companionship services to pay the minimum wage and overtime. It also extended the FLSA to live-in domestics if employed by someone other than a member of the family in whose home they reside and work. ESA performed an initial regulatory flexibility analysis and determined that the rule would not have a significant economic impact on a substantial number of small entities. The Office of Advocacy commented on the proposal on July 20, 2001, citing industry contentions that the proposal would be harmful to small home health care providers. Advocacy argued that the proposal could result in increased rates that would be beyond the financial means of the members of the public that use companionship services. Also, the information provided was insufficient to meet the requirements of the RFA and the proposed rule lacked fundamental elements of an IRFA.

U.S. Department of Transportation

The U.S. Department of Transportation (DOT) shapes and administers policies and programs to protect and enhance the safety, adequacy, and efficiency of the national transportation system and services. DOT has continued to make progress over the past year in considering small business effects when drafting regulations. However, more work needs to be done to ensure that small business concerns are being addressed uniformly throughout the department. During fiscal year 2001, DOT issued numerous regulations affecting small businesses, and the Office of Advocacy maintained a productive relationship with various DOT agencies regarding pre-proposal regulatory analysis.

Issue: Participation by Disadvantaged Business Enterprises in Department of Transportation Financial Assistance Programs

On May 8, 2001, the Department of Transportation published a proposed rule that would, among other things, make substantive changes to its disadvantaged business enterprise (DBE) program. Several provisions include personal net worth, retainage, the size standard, proof of ethnicity, confidentiality, and proof of economic disadvantage. The agency certified that this proposed rule would not have a significant impact on a substantial number of small entities. On June 7, 2001, the Office of Advocacy commented that the certification lacked documentation to support this conclusion and asked DOT to conduct an IRFA before proceeding further.

Federal Aviation Administration

The FAA is responsible for air safety in the United States and promulgates many regulations to ensure the safety of the nation's skies. Most FAA regulations promulgated during the past year have been tailored for problems experienced by larger airline companies. As a consequence, in another example of the "one-size-fits-all" syndrome, the Office of Advocacy has heard from small businesses that feel they are unduly burdened by "big airline" regulations. Advocacy continues to work with these businesses and the FAA to buttress the agency's compliance with the RFA. An additional complaint Advocacy heard during the year concerned FAA's issuance of policy guidance. Small airlines are concerned that these actions are not mere guidance and supplemental information, but directives mandated by the FAA without public comment in violation of the Administrative Procedure Act. The Office of Advocacy will be examining these issues further to ensure FAA's full compliance with the RFA in all of its regulatory actions. The FAA has made great strides in its analysis of the small business impacts of some of the agency's rules over fiscal year 2001; however, more work needs to be done.

Federal Motor Carrier Safety Administration

Issue: Hours of Service of Drivers

On May 2, 2000, FMCSA published a proposed rulemaking revising its hours of service regulations for drivers of motor carriers. The proposal was designed to require motor carriers to provide drivers with better opportunities to sleep, thereby reducing the risk of drivers operating commercial motor vehicles while drowsy, tired, or fatigued, with the objective of reducing collisions. The proposed rule also mandates the purchase and use of costly electronic on-board recording devices. Before the proposal was published, the Office of Advocacy held meetings and discussions with FMCSA in an effort to bring the agency into compliance with the RFA. Since the rule was proposed, Advocacy has responded to numerous requests for participation in meetings, roundtables and discussions about the rule. Small motor carrier operators have indicated that the rule would have a devastating impact on them. Industry representatives have said that the rule would necessitate more than 40,000 new truck drivers on the road. Small business complaints have focused on the sleeper berth requirements, communications during rest periods, end of workweek rest periods, hours of work permitted each day, and the mandatory purchase and use of an electronic on-board recording device. A congressional hearing was held to discuss the severity of the proposal's impact on the industry as a whole. After a number of comment deadline extensions, FMCSA closed the comment period on December 15, 2000. The DOT has been looking further into the costs of the rule and has sponsored a cost-benefit study by an outside party while they compile and review the 50,000 comments submitted on the proposed rule. Advocacy will continue to work with both the agency and OMB on this important rule and will attempt to ensure FMCSA's compliance with the RFA.

Research and Special Programs Administration

Issue: Pipeline Safety – Accident Reporting Revisions

In March 2001, the Research and Special Programs Administration published a notice of proposed rulemaking on its hazardous liquid pipeline accident reporting revisions. The RSPA proposal would amend the pipeline safety regulations by lowering the reporting threshold to hazardous liquid pipeline spills below 50 barrels. Advocacy reviewed RSPA's RFA certification contained in the proposal and found that additional information was needed to ascertain the validity of RSPA's certification of no significant impact on a substantial number of small entities. Advocacy filed comments on the proposal on May 21, 2001, and will continue to follow the progress of this rule to ensure RSPA's compliance with the RFA.

Issue: Pipeline Safety – Pipeline Integrity Management

On March 21, 2001, RSPA published a notice of proposed rulemaking on pipeline integrity management in high consequence areas. The RSPA proposal would extend the requirements for protection of populated areas, commercially navigable waterways, and areas unusually sensitive to environmental damage from hazardous liquid pipeline spills to those regulated hazardous liquid pipeline operators who own or operate less than 500 miles of pipeline. On May 25, 2001, Advocacy filed comments with RSPA stating that the agency had failed to 1) indicate the need for the regulation; 2) provide a factual basis for the certification; 3) utilize the SBA size standard as required; and 4) include equipment and maintenance costs in the estimated costs to small entities. Advocacy will continue to follow the progress of this rule to ensure RSPA's compliance with the Regulatory Flexibility Act.

U.S. Department of the Treasury

Internal Revenue Service

The RFA requires analysis of a proposed regulation only where notice and comment rulemaking is required. Under the Administrative Procedure Act, interpretative rules are exempt from notice and comment rulemaking. For years the IRS escaped the requirements of the RFA because it categorized most of the rules it promulgates as "interpretative," meaning the rules simply carry out the intent of Congress and do not impose any additional requirements within the discretion of the agency. In 1996, the SBREFA amended the RFA to require that interpretative rules—including revenue regulations carrying out statutes—that imposed a collection of information requirement would be subject to the RFA. Since passage of the SBREFA, the IRS has worked with the Office of Advocacy to learn more about complying with the RFA. The IRS is performing more certifications and has done IRFAs with more frequency. In FY 2001, the IRS was responsive to the Office of Advocacy's questions, and arranged meetings when requested with concerned small business groups to discuss controversial rules.

When is an RFA Analysis of an IRS Proposal Not Warranted?

Most IRS regulations published in FY 2001 or any other year are not subject to the RFA even though SBREFA extended application of RFA to interpretative rules that impose a collection-of-information requirement. Advocacy recognizes it would be time-consuming and unproductive to compel an RFA analysis or SBREFA panel in cases where it would not produce results. The following are examples of the types of IRS regulations that do not require analysis:

1. The RFA applies only to "legislative" regulations except where an interpretative regulation requires a collection of information. The IRS has always maintained that virtually all its regulations are interpretative and thus exempt from the RFA. Many IRS regulations simply clarify definitions or provide examples of application of requirements that were set by Congress. These do not require analysis under the RFA.

2. Most IRS regulations have an impact on groups other than small businesses, such as individuals or large businesses; these are not covered by the RFA.

3. Any interpretative regulation proposed prior to March 29, 1996, is not subject to the RFA even as amended by SBREFA.

4. Because the IRS has been specifically subject to portions of the RFA only since 1996, the agency is not required to form a plan under RFA section 610 to review previous RFA regulations. However, the Office of Advocacy believes it would be useful to combine a review process with the feedback the agency is getting from the small business community about overly burdensome or confusing rules. The "Complexity Conference" held in conjunction with the OMB's Office of Information and Regulatory Affairs in 2000 and follow-up tax forums and studies this past year represent an excellent start in that direction.

IRS Rulemakings that would Benefit from Analysis

In some instances the IRS has made the conscious decision not to perform an IRFA. In certain kinds of situations, Advocacy argues that an IRFA would lead to better understanding and better policy because the results are shared with those about to be regulated. In fact, it is sometimes hard to see how it was possible to draft regulations without certain basic information. An IRFA should pose no additional burden where an agency has done its homework properly. Examples of the types of rules for which the IRS could do more are as follows:

1. Even where the rule imposes a "collection of information" requirement (which the SBREFA defines to include "recordkeeping"), the IRS has taken the view that only the portion of the regulation that contains such a requirement needs to be analyzed for its impact on small businesses. Advocacy believes that once the agency has undertaken to look at the regulation, it should analyze how the entire regulation will affect small businesses.

2. The IRS has often taken the view that unless a "form" is required (literally a paper document a taxpayer must complete), no recordkeeping requirement is imposed by the rule. In cases

where a proposed regulation would add a line or a section to an *existing* form, the change is generally deemed insignificant by the IRS and therefore not a new "collection of information" requirement for RFA purposes. But additions to a form add cumulatively to the burden and Advocacy believes it is fair for the entire burden to be reviewed and presented to the public for comment. The law requires the regulator to review the entire burden anyway, and to make an informed decision about the significance of the information collection.

3. The IRS occasionally maintains that a proposed regulation in an entirely new area will have a significant impact on a substantial number of small businesses, but that its requirements simply and specifically "flow from mandates set by Congress." The Office of Advocacy understands that directives from the Congress may preclude some or even any alternatives but believes that an analysis needs to be done where there is such an impact. The analysis alerts small businesses of what is coming so they can prepare for compliance and gives them an opportunity to suggest useful alternatives. It also may serve to inform legislative and administrative policymakers of the true burden their decision may impose in practice.

Consumer Product Safety Commission

Issue: Flame Retardant Chemicals of Upholstered Furniture

The Office of Advocacy submitted comments to the Consumer Product Safety Commission (CPSC) on April 28, 1998, concerning an advance notice of proposed rulemaking on the toxicity, exposure, bioavailability, and environmental effects of flame-retardant chemicals suitable for use in residential upholstered furniture. Advocacy urged the agency to weigh carefully the small business impact, to examine whether there was a true need to regulate, and to identify possible regulatory alternatives. An industry report released on February 6, 2001, concluded that the draft proposed standard for the open-flame ignition resistance of upholstered furniture was not cost-justified. The report indicated that CPSC may have overestimated the benefits of the proposed standard by nearly 10 times, and may have underestimated the cost by $2 billion. CPSC disagreed with the report's findings and the methodology used, but has not finalized the standard.

Environmental Protection Agency

Issue: Metal Products and Machinery: Update

The SBREFA panel completed its report on the metals products and machinery water pollution rule in March 2000. The EPA estimated that this rule would affect about 10,000 facilities and cost in excess of $1 billion annually. Although this SBREFA panel produced a useful set of recommendations, which EPA followed in formulating the proposal, the January 2001 proposal incorrectly projected that the costly rule would generate substantial pollution savings and was fatally flawed because the agency made substantial errors in data analysis. As a result, for most affected facilities, which already are complying with existing EPA water pollution requirements, there would be no significant pollution reduction, but there would be substantial additional cost.

The Office of Advocacy is working with EPA on a new notice of data availability that would correct the errors in this major rulemaking and substitute a less stringent regulatory scheme, in light of the insubstantial additional pollutant reductions available to be achieved. EPA expects the new notice in early 2002, with a final rule due in December 2002.

Issue: Arsenic in Drinking Water

In January 2001, EPA completed a rulemaking revising the standard for arsenic in drinking water from 50 parts per billion (ppb) to 10ppb. The Office of Advocacy had been working for two years with the agency on this issue, starting with a SBREFA panel that completed its report in 1999. Advocacy wrote in March 2001 commending EPA Administrator Christie Whitman on instituting a review of the costs and benefits of lowering the standard to 10ppb, in light of the significant uncertainties about risks in the vicinity of this very low standard. EPA asked the National Research Council (NRC) to review the risks of arsenic. Based on the NRC review, EPA announced in October 2001 that it would reaffirm the January 2001 10ppb standard. The Office of Advocacy found that the risk of arsenic at low levels was in significant dispute, and that thousands of small water systems and rural communities faced severe costs to achieve the 10ppb standard, with questionable benefit to public health. The only significant study in the United States provided no evidence of excess risks due to arsenic in drinking water. EPA estimated the costs for the smallest system to be of the order of $300/year and higher. The Office of Advocacy found that the NRC had probably significantly overestimated both the risks of arsenic in drinking water and the public benefit of reducing the naturally occurring concentration of arsenic in drinking water. The NRC failed to follow its own procedures for ensuring the scientific integrity of the final report on arsenic, released in September 2001.

Issue: Sanitary Sewer Overflows Proposal

The EPA has released a draft proposal before publication in the *Federal Register* to eliminate sewer leaks to lakes, streams, etc., even though achieving this level of control is, according to its own contractor, technically not feasible at any cost. The Office of Advocacy has noted that the agency is dealing with this problem in a cost-ineffective manner that provides little, if any, regulatory certainty for the facilities that would be subject to the rule. Instead of providing exceptions to the regulation, EPA should establish an appropriate pollution limit or, alternatively, base compliance on the successful development and implementation of plans, similar to the approach used to address stormwater pollution. But until EPA acknowledges the proposal's full impact, measured in billions of dollars on thousands of small governments, Advocacy is concerned that EPA will fail to explore significant opportunities to address the sewer pollution problems and minimize costs on smaller systems. Recently, EPA withdrew the draft proposal from the Office of the *Federal Register* and said it would issue the proposal in its current form but with alternatives. Advocacy has asked its contractor to develop and evaluate the range of alternatives and will continue working with EPA during review under Executive Order 12866.

Issue: Combustion Turbine and Reciprocating Internal Combustion Engine Proposals

As the fiscal year came to an end, the Office of Advocacy expected the EPA to propose two rules addressing hazardous air pollutants from electricity generators used by utilities or "nonutilities"—businesses that sell to utilities or use the electricity themselves. Depending on the formulation, these proposals could impose millions of dollars in costs on hundreds of small producers. During Executive Order 12866 review, the Office of Advocacy will examine these proposals to ensure that they do not raise unnecessary barriers to competition, thereby further restricting already tight energy supplies and raising prices. Advocacy also intends to ensure that the standards and pollution control technologies under consideration have an adequate basis in both fact and law and that the technologies will not cause more environmental damage than they reduce. The Office of Advocacy is concerned that, for certain rules affecting a small number of small entities, EPA appears to be applying different standards for RFA review of regulatory impact. EPA's guidance for EPA rule writers states that the rule cannot be certified under the RFA/SBREFA if the regulation has a significant effect on more than 100 small entities. However, where fewer than 100 small entities are affected, rule writers are given the discretion to certify, even if the impacts are both unnecessary and disproportionate. The Office of Advocacy has asked EPA to reconsider and clarify its guidance on this point.

Issue: Final Rule Revisions to the Total Maximum Daily Loads Program.

EPA issued a rule in July 2000 to revise the total maximum daily loads (TMDL) program. A TMDL is an estimate of the quantity of pollutants that may be present in the water and still meet water quality standards. The rule was to go into effect in October 2001, but the effective date of the rule was delayed for 18 months to allow for review and revisions. This rule has been an ongoing source of controversy, prompting litigation and even congressional action, including requests for additional cost information and the denial of funds to implement the rule. EPA expedited the rule and in doing so, may have failed to satisfy its statutory obligations under both the APA and the RFA. The substantive concerns include unworkable deadlines for states to develop TMDLs and failure to provide for use of credible scientific information in both TMDL development and prioritization. This virtually guarantees that either (a) small entities will be forced to bear a disproportionate share of the burden or (b) eventual federal intervention in a state matter will be required. In August 2001, in response to a congressional request, the EPA released its draft study suggesting that the cost of implementing the TMDL program as revised would range between approximately $1 billion and $3.4 billion annually. Unfortunately, EPA failed to fully comply with this request when it did not provide an estimate of the cost to small entities imposed by states in response to TMDL program revisions. Advocacy argued that the Congress had requested this information, but EPA disagreed. The Congress recently clarified its request and it does include the costs imposed by the states. The EPA has now announced its intention to provide this information when it issues the final study, expected in spring 2002. Advocacy plans to be involved in the E.O. 12866 reviews of the draft final study and of the draft revised proposal, also expected in the spring.

Federal Acquisition Regulation Council

Issue: Regulation on Designating "FedBizOpps" as the "Government-wide Point of Entry" for Electronic Commerce in Federal Procurement Systems

On May 16, 2001, the FAR Council published FAR case 1997-304 as a proposed interim rule to designate "FedBizOpps" as the government-wide point of entry or electronic commerce in the conduct and administration of federal procurement. Agencies were given until October 1, 2001, to complete their transition to or integration with FedBizOpps. By that date, all agencies were required to use FedBizOpps to provide access to public notices of procurement actions over $25,000 that were previously required to be published in the *Commerce Business Daily* (CBD) along with associated solicitations and amendments. In addition, agencies would not be required to provide notice in the CBD as of January 1, 2002, since access to this information would be provided through FedBizOpps. Advocacy provided comments on the proposed interim regulation, expressing concern that the IRFA did not provide small businesses and small entities with any degree of analytical sufficiency to reach a reasonable conclusion about the negative or positive impact of this proposed interim regulation. The IRFA indicated that 47,340 small businesses might be affected, but it failed to examine any of the unique e-commerce business characteristics of these businesses. For example, would there be negative impacts of this rule on small rural businesses, Native American businesses, small construction companies, and micro-enterprises? Advocacy provided the FAR Council with several sources of data that would indicate that small businesses are not yet fully operational in the area of e-commerce. One report published by Access Markets International reported that only 33 percent of all small businesses are connected to the Internet. FedBizOpps has subsequently been implemented.

Federal Communications Commission

Issue: Auction of Licenses in the 3650-3700 MHz and 4.9 GHz Band

In October 2000, the Federal Communications Commission (FCC) proposed rules governing the auction of the 3650-3700 MHz spectrum band, which was transferred from federal government to private sector use. The commission proposed auctioning spectrum licenses in this band on a geographic basis, and requested input on the size of area it should use. The commission also proposed granting bidding credits to small businesses, and proposed three tiers of credit based on different business sizes. In a comment letter dated December 12, 2000, Advocacy recommended that the commission use small geographic areas, such as metropolitan statistical areas (MSAs) and rural service areas (RSAs), which would encourage small business participation in the spectrum auction and would speed service to rural areas. The commission should avoid larger areas, such as economic areas (EAs), which are too large for most small businesses to bid for or serve. Also, for this purpose, geographic partitioning or spectrum disaggregation are inadequate as means to encourage small business participation in this spectrum auction. To the extent that this auction would establish small business sizes for 3650-3700 MHz services that differ from those set by the SBA, Advocacy urged the commission to seek SBA permission to alter the sizes prior to issuing final rules.

Issue: Automatic and Manual Roaming Obligations of Commercial Mobile Radio Services

In a proposed rulemaking issued in November 2000, the FCC considered whether to adopt a new automatic roaming rule for commercial mobile radio service systems and whether to sunset its existing manual roaming requirements. The FCC explored whether an automatic roaming rule remains unnecessary and indicated that it would not require automatic roaming unless market forces alone are not sufficient to ensure the widespread availability of competitive roaming services. Advocacy filed comments on January 9, 2001, stating that the IRFA was significantly flawed and did not address the mandates of the RFA. The FCC does not describe the impact an automatic roaming rule would have on businesses, particularly small businesses. In fact, the FCC implied that such a rule might be costly, but also suggested it might actually benefit small businesses. The FCC is vague and fails to comply with the RFA in this regard.

Issue: Children's Television Obligations for Digital Television Broadcasters

In November 2000, the FCC proposed a wide range of new obligations for digital television broadcasters to enhance children's programming. While it is likely that many, if not all, of these proposals would benefit children's programming, they impose compliance costs on small broadcasters. The FCC does not describe the reporting, recordkeeping, and other compliance requirements for most of these proposals in the IRFA. Advocacy filed a letter with the FCC in January 2001 stating that the current IRFA does not satisfy the requirements of the RFA. It fails to describe many of the compliance burdens that the proposed regulations would impose on small businesses. Further, it does not describe alternatives available to the commission that would lessen the impact on small entities while still achieving the FCC's regulatory goals. These deficiencies can be cured if the commission issues a supplemental IRFA that explores the costs of and alternatives to the proposed regulations. After speaking with the broadcast industry, Advocacy submitted a letter in February 2001 stating that the FCC should convert the notice of proposed rulemaking to a notice of inquiry. The FCC would then be in a better position to craft specific regulatory language and to perform the congressionally mandated regulatory flexibility analysis in support of its proposal on which the public could comment. This will reduce uncertainty and doubt for small businesses and make it easier for them to comment.

Issue: Eligibility Requirements for the Personal Communications Services (PCS) Frequency Blocks C and F Auction

In August 2000, the FCC decided to divide the 30 MHz C-Block licenses into three licenses of 10 MHz each and lifted small business eligibility restrictions on C-Block and F-Block licenses. That same month, Advocacy submitted a petition for reconsideration, which stated that the FCC had offered no rationale sufficient to alter the well-reasoned and longstanding PCS small business "set-aside." The FCC should reconsider its decision and should re-auction the spectrum according to its prior rules, Advocacy maintained.

Issue: Enhanced 911 Emergency Calling Systems

In November 2000, the FCC issued an order designed to ensure that wireless carriers introduce enhanced 911 services (E911) in a timely manner. The FCC adopted rules in 1996 that, among other things, mandated that wireless carriers would provide 911 operators with the ability to locate automatically the position of callers using wireless telephones to obtain emergency service. Carriers were permitted to defer implementation of this mandate until a mechanism was developed allowing the states to reimburse the carriers for their costs. The FCC modified this rule and removed the precondition of cost recovery from the states to hasten the introduction and rollout of E911. Advocacy's letter of April 19, 2001, said that the FCC's decision not to address the small business issues raised in the petitions for reconsideration does not comply with the RFA. Further, the most recent rulemaking drew conclusions on issues not raised in an IRFA and without an opportunity for small businesses to comment on an IRFA. Small businesses brought serious issues to the FCC's attention in petitions for reconsideration that should have been addressed in the supplemental IRFA. Advocacy requested that the FCC issue a supplemental IRFA requesting comment on the effect on small businesses of the FCC's decision to remove the cost recovery mechanism. Once that is done, the commission should prepare a supplemental FRFA drawn from the comments received.

Issue: Numbering Resource Optimization

In December 2000, the FCC issued a rule to prevent the depletion of telephone numbers. Because of recent advances in telecommunications, including faxes, the Internet, and wireless technology, the number of lines in the country has been multiplying faster than expected. The order adopted several strategies to ensure that numbers are used efficiently, such as setting a utilization threshold of numbers assigned to a carrier before the carrier can obtain more numbers, distributing numbers to carriers in blocks of 1,000 instead of 10,000, and conducting audits of carriers to ensure they are using their numbers efficiently. Advocacy filed a letter with the FCC on March 30, 2001, stating that the FCC did not adequately assess the economic impacts of these actions on small businesses. It also did not consider alternatives, such as exemptions, that minimize the impact. Advocacy recommended that the FCC issue a revised FRFA.

Issue: Spectrum Aggregation Limits for Commercial Mobile Radio Services

In January 2001, the FCC issued a rulemaking reviewing its spectrum cap and cross-ownership policies for commercial mobile radio services (CMRS) providers. The FCC sought comment on whether it should modify its limits on the amount of spectrum that any single entity may hold in a market and whether it should modify its restrictions on cross-ownership between cellular telephony providers located in the same market. Advocacy filed comments that the IRFA was inadequate, as the FCC failed to clearly state its regulatory objectives, failed to describe the impact on small businesses, and failed to propose alternatives designed to minimize this impact.

Issue: Streamlining Contributions to the Universal Service Fund

In May 2001, the FCC proposed several means of reforming how the FCC assesses carrier contributions to the universal service fund (USF) and how carriers may recover these costs from their customers. Most notably, the FCC proposed assessing contributions on current projected revenues instead of historical gross-billed revenues, and on a flat-fee basis, such as a per-line or per-account charge, instead of on a percentage of interstate revenue. The FCC also proposed possible restrictions on how carriers can recover their USF contributions reimbursement. The FCC also proposed removing the contribution exception for *de minimis* carriers. In its July 9, 2001, comments, Advocacy said the FCC should continue to assess contributions on a percentage of historical interstate gross-billed revenues. Advocacy saw some value to the consumer in creating a uniform charge for USF reimbursement, but does not believe the FCC should regulate the amount of the charge. Advocacy strongly supported maintaining the exception for carriers when their compliance costs exceeded their contribution to the USF.

Issue: Transfer of the 3650-3700 MHz Government Band

In this rulemaking adopted in October 2000, the agency acted to allocate 50 MHz of spectrum to fixed and mobile terrestrial services to facilitate a broad range of advanced services. Both new and existing fixed satellite service earth stations would be subject to Part 25 of the commission's rules. These actions and proposals are designed to benefit the public by encouraging the introduction of new services, particularly in rural areas. Advocacy's letter to the FCC stated that the final regulatory flexibility analysis failed to describe what steps the agency took to minimize the rule's significant economic impact on small entities, consistent with the agency's regulatory goals. The analysis makes no mention of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule, and it does not indicate whether the FCC considered but rejected any significant alternatives that would minimize adverse impact on small entities.

Issue: Unauthorized Changes of Consumers' Long Distance Carriers

In August 2000, the FCC adopted a rulemaking to discourage "slamming"—the illegal practice of changing a consumer's telephone service without permission. One of the measures adopted was the "drop-off requirement," which mandates that telephone carrier representatives must drop off the line while the customer speaks with the third-party verifier. The commission said this measure would help ensure the independence of third-party verification and prevent the carrier's sales representative from improperly influencing subscribers. Advocacy commented that the FCC did not comply with the RFA for a number of reasons: it adopted the drop-off requirement without raising the issue in an IRFA or soliciting comment on compliance costs and significant alternatives, and the FRFA did not analyze compliance costs of the drop-off requirement or significant alternatives. Advocacy suggested that the FCC issue a supplemental IRFA that requests comment on the effect on small businesses of the FCC's decision to require that carrier employees drop off the phone call during a third-party verification, then conduct a supplemental FRFA drawn from the comments received.

Federal Reserve System

Issue: Regulation W

In May 2001, the Federal Reserve System published a proposed rule on transactions between banks and their affiliates. The proposal would implement a new Regulation W that would comprehensively implement Sections 23A and 23B of the Federal Reserve Act. These sections restrict loans by a bank to an affiliate, asset purchases by an affiliate, and other transactions between a bank and its affiliates. The purpose of Sections 23A and 23B and of Regulation W is to limit a bank's risk of loss in transactions with affiliates and limit a bank's ability to transfer to its affiliates the benefits arising from its access to the federal safety net. In the proposal, the Federal Reserve System acknowledges that a regulatory flexibility analysis is required. However, from the information provided, Advocacy could not ascertain whether the Federal Reserve was certifying that the rule would not have a significant economic impact on a substantial number of small entities or stating that an IRFA was required. Advocacy was concerned that there was no indication in the proposal that the Federal Reserve had truly considered the economic impact of the proposal on small banking institutions. The proposal lacked information about the type and number of small entities to which the rule will apply; the projected reporting, recordkeeping, and other compliance requirements; the federal rules that may duplicate, overlap or conflict with the proposed rule; and a discussion of the alternatives that may minimize the impact on small entities. Accordingly, Advocacy submitted comments regarding the Federal Reserve System's failure to comply with the RFA.

United States Postal Service

The United States Postal Service (USPS) is an independent establishment of the executive branch that provides mail processing and delivery services to individuals and businesses; protects the mails from loss or theft; and apprehends those who violate postal laws. USPS rules are not subject to the notice and comment provisions of the APA and therefore are not subject to the RFA. However, Advocacy began monitoring USPS activities when the agency promulgated a rule concerning commercial mail receiving agencies (CMRA). The CMRA rule is an example of why USPS should be subject to the APA and the RFA.

Issue: Commercial Mail Receiving Agencies

In 1999, USPS published a final rule in the *Federal Register* on delivery of mail to CMRAs. At the time the rule was finalized, USPS asserted that "the sole postal purpose of the rule is to increase the safety and security of the mail" and that the rule was necessary to combat mail fraud. However, the agency did not provide any statistics or studies to substantiate its claim that fraud occurred at any greater rate at CMRAs than at USPS post office boxes. Among other things, the rule required CMRA users to use the terms "private mail box" (PMB) or the pound (#) sign in their mailing addresses, and provide two forms of identification when renting a mailbox. If a CMRA user did not comply with the rule, USPS stated that its mail would not be delivered. Advocacy opposed the rule at meetings and by submitting public comments on several

grounds: the rule did not have a rational basis; customers might have difficulty contacting small businesses if they relied on old materials; the term PMB might stigmatize small businesses; and there was no indication that the rule would actually combat mail fraud. Although USPS received more than 8,000 comments in opposition to the proposal and only 10 in favor, the agency finalized the rule and set a compliance deadline for August 2001. In On April 9, 2001, the USPS Office of the Inspector General (OIG) issued a report on the USPS rulemaking process in the CMRA rule. The OIG found that USPS did not "demonstrate the need for regulatory change by presenting statistical or scientific data to support claims of mail fraud conducted through private mailboxes." The proposal "did not show how the regulations would curb fraud, assess the impact of the proposed rules on receiving agencies and private boxholders, or consider alternatives to revising the rules." The OIG also found that the rules represented significant changes that could cost receiving agencies and their customers millions of dollars.

Issue: Classifying Office Business Centers as CMRAs

On July 11, 2001, the USPS published a proposed rule on delivery of mail to a commercial mail receiving agency. The proposed rule revises USPS regulations governing procedures for delivery of an addressee's mail to a CMRA by removing the monetary requirement for defining an office business center (OBC) and setting forth procedures for identifying when an OBC or part of its operation is considered a CMRA for purposes of complying with the CMRA regulations. Specifically, under the proposed regulation, an OBC customer is considered to be a CMRA if its contract with the OBC provides for mail service only or mail along with other business services without regard to occupancy. As with the initial CMRA rule, there were no studies to indicate the rate of fraud or support the necessity of the rule. There was also no indication that USPS had considered the impact of the rule on competition. In short, USPS had not demonstrated the need for regulatory change or that the change would in any way curb fraud. In its August 14, 2001, comments, the Office of Advocacy argued that requiring OBC customers to use "PMB" or the "#" sign in the address, without any evidence that the action would deter fraud, was unreasonable and inappropriate in that it placed an unwarranted stigma on OBC users. Advocacy also asserted that the proposal placed OBCs that offer less extensive services at a competitive disadvantage. Before expanding the CMRA rule to include certain OBC customers, USPS should follow the findings of the OIG and perform a study to determine if these regulations are indeed necessary and, if so, whether they are the proper manner for addressing the problem.

CONCLUSION

Federal agencies have made noticeable progress in complying with the Regulatory Flexibility Act, in large part because of the SBREFA amendments. However, significant work remains to be done to bring all agencies into compliance on a consistent basis. Several agencies still have much to learn about the importance of small businesses in the economy and the underlying rationale of the RFA. Some have yet to comprehend that the RFA does not require special treatment for small businesses. Rather, it establishes a process for analyzing how to achieve public policy objectives while still preserving a level playing field for small businesses.

The Office of Advocacy has devoted significant resources to educating federal agencies about the law and its overriding objectives. Staff of the Office of Advocacy have been available for consultation on specific regulatory proposals, economic impact analyses, and overall RFA compliance. When such consultation is not completely successful, the Chief Counsel for Advocacy submits extensive comments on regulatory proposals and economic analyses, and monitors challenges to final rules by small entities—all with the objective of ensuring that small business interests are appropriately considered.

The potential for review of RFA issues in appellate litigation unquestionably has provided a major incentive for federal agencies to take greater care to ensure compliance with the act. The Office of Advocacy's increasingly direct involvement in regulatory development, and its potential role as *amicus curiae* in regulatory appeals, provides more opportunities to resolve RFA disputes and to bring agencies into compliance.

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 though 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

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: ABBREVIATIONS

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
APA	Administrative Procedure Act
BLM	Bureau of Land Management
CBD	*Commerce Business Daily*
C.F.R.	*Code of Federal Regulations*
CGMP	current good manufacturing practice
CMS	Centers for Medicare and Medicaid Services
CSA	Controlled Substances Act
DBE	disadvantaged business enterprise
DEA	Drug Enforcement Administration
DOC	U.S. Department of Commerce
DOD	U.S. Department of Defense
DOI	U.S. Department of the Interior
DOJ	U.S. Department of Justice
DOL	U.S. Department of Labor
DOT	U.S. Department of Transportation
EIS	environmental impact statement
EPA	Environmental Protection Agency
ESA	Employment Standards Administration
ESA	Endangered Species Act
FAA	Federal Aviation Administration
FAR	Federal Acquisition Regulation
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FHWA	Federal Highway Administration
FLSA	Federal Labor Standards Act
FMC	Fishery Management Council
FMCSA	Federal Motor Carrier Safety Administration
FNS	Food and Nutrition Service
FPI	Federal Prison Industries
FRA	Federal Railroad Administration
FRFA	final regulatory flexibility analysis
FS	Forest Service
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
FWS	Fish and Wildlife Service
GAO	General Accounting Office
GSA	General Services Administration
HACCP	hazard analysis critical control point
HCFA	Health Care Financing Administration
HHS	U.S. Department of Health and Human Services

HUD	U.S. Department of Housing and Urban Development
ICANN	Internet Corporation for Assigned Names and Numbers
IRFA	initial regulatory flexibility analysis
IRS	Internal Revenue Service
LOC	Library of Congress
MMS	Minerals Management Service
MSA	metropolitan statistical area
MSHA	Mine Safety and Health Administration
NAS	National Academy of Sciences
NASA	National Aeronautics and Space Administration
NEPA	National Environmental Policy Act
NHTSA	National Highway Traffic Safety Administration
NIST	National Institute of Standards and Technology
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NPRM	notice of proposed rulemaking
NPS	National Park Service
NRC	National Research Council
OFPP	Office of Federal Procurement Policy
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
PWBA	Pension and Welfare Benefits Administration
RFA	Regulatory Flexibility Act
RSA	rural service areas
RSPA	Research and Special Programs Administration
SBA	Small Business Administration
SBDC	small business development center
SBIC	small business investment company
SBREFA	Small Business Regulatory Enforcement Fairness Act
SEC	Securities and Exchange Commission
SIMPLE	Savings Incentive Match Plan for Employees
STAWRS	Simplified Tax and Wage Reporting System
USDA	U.S. Department of Agriculture
U.S.C.	United States Code
USPS	United States Postal Service
VA	U.S. Department of Veterans Affairs
WIPO	World Intellectual Property Organization