

# A Guide for Government Agencies

## How to Comply with the Regulatory Flexibility Act



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

*May 2012*

## FOREWORD

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

President Obama's Executive Order 13563, Improving Regulation and Regulatory Review, his regulatory memoranda, and several laws passed since 2002 have strengthened the RFA and underscored the importance of considering small entity effects early in the regulatory process. Executive Order 13272, signed August 13, 2002, among other provisions, directs the Small Business Administration's (SBA) Office of Advocacy to provide agencies with training and information on how to comply with the Regulatory Flexibility Act (RFA).

The Office of Advocacy continues to provide training to agency personnel in RFA compliance and welcomes additional opportunities to assist in new phases of training. This compliance guide, prepared with input from regulatory agencies, is designed to be used by agency rule writers and policy analysts as a step-by-step manual for complying with the RFA. A careful review of the requirements is recommended before policy analysts begin to draft regulations, and then again at each stage of the process.

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

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



Winslow Sargeant, Ph.D.  
Chief Counsel for Advocacy

## **ACKNOWLEDGMENTS**

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

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

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## INTRODUCTION: THE RFA AND RELATED LAW

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

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

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

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

In essence, the RFA asks agencies to be aware of the economic structure of the entities they regulate and the effect their regulations may have on small entities. To this end, the RFA requires agencies to analyze the economic impact of proposed regulations when there is likely to be a significant economic impact on a substantial number of small entities, and to consider regulatory alternatives that will achieve the agency's goal while minimizing the burden on small entities. The concept underlying this analytical

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

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

requirement is that agencies will revise their decisionmaking processes to take account of small entity concerns in the same manner that agency decisionmaking processes were modified subsequent to the enactment of the National Environmental Policy Act (NEPA).<sup>3</sup> The RFA then acts as a statutorily mandated analytical tool to further assist agencies in meeting the rational rulemaking standard set forth in the Administrative Procedure Act (APA), just as NEPA was intended to rationalize decisions concerning major federal actions that would affect the environment.

The Small Business Regulatory Enforcement Fairness Act (SBREFA), enacted in March 1996,<sup>4</sup> amended the RFA and provided additional tools to aid small business in the fight for regulatory fairness. The amendments made by SBREFA include:

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

Subsequently, several laws have been passed amending and strengthening SBREFA and the RFA:

- **The Small Business and Work Opportunity Act of 2007** amended SBREFA to strengthen the requirement that agencies prepare compliance guides for any rule for which they must prepare a final regulatory flexibility analysis. Agencies are required to publish the guides not later than the effective date of the requirements, post them to websites, distribute them to industry contacts, and report annually to Congress.<sup>5</sup>
- **The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010** established the Consumer Financial Protection Bureau (CFPB) and required the CFPB to comply with the RFA Section 609 panel process, making it the third such agency, along with the Environmental Protection Agency and the Occupational Safety and Health Administration.<sup>6</sup> In addition to the regular requirements of the initial regulatory flexibility analysis (IRFA) found in 5 USC 603, a CFPB IRFA must include “a description of (A) any projected increase in the cost of credit for small entities; (B) any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any increase in the cost of credit for small entities; and (C) advice and

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

<sup>4</sup> Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 857 (codified at 5 U.S.C. § 601 et seq.).

<sup>5</sup> Pub. Law 110-28 (May 27, 2007), Title 6, subtitle B, § 7005.

<sup>6</sup> Pub. Law 111-203 (July 21, 2010).



recommendations of representatives of small entities relating to issues described in subparagraphs (A) and (B) and subsection (b).”<sup>7</sup> When the CFPB produces a final regulatory flexibility analysis, it must include “a description of the steps the agency has taken to minimize any additional cost of credit for small entities.”

- **The Small Business Jobs Act of 2010** amended several requirements in the final regulatory flexibility analysis (FRFA) section of the RFA.<sup>8</sup> (1) It struck the word “succinct” from the requirement for “a succinct statement of the need for, and objectives of, the rule.”<sup>9</sup> (2) It replaced the word “summary” with the word “statement” twice in the requirement for “a summary of the significant issues raised by the public comments..., a summary of the assessment of the agency of such issues...,”<sup>10</sup> and (3) it codified a requirement of Executive Order 13272<sup>11</sup> by adding a paragraph requiring the FRFA to include “the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.”<sup>12</sup>

In addition to legislation strengthening the RFA, presidents have issued a number of executive orders laying out additional requirements.

- **Executive Order 13272**, “Proper Consideration of Small Entities in Agency Rulemaking,” was signed August 13, 2002, and requires federal agencies to publish how they will comply with the statutory mandates of the RFA.<sup>13</sup> The purpose of E.O. 13272 is to ensure that agencies work closely with Advocacy to address small business issues as early as possible in the regulatory process, particularly as they relate to disproportionate regulatory burden. The order sets out a series of responsibilities for both regulating agencies and the Office of Advocacy.
  - ✓ Agencies will establish policies on how to measure their impact on small entities and will work with Advocacy to establish those procedures.
  - ✓ The Office of Advocacy is instructed to train agencies on how to properly account for small entity impact when agencies draft regulations and to continue to work with agencies.
  - ✓ Agencies are to submit proposed rules with significant small entity effects to the Office of Advocacy prior to publication and are required to consider the Office of Advocacy’s comments on the rule.<sup>14</sup>

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<sup>7</sup> Title X, § 1100G(b) of the Dodd-Frank Act amending 5 U.S.C. § 603(d)(1)-(2), §604(a)(6) and § 609(d)(2). See Appendix A.

<sup>8</sup> Pub. Law 111-240 (September 27, 2010).

<sup>9</sup> *Id.*, § 1601(1), amending 5 U.S.C. § 604(a)(1).

<sup>10</sup> *Id.*, § 1601(2), amending 5 U.S.C. § 604(a)(2).

<sup>11</sup> See the full executive order in Appendix F.

<sup>12</sup> *Id.*, § 1601(3), amending 5 U.S.C. § 604(a)(3).

<sup>13</sup> Exec. Order No. 13,272, 67 Fed. Reg. 53,461 (Aug. 13, 2002).

<sup>14</sup> The Small Business Jobs Act, P.L. 111-240, codified this requirement of E.O. 13272 in 5 U.S.C. § 604(a)(3). See earlier discussion in the Introduction to this guide.

- ✓ The Office of Advocacy is required to report annually to the Office of Management and Budget (OMB) on whether agencies are complying with this executive order.
- **Executive Orders 13563 and 12866** lay out additional analytical requirements for agencies when promulgating rules pursuant to delegations from Congress and the overarching mandate of the APA.<sup>15</sup> Both of these executive orders establish regulatory goals that can help agencies to which the executive orders apply<sup>16</sup> understand the importance of conducting regulatory flexibility analyses. As Executive Order 13563 states:

(b) This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866<sup>17</sup> of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.<sup>18</sup>

In addition, Executive Order 12866 specifies 12 principles agencies should use when developing regulations. Of the 12, number 11 has particular relevance to the analysis of small business regulatory alternatives under the RFA:

Concurrent with the issuance of E.O. 13563, President Obama also issued a memorandum titled “Regulatory Flexibility, Small Business, and Job Creation” on January 18, 2011. In the memorandum, the president reaffirmed E.O. 12866 and reiterated the RFA’s provisions for providing regulatory flexibility. The

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<sup>15</sup> Exec. Order No. 13,563 of January 18, 2011, reaffirms Exec. Order No. 12,866. Two other executive orders, 13,258 and 13,422, that had previously amended Exec. Order No. 12,866, were revoked by Exec. Order No. 13,497 of January 30, 2009.

<sup>16</sup> Exec. Order No. 12,866 does not apply to independent regulatory commissions such as the Federal Election Commission, the Federal Communications Commission, and the Securities and Exchange Commission.

<sup>17</sup> Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993).

<sup>18</sup> Exec. Order No. 13,563, 76 Fed. Reg. 3821 (January 21, 2011).

memorandum directs that “whenever an executive agency chooses, for reasons other than legal limitations, not to provide such flexibility in a proposed or final rule that is likely to have a significant economic impact on a substantial number of small entities, it should explicitly justify its decision not to do so in the explanation that accompanies that proposed or final rule.”<sup>19</sup>

- **Executive Order 13579**, “Regulation and Independent Regulatory Agencies,” signed by President Obama on July 11, 2011, reaffirms the directives of Executive Order 13563 and says that “to the extent permitted by law, independent agencies should comply with these provisions as well.”<sup>20</sup>

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

The Office of Advocacy’s compliance guide should be utilized by regulatory agencies as a tool for following the requirements of the Regulatory Flexibility Act and related law and executive orders. This revised guide is the product of Advocacy’s decades of experience with the RFA and reflects the spirit of interagency cooperation, as well as the vital importance of small business to the economy. Advocacy hopes the guide will be a useful tool and welcomes comments on ways to improve its usefulness to regulatory agencies.

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

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<sup>19</sup> This language mirrors the RFA language at 5 U.S.C. § 604 (a)(6) for final rules.

<sup>20</sup> Exec. Order No. 13,579 § 1(c).

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

We begin by briefly examining the general purpose of the Regulatory Flexibility Act and its overall requirements. The Regulatory Flexibility Act requires agencies to consider the impact of their rules on small entities.<sup>21</sup> When the proposed regulation will impose a significant economic impact on a substantial number of small entities, the agency must evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities. Inherent in the RFA is a desire to remove barriers to competition and encourage agencies to consider ways of tailoring regulations to the size of the regulated entities.<sup>22</sup>

The RFA, like the National Environmental Policy Act, imposes analytical requirements on federal agencies. Both statutes require disclosure of effects and mechanisms to reduce adverse consequences and improve beneficial consequences.<sup>23</sup> The RFA does not require that agencies necessarily minimize a rule's impact on small entities if there are significant legal, policy, factual, or other reasons for not minimizing the impact. The RFA requires only that agencies determine, to the extent practicable, the rule's economic impact on small entities and explore regulatory alternatives for reducing any significant economic impact on a substantial number of such entities. Once that process is finished, agencies must explain the reasons for their ultimate regulatory choices.

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

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

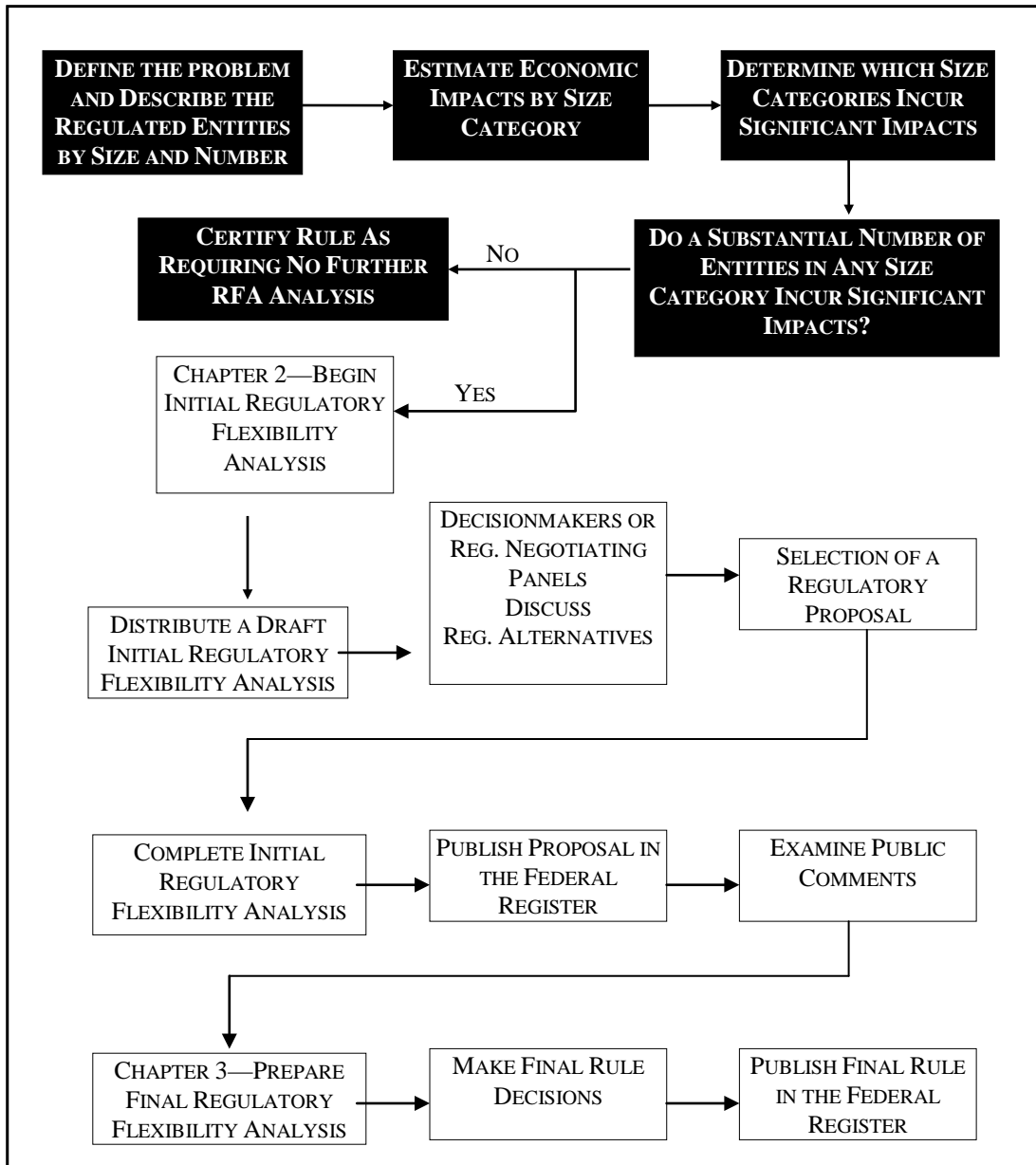
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<sup>21</sup> See this chapter's section titled "What is the definition of a small entity?"

<sup>22</sup> See generally, FINDINGS AND PURPOSES, SEC. 2(a)–(b).

<sup>23</sup> Nothing in the RFA states that an economic impact must be adverse prior to performing an analysis.

## The RFA decision process



## Does the RFA apply?

One of the first decisions to make is whether the Regulatory Flexibility Act applies to the particular regulation. The RFA applies to any rule subject to notice and comment rulemaking under section 553(b) of the Administrative Procedure Act (APA)<sup>24</sup> or any other law. This includes any rule of general applicability governing federal grants to state and local governments, for which agency procedures provide opportunity for notice and comment. For instance, some agencies, such as the Rural Utilities Service, have their own administrative rules that require notice and comment even though the agency's rules may be exempt from the APA notice and comment requirement.<sup>25</sup>

### ***RFA exemptions***

Rules that are exempt from APA notice and comment requirements are also exempt from the RFA requirements when any of the following is involved: (1) a military or foreign affairs function of the United States, or (2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.<sup>26</sup> In addition, except where notice or hearing is required by statute, the APA does not apply (1) to interpretative rules,<sup>27</sup> general statements of policy, or rules of agency organization, procedure or practice; or (2) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.<sup>28</sup> Under any of the circumstances described above, the RFA would not apply.

Interpretative rules generally interpret the intent expressed by Congress. The easiest type of interpretative rule to recognize is one in which an agency does not insert its own judgments in implementing a rule, and simply regurgitates statutory language. One legal treatise on the subject says that interpretative rules are any rules that an agency issues without exercising delegated legislative power to make law through rules.<sup>29</sup> The treatise goes on to state that the difference between legislative and interpretative rulemaking is the weight courts give the agency decisions on review.<sup>30</sup>

In the case of legislative rules, agencies are given the authority to establish requirements not specifically mentioned in the authorizing statute that may be the basis for a rule. An example of this would be setting an ambient air quality standard or regulating in the public interest as set out in the Communications Act of 1934. See *Whitman v. American*

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<sup>24</sup> 5 U.S.C § 553(b); see also § 601(2).

<sup>25</sup> The “other law” requirement includes situations where the agency binds itself by rule to act through rulemaking rather than by a procedure that does not require notice and comment.

<sup>26</sup> *Id.* at § 553(a). There are statutes, such as the Competition in Contracting Act, the Federal Acquisition Streamlining Act, and the Federal Acquisition Reform Act, that mandate that changes to contracting rules be issued pursuant to notice and comment.

<sup>27</sup> The exception is certain Internal Revenue Service interpretative rules. See the discussion below.

<sup>28</sup> *Id.* at § 553(b)(A).

<sup>29</sup> K. Davis, *Administrative Law Treatise*, § 7:8 (1958).

<sup>30</sup> Davis at §§ 7:8-7:13.

*Trucking Associations* for a discussion of what constitutes a standard governing delegation of legislative authority by Congress to the executive branch.<sup>31</sup>

The RFA presents its own exemptions as well. Section 601(2) states that the RFA does not apply to rules of *particular applicability* relating to rates, wages, corporate or financial structures, or reorganizations thereof, prices, facilities, appliances, services or allowances therefor, or to valuations, costs or accounting, or practices relating to such rates, wages, structures, appliances, services, or allowances.<sup>32</sup> The RFA’s definition of a rule is less inclusive than the definition of a rule under the Administrative Procedure Act, which defines a “rule” as “an agency statement of *general or particular applicability*.” The original draft of the APA limited the definition of rules to “statements of general applicability” or “having a *general* application to members of a broadly identifiable class.”<sup>33</sup> This is contrasted with statements of “particular applicability” or applying “only to specific individuals or situations” or “named parties.”<sup>34</sup> Therefore, the RFA applies to rules affecting the general public, as opposed to those that affect specific individuals.

### ***RFA now applies to certain IRS interpretative rules***

The Small Business Regulatory Enforcement Fairness Act amended the RFA to bring certain interpretative rulemakings of the Internal Revenue Service (IRS) within the scope of the RFA. The law now applies to those IRS rules published in the *Federal Register* (that would normally be exempt from the RFA as interpretative rules) that impose a “collection of information” requirement on small entities.<sup>35</sup> Congress took care to define the term “collection of information” to be identical to the term used in the Paperwork Reduction Act, which means that a collection of information includes any reporting or recordkeeping requirement for more than nine people.<sup>36</sup>

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<sup>31</sup> *American Trucking Ass’ns v. EPA*, 175 F.3d 1027, 1044 (D.C. Cir. 1999); *Whitman v. American Trucking Ass’ns*, 531 I/S/ 457 (2001).

<sup>32</sup> 5 U.S.C. § 601(2).

<sup>33</sup> Bernard Schwartz, *Administrative Law: A Casebook*, at 255-262 (2d ed. 1984).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at § 603(a).

<sup>36</sup> *Id.* at § 601(7).

(7) The term “collection of information”

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

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

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

(B) shall not include a collection of information described under section 3518(c)(1) of title 44, United States Code. (8) The term “record-keeping requirement” means a requirement imposed by an agency on persons to maintain specified records.

## The RFA threshold analysis: Can we certify?

After an agency begins regulatory development and determines that the RFA applies, it must decide whether to conduct a full regulatory flexibility analysis or to certify that the proposed rule will not “have a significant economic impact on a substantial number of small entities.”<sup>37</sup> The record an agency builds to support a decision to certify is subject to judicial review.<sup>38</sup>

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

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

If, after conducting an analysis for a proposed or final rule, an agency determines that a rule will not have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify. The certification must include a statement providing the *factual basis* for this determination, and the certification shall be published in the *Federal Register* at the time the proposed or final rule is published for public comment. The agency is also required to provide such certification and statement to the SBA’s Chief Counsel for Advocacy.<sup>39</sup> A certification must include, at a minimum, a description of the affected entities and the impacts that clearly justify the “no impact” certification. The agency’s reasoning and assumptions underlying its certification should be explicit in order to obtain meaningful public comment and thus receive information that would be used to re-evaluate the certification.

Clearly, an agency should identify the scope of the problem and the impact of the solution on affected entities before moving forward with a regulatory proposal. At times, despite a good-faith effort on the part of an agency to obtain data, an agency may still be uncertain about whether to certify. In those instances, an advance notice of proposed rulemaking (ANPRM) may be necessary to solicit data. As a final recourse, the agency should err on the side of caution and perform an initial regulatory flexibility analysis (IRFA) with the available data and information, and solicit comments from small entities regarding impact.<sup>40</sup> Then, if appropriate, the agency can certify the final rule. If an

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<sup>37</sup> 5 U.S.C. § 605(b). The decision to certify a rule parallels the finding of no significant impact under NEPA. As with a NEPA determination, the decision to certify, because it is subject to judicial review, should be based on a sound threshold analysis similar to the environmental assessment mandated in Council on Environmental Quality regulations to support a finding of no significant impact or laying the groundwork for a full environmental impact statement.

<sup>38</sup> *Id.* at § 611(a).

<sup>39</sup> There are circumstances where it may be appropriate to publish an IRFA for the proposed rule, and based on comments received, publish a certification for the first time in the final rule. See Chapter 3 of this guide for a detailed discussion of final regulatory flexibility analyses.

<sup>40</sup> 5 U.S.C. § 605(b). The Office of Advocacy would expect this situation to be rare because agency efforts to develop the rule should include a reasonable effort to explore all the effects of the rule, including the



agency lacks sufficient information to make a certification decision, the agency should engage in reasonable outreach efforts.<sup>41</sup>

### **Organizing the threshold report**

Certification analysis discussed in this chapter does not require the depth of analysis necessary in an initial regulatory flexibility analysis,<sup>42</sup> as discussed in Chapter 2 of this guide. Nevertheless, this “threshold” analysis can offer important insights into the nature of regulatory impacts. Although a study of alternatives is not required at this stage, it often leads to the skeleton of regulatory alternatives that can reduce or eliminate any disproportionate impacts on small entities. For this reason, Advocacy encourages certification analysis as early in the rule development process as possible.

Agency certifications of final rules are subject to judicial review<sup>43</sup> and courts evaluate them by determining whether the statement of basis and purpose accompanying the rule identifies a “factual basis” to support the certification.<sup>44</sup> A helpful threshold report will directly support the elements that must appear in the *Federal Register* Notice of Proposed Rulemaking preamble. The Office of Advocacy believes the threshold analysis should discuss the following items:<sup>45</sup>

- 1) Description of small entities affected
  - ✓ A brief economic and technical statement on the regulated community, describing some of the following types of information:<sup>46</sup>
    - a) The diversity in size of regulated entities
    - b) Revenues in each size grouping
    - c) Profitability in each size grouping
- 2) Economic impacts on small entities
  - ✓ A fair, first estimate of expected cost impacts, or a reasonable basis for assuming costs would be *de minimis* or insignificant within all economic or size groupings of the “small” regulated community
  - ✓ The rationale for the certification decision, based on the analysis presented
- 3) Significant economic impact criteria
  - ✓ The criteria used to examine whether first-estimate costs are significant
- 4) Substantial number criteria

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effects on small entities. For more information on preparing an initial regulatory flexibility analysis, see Chapter 2.

<sup>41</sup> *Id.* at § 609. Outreach is important to obtain information required by the RFA, to obtain relevant input from affected small entities. See Chapters 4 and 7 for a discussion of agency outreach to small entities.

<sup>42</sup> An initial regulatory flexibility analysis (IRFA) is a document containing the agency’s data and analysis regarding the potential impact of the proposed rule. A detailed description of the requirements of an IRFA can be found in Chapter 2 of this guide.

<sup>43</sup> 5 U.S.C. § 611.

<sup>44</sup> *Id.* at § 605(b).

<sup>45</sup> For additional detail, see the certification checklist at the end of this chapter.

<sup>46</sup> When an agency does not have quantitative data to support its certification, the agency should explain why such data are not available and request comments.

- ✓ The criteria used to examine whether the entities experiencing significant impacts constitute a substantial number of entities in any of the regulated size groupings
- 5) Description of assumptions and uncertainties
  - ✓ The sources of data used in the economic and technical analysis<sup>47</sup>
  - ✓ The degree of uncertainty in the cost estimates, when uncertainty is large
- 6) Certification statement

### ***“Factual basis” requirement for certification***

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

The agency’s reasoning and assumptions underlying its certification should be explicit in order to elicit public comment. Certifications of “no significant economic impact on a substantial number of small entities” have major legal implications for agencies. Consequently, certifications that simply state that the agency has found that the proposed or final rule will not have a significant economic impact on a substantial number of small entities are not sufficient under section 605(b).

The “more than just a few” standard for determining if a rule will have a significant economic impact on a “substantial number of small entities” is a rigorous test for agencies to follow. However, the Office of Advocacy encourages a conservative approach.<sup>48</sup> In other words, if an agency has set its standard for determining “substantial number” too high, the certification may give rise to court challenges that could have been avoidable.<sup>49</sup>

Prior to the enactment of the SBREFA amendments in 1996, the RFA required only that a certification be supported by a “succinct statement explaining the reasons for the

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<sup>47</sup> Section 607 of the RFA directs agencies to provide a “quantifiable or numerical description of the effects of the proposed rule or alternatives to the proposed rule” and allows a qualitative approach if “quantification is not practical or reliable.” Thus, agencies are expected to make reasonable efforts to acquire quantitative or other information to support analysis of the rules under sections 603 and 604 of the RFA. Such a standard is not required for section 605 certifications, but some agencies use section 607 as a model for preparing certifications. With regard to certification analyses, EPA advises its rulewriters that “where the information necessary to conduct a quantitative analysis is not reasonably available, it may be appropriate to certify the rule based on the qualitative assessment alone.” Regulatory Management Division, EPA Office of Policy, *EPA’s Action Development Process: Final Guidance for EPA Rulewriters: Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act* (November 2006), p. 20.

<sup>48</sup> Five small firms in an industry with more than 1,000 small firms is not likely to be interpreted as a “substantial number”; on the other hand, the same five small firms in an industry with only 20 firms would be a substantial number. See the discussion of the definitions of “significant” and “substantial” later in this chapter.

<sup>49</sup> See Chapter 5 of this guide for information on what the courts have held in these types of cases.

certification,”<sup>50</sup> and since such statements were not subject to judicial review, even as part of the record on review, agencies could avoid substantive explanations by using boilerplate certifications. The amended version of the RFA now requires that certifications be supported by a “statement of factual basis.” In amending the RFA, Congress intended that agencies should do more than provide boilerplate and unsubstantiated statements to support their RFA certifications. Courts will overturn an agency’s final certification if it is not adequate.<sup>51</sup>

### ***What is the definition of a small entity?***

The definition of “small entity” is important because it is the starting point for determining the degree of impact a regulation will have on small entities. Three types of small entities are defined in the RFA:<sup>52</sup>

**Small business.** Section 601(3) of the RFA defines a “small business” as having the same meaning as “small business concern” under section 3 of the Small Business Act. This includes any firm that is “independently owned and operated” and is “not dominant in its field of operation.”<sup>53</sup> The Small Business Administration (SBA) has developed size standards to carry out the purposes of the Small Business Act and those size standards can be found in 13 C.F.R., section 121.201. The Small Business Act prohibits an agency from adopting a different definition of small business when promulgating regulations to carry out a delegation of authority from Congress unless the agency follows the procedures set forth in SBA’s regulations.<sup>54</sup> In addition, an agency may feel that the classification used by the Administrator for a particular sector is inappropriate in doing the analysis required by the RFA. The agency is then authorized to use a different definition, solely for purposes of complying with the RFA, after consultation with the Chief Counsel. That consultation does not obviate the need for the agency to comply with section 3 of the Small Business Act should the agency be interested in promulgating a regulation that utilizes a different definition of small business than that developed by the Administrator.<sup>55</sup>

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

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<sup>50</sup> See *Lehigh Valley Farmers, Inc., v. Block*, 640 F. Supp. (E.D. Pa. 1986), *aff’d on other grounds*, 828 F.2d.

<sup>51</sup> See *North Carolina Fisheries Association v. Daley*, 27 F. Supp. 2d 650 (E.D. Va. 1998).

<sup>52</sup> Appendix D lists data sources that may be helpful in drawing distinctions between large and small entities.

<sup>53</sup> 15 U.S.C. § 632.

<sup>54</sup> 13 C.F.R. § 121.902(b).

<sup>55</sup> *Northwest Mining Ass’n v. Babbitt*, 5 F. Supp. 2d 9 (D.D.C. 1998).

**Small governmental jurisdiction.** Section 601(5) defines small governmental jurisdictions as governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000. Agencies may develop one or more alternative definitions for this term provided that they: (1) give opportunity for public comment, (2) base definitions on factors such as low population density and limited revenues, and (3) publish final definitions in the *Federal Register*. The alternative definition developed under this section applies only to the agency's compliance with the RFA. The agency may develop different size standards for small governmental jurisdictions in the development of its regulations. Any agency size standard determination that differs from the SBA's size standard is subject to judicial review.<sup>56</sup>

### ***Changing a size standard***

It is important to draw a distinction when it comes to determining appropriate size standards. If an agency chooses to change a size standard after a determination that SBA's size standard is inadequate, the agency must either consult with the Office of Advocacy or seek approval of SBA's Administrator, depending on the circumstances.

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

On the other hand, if an agency seeks to change the definition of a small business for rulemaking purposes, that is, for purposes of determining how to apply a regulation to a business of a certain size, the agency must seek approval from the SBA's Administrator.<sup>57</sup>

### ***Assessing the impact on small entities***

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

Every rule is different. The level, scope, and complexity of analysis may vary significantly depending on the characteristics and composition of the industry or small-

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<sup>56</sup> 5 U.S.C. § 611(a); see also Chapter 5 of this guide for a discussion of how the courts have handled this issue.

<sup>57</sup> Section 3(a)(2)(C)(i)-(ii) of the Small Business Act and SBA's regulations found in 13 CFR 121.902(b) essentially outline the information an agency needs to submit in order for SBA's Administrator to approve a new size standard, as well as when in the rulemaking process an agency needs to obtain that approval.

entity sectors to be regulated. This is why it is important that agencies make every effort to conduct a sufficient and meaningful analysis when promulgating rules. The preparation of the required analysis calls for due diligence, knowledge of the regulated small entity community, sound economic and technical analysis, and good professional judgment.<sup>58</sup> One of the first steps in the analytical process includes understanding the nature and economics of the industry/entities being regulated, and identifying how much each sector is contributing to the problem the agency is trying to address and mitigate. A goal of the entire APA/RFA process is to give the public a complete understanding of what the agency is doing. Small businesses cannot provide informed comments if the agency fails to identify the rule as one that will have a significant impact on a substantial number of small businesses. In turn, informed comments provide useful tools for the agency to construct the least burdensome, most effective regulations.

Because almost every industrial category will have more small than large businesses,<sup>59</sup> determining the impact on small businesses plays a key role in compliance with the RFA. In turn, to the extent that the costs of compliance are sufficiently significant that some entities will be unable to comply, the agency's selected regulatory solution probably will not achieve its statutory goal. Thus the analytical requirements, including the decision to certify, play a key role in the agency meeting its overall requirement of rational rulemaking, i.e., that the solution selected by the agency will achieve the agency's objectives.

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

### ***Which segment of the economy or industry will be regulated?***

To know whether a regulatory proposal affects a substantial number of small entities, the regulator must first know how many regulated entities exist and which are small. In examining this, the analyst best serves the process by identifying each group of regulated entities with similar economic and industrial characteristics. Each group constitutes its

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<sup>58</sup> See OMB's government-wide information guidelines, 67 Fed. Reg. 8452 (Feb. 22, 2002). These guidelines were issued under authority contained in the Information Quality Act, Pub. L. 106-554.

<sup>59</sup> This does not mean that small businesses dominate that sector of the market; for example, in telecommunications, although there are many small businesses, a handful of large regional telephone companies still dominate the market.

own universe of regulated small entities that the proposal may influence significantly. If the regulated community is segmented properly, the members of each group will have similar economic characteristics, and an examination of a typical entity or use of the group's mean characteristics will normally allow very rapid economic analysis for the group. This approach allows identification of those groups covered by the RFA.

Congress enacted the Small Business Regulatory Enforcement Fairness Act to achieve “fundamental changes . . . needed in the regulatory and enforcement culture of Federal agencies to make agencies more responsive to small business . . . without compromising the statutory missions of the agencies.”<sup>60</sup> Thus, to meet the basic SBREFA goal, analysts will routinely want to economically segment industrial sectors into several appropriate size categories smaller than the Small Business Act section 3 definition. Only by so doing will the analyst accurately identify and analyze those entities covered by the RFA where there is a large disparity in economic and industrial characteristics within the single category of small entities.<sup>61</sup> Consider the following example of how the SBA definition of a small business may not adequately address the nuances that exist within the universe of affected small entities:

SBA established a size standard for the drinking water supply industry at \$5 million in revenues, equating approximately to a city serving 30,000 people. EPA has proposed an alternative definition—a small water supply would serve no more than 10,000 people. Such a system generates somewhat less than a million dollars in annual revenue. However, EPA does not stop by looking only at the supply serving 10,000 people. It also examines sub-populations of the water supply industry serving fewer than 100 people, 101-500 people, 501-3,300 and 3,300-10,000. Water supplies in the smallest size category generate revenues less than one-tenth that of those in the 10,000-25,000 size category. More significantly, 90 percent of regulated water supplies serve fewer than 500 people, and on average, water supplies in those two size categories have net losses, costs being spread to other municipal revenue streams. EPA typically examines each of these small water supply size categories and, in keeping with the Regulatory Flexibility Act, has proposed different “available treatment technologies” for each water supply size, reflecting the wide range in economic viability within the industry. Each of the size categories below the “small water supply” size cut-off stands as its own universe of economically similar regulated entities. EPA recognized the regulatory significance of this and incorporated it into its analysis.<sup>62</sup>

Agencies should identify and examine various economically similar small regulated entities so that they will have a baseline from which to determine whether a significant regulatory cost will have an impact on a substantial number of small entities. An

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<sup>60</sup> SBREFA § 202(3).

<sup>61</sup> Conversely, if all small entities are equally affected by the proposed regulation, subcategorization is not required.

<sup>62</sup> For a full discussion of this issue, see EPA's National Primary Drinking Water Regulations; Arsenic Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976, 6987 (Jan. 22, 2001).

understanding of the differences in economic impacts across the various regulated communities often generates different regulatory alternatives. A sound analysis requires that agencies examine the various subsectors of the regulated community, the differences among them, and additional appropriate regulatory alternatives that can achieve the statutory mission while mitigating unnecessary economic impacts on small entities.

### ***How to categorize small entity sectors***

The agency's first step in a threshold analysis consists of identifying the industry, governmental and nonprofit sectors they intend to regulate. Using the North American Industry Classification System (NAICS) classifications, SBA defines small businesses in terms of firm revenues or employees.<sup>63</sup> Different criteria may be helpful to agencies in assessing the composition of a small entity sector. The IRS categorizes firm (corporation and partnership) size by assets. Industry associations apply some or all of these three criteria (revenues, employment, and/or assets) and often add to or replace them with their own technical criteria. In addition to SBA definitions, federal regulators may use any one or multiple criteria to identify their universes of small regulated entities.<sup>64</sup>

### ***Determination of "significant impact"***

The agency's second step in a threshold analysis is to determine whether there is a significant economic impact on a substantial number of small entities. The RFA does not define "significant" or "substantial." In the absence of statutory specificity, what is "significant" will vary depending on the economics of the industry or sector to be regulated. The agency is in the best position to gauge the small entity impacts of its regulations.

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

One measure for determining economic impact is the percentage of revenue or percentage of gross revenues affected. For example, if the cost of implementing a particular rule represents 3 percent of the profits in a particular sector of the economy and the profit margin in that industry is 2 percent of gross revenues (an economic structure that occurs in the food marketing industry, where profits are often less than 2 percent), the

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<sup>63</sup> Effective January 1, 1997, the federal government, for statistical purposes, replaced the Standard Industrial Classification (SIC) system with NAICS. For purposes of small business size standards, SBA adopted the NAICS definitions for all industries effective October 1, 2000. NAICS made changes to the descriptions of many industry structures.

<sup>64</sup> The SBA definitions here are found in § 3(a)(2) of the Small Business Act and are not the RFA definitions referenced above. See <http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards>.

implementation of the proposal would drive many businesses out of business (all except the ones that beat a 3 percent profit margin). That would be a significant economic impact.

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

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

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

- The Department of Health and Human Services (HHS) has determined that a rule is significant if it would reduce revenues or raise costs of any class of affected entities by more than 3 to 5 percent within five years. This approach may work well for an agency, depending upon the circumstances. It becomes complex, however, in the attempt to apply a simple rule fairly to varied industries and regulatory schemes. A 2 percent reduction in revenues in one industrial category would be significant if the industry's profits are only 3 percent of revenues. More than 60 percent of small businesses do not claim a profit and do not pay taxes; therefore, an agency would not be able to apply a profit-based criterion to these firms.
- The EPA has prepared extensive guidance for its rulewriters concerning "significant economic impact" and "substantial number." With respect to small businesses, the agency advises that the offices compare the annualized costs as a percentage of sales ("sales test") to examine significant economic effect. For the same purpose, it also discusses alternative uses of a cash flow test and a profits test.<sup>65</sup>

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<sup>65</sup> U.S. Environmental Protection Agency, Office of Policy, Regulatory Management Division, *EPA's Action Development Process: Final Guidance for EPA Rulewriters: Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act* (November 2006), section 2.6.2, available at <http://www.epa.gov/rfa/documents/Guidance-RegFlexAct.pdf>.



**Legislative history of “significant economic impact.”** The absence of a particularized definition of either “significant” or “substantial” does not mean that Congress left the terms completely ambiguous or open to unreasonable interpretations. Thus, the Office of Advocacy relies on legislative history for general guidance in defining these terms.<sup>66</sup> With regard to the term “significant economic impact,” Congress said:

The term ‘significant economic impact’ is, of necessity, not an exact standard. Because of the diversity of both the community of small entities and of rules themselves, any more precise definition is virtually impossible and may be counterproductive. Any more specific definition would require preliminary work to determine whether the regulatory analysis must be prepared.<sup>67</sup>

Congress also stated that,

Agencies should not give a narrow reading to what constitutes a “significant economic impact”...a determination of significant economic effect is not limited to easily quantifiable costs.<sup>68</sup>

Congress has identified several examples of “significant impact”: a rule that provides a strong disincentive to seek capital;<sup>69</sup> 175 staff hours per year for recordkeeping;<sup>70</sup> impacts greater than the \$500 fine (in 1980 dollars) imposed for noncompliance;<sup>71</sup> new capital requirements beyond the reach of the entity;<sup>72</sup> and any impact less cost-efficient than another reasonable regulatory alternative.<sup>73</sup> Note that even below these thresholds, impacts may be significant. Other, more specific examples are contained in the House of Representatives Report on the RFA.<sup>74</sup>

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<sup>66</sup> Admittedly, throughout this guide, references are made to “adverse” impacts and efforts to “mitigate” impacts. This, after all, is the primary concern of the law. Legislative history, however, makes it clear that Congress intended that regulatory flexibility analyses also address “beneficial” impacts. Therefore, an agency cannot certify a proposed rule if the economic impact will be significant but positive. If an agency so finds, it should conduct a regulatory flexibility analysis to determine if alternatives can enhance the economic benefits flowing to small entities. See discussion in this chapter on adverse versus beneficial impacts.

<sup>67</sup> 126 Cong. Rec. S10,942 (Aug. 6, 1980).

<sup>68</sup> *Id.* at S10,940.

<sup>69</sup> *Id.* at S10,938.

<sup>70</sup> *Id.*

<sup>71</sup> 126 Cong. Rec. H24,578 (Sept. 8, 1980).

<sup>72</sup> *Id.* at H24,593.

<sup>73</sup> *Id.* at H24,595.

<sup>74</sup> “A gas station owner spent 600 hours last year filling out just his federal reporting forms. An Idaho businessman paid a \$500 fine [in 1980 dollars] rather than fill out a federal form which was 63 feet long. A New Hampshire radio station paid \$26.23 in postage to mail its license renewal back to Washington. A dairy plant licensed by 250 local governments, 3 states, and 20 agencies had 47 inspections in one month. A butcher had one Federal agency tell him to put a grated floor in his shop one month and then the next month was told by another federal agency he could not have a grated floor. A company was forced out of the toy business because one of its main products was inadvertently placed on a federal ban list. An Oregon company with three small shops received Federal forms weighing 45 pounds.” 126 Cong. Rec. H8,467 (Sept. 8, 1980).

### ***Determination of “substantial number”***

The next step is to determine whether it is a substantial number of small entities for whom the rule has a significant economic impact. In this instance, the number may be a ratio or it may be a whole number. In some instances, a very small number of small businesses who would experience a significant economic impact can represent the entire universe of affected small businesses. However, if a very small number of small businesses represents a small fraction of the universe of affected small businesses, the agency can conclude that the number is not substantial.

For example, suppose a rule is expected to affect 20 small entities in a given category. The agency must determine, as best it can, how extensive the economic impact will be on those small entities. Suppose further that the agency can conclude that for five of these small entities, the impact will be significant. Is five a “substantial number” of the small entities affected? When a rule will have a significant economic impact on 25 percent of the small entities affected, this would be considered a substantial number.

**Legislative history of “substantial number.”** Legislative history also says that the term “substantial” is intended to mean a substantial number of entities within a particular economic or other activity.<sup>75</sup> The intent of the RFA, therefore, was not to require that agencies find that a large number of the entire universe of small entities would be affected by a rule. Quantification of “substantial” may be industry- or rule-specific. However, it is very important that agencies use the broadest category, “more than just a few,” when initially reviewing a regulation before making the decision to certify or do an initial regulatory flexibility analysis. The goal at this stage of the process is to ensure that the broadest possible impacts are fully considered.

“Substantial number” depends on the number of regulated entities and the size of the regulated industry. The interpretation of the term “substantial number” is not likely to be five small firms in an industry with more than 1,000 small firms. On the other hand, it is important to recognize that five small firms in an industry with only 20 small firms would be a substantial number. Depending on the rule, the substantiality of the number of small businesses affected should be determined on an industry-specific basis and/or on the number of small businesses overall. For example, the Internal Revenue Service, when changing the tax deposit rules, would examine the entire universe of small businesses to see how many would be affected. On the other hand, a change by the Food and Drug Administration in the regulation of meat irradiators might affect only 15 firms, but that would be the entire industry.

As EPA explains in its guidance, “analysts should examine both the total number and percentage of regulated small entities experiencing significant economic impacts when determining whether a ‘substantial number’ of small entities may be significantly affected.”<sup>76</sup> In its guidance, EPA provides a matrix of different combinations of “significant economic impact” in terms of annual costs/sales and “substantial number”

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<sup>75</sup> 126 Cong. Rec. S10,938 (Aug. 8, 1980) (Section-by-Section Analysis of the Regulatory Flexibility Act).

<sup>76</sup> 2006 EPA Final Guidance, section 2.7.2.

for its certification decision. The larger the economic impacts, the smaller the substantial number that would eliminate the basis for a certification of no impact.<sup>77</sup> For example, for a group of 100-999 affected small entities, EPA presumes no significant effect on a substantial number, where the costs/sales are 1 percent or greater for one or more of the affected small entities and the percent of small entities experiencing a given impact is less than 20 percent of all regulated small entities. However, if the costs/sales were 3 percent or greater, the presumption would no longer apply where the percentage was less than 20 percent of all regulated entities, for the same number of regulated entities.

In calculating the percentage of small entities significantly regulated within a regulated industry for the purpose of making the certification determination, the agency should be careful to count in the denominator only the firms that are regulated by the rule. For example, a regulation of firms with concentrated animal feeding operations (CAFOs) should count only the farms with CAFO operations, and not all farms, when calculating the percentage of CAFOs with a given economic impact. If all farms are included in the denominator rather than all CAFOs, heavy regulation of a segment of the CAFOs would be much less likely to exceed a 1 percent or 3 percent cost/sales ratio. Thus the impact would be underestimated. This is a common mistake by agencies using percentage tests. EPA further explains that analysts should aggregate the impacts of entities of the same type (such as small businesses or small governments) in making this determination. In addition, EPA explains where the rule applies to more than one type of small entity, the impacts should be analyzed separately for each type of entity, using an economic measure appropriate to each type of entity.<sup>78</sup>

### ***Direct versus indirect impact***

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

The primary case on the issue of direct versus indirect impacts for RFA purposes is *Mid-Tex Electric Cooperative, Inc., v. FERC (Mid-Tex)*.<sup>79</sup> In *Mid-Tex*, the Federal Energy Regulatory Commission (FERC) was proposing regulations affecting how generating utilities included construction work in progress in their rates. Generating utilities were large businesses, but their customers included numerous small entities, such as electric cooperatives. FERC authorized large electric utilities to pass these costs through to their transmitting and retail utility customers. This increased the cost to the transmitting utilities, which may or may not have been able (because of regulation by their rates commissions) to pass the costs on to their residential and business customers. These smaller utilities challenged the rule, asserting that the impact on them should have been considered. The court concluded that an agency may certify the rule pursuant to section 605(b) when it determines that the rule will not have a direct impact on small entities.<sup>80</sup>

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<sup>77</sup> 2006 EPA Final Guidance, section 2.7.1, table 2.

<sup>78</sup> 2006 EPA Final Guidance, section 2.7.3.2.

<sup>79</sup> *Mid-Tex Elec. Coop v. FERC*, 773 F.2d 327 (D.C. Cir. 1985).

<sup>80</sup> *Id.* at 342.

The U.S. Court of Appeals for the District of Columbia applied the holding of the *Mid-Tex* case in *American Trucking Associations, Inc., v. EPA*<sup>81</sup> (hereafter *ATA*). In the *ATA* case, EPA established a primary national ambient air quality standard (NAAQS) for ozone. The basis of the EPA's certification was that the NAAQS regulated small entities indirectly through state implementation plans. The plans impose requirements on the small entities, whereas states are required to take action to attain compliance with the NAAQS standards. The court found that since the states, not EPA, had the direct authority to impose the burden on small entities, EPA's regulation did not have a direct impact on small entities.

Although it is not required by the RFA, the Office of Advocacy believes that it is good public policy for the agency to perform a regulatory flexibility analysis even when the impacts of its regulation are indirect. An agency should examine the reasonably foreseeable effects on small entities that purchase products or services from, sell products or services to, or otherwise conduct business with entities directly regulated by the rule. In the case of the NAAQS standard at issue in *ATA*, EPA had to estimate the impacts of the proposed rules on small entities in order to comply with the mandate of E.O. 12866. Therefore, the agency could have examined alternatives that would have been less burdensome on small entities (and is required to under the E.O. 12866). If an agency can accomplish its statutory mission in a more cost-effective manner, the Office of Advocacy believes that it is good public policy to do so. The only way an agency can determine this is if it does not certify regulations that it knows will have a significant impact on small entities, even if the small entities are regulated by a delegation of authority from the federal agency to some other governing body.<sup>82</sup>

### ***Adverse versus beneficial impact***

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

Agencies may undertake initiatives which would directly benefit such small entities. Thus, the term 'significant economic impact' is neutral with respect to whether such impact is beneficial or adverse. The statute is designed not only to avoid harm to small entities but also to promote the growth and well-being of such entities.<sup>83</sup>

Moreover, early drafts of the RFA used the term "significant adverse" impact, but the final bill used only the term "significant impact."<sup>84</sup>

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<sup>81</sup>*American Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1044 (D.C. Cir. 1999), *aff'd in part and rev'd in part on other grounds*, *Whitman v. American Trucking Ass'ns*, 531 U.S. 457 (2001).

<sup>82</sup> See Chapter 5 of this guide for a more detailed discussion of the direct versus indirect impact issue.

<sup>83</sup> 126 Cong. Rec. H8,468 (daily ed. Sept. 8, 1980).

<sup>84</sup> See an early draft of the RFA, S2147, 1st Sess. (1979).

Courts have applied definitions for “significant impact” in cases involving other statutes. For example, in a case involving the National Environmental Policy Act (NEPA), *Friends of Fiery Gizzard v. Farmers Home Administration*,<sup>85</sup> the court held that a full environmental impact statement (EIS) does not need to be prepared if the only impact of the project will be beneficial. However, the court acknowledged that when both negative and beneficial effects are present, an EIS must be prepared even if the agency feels that the beneficial effects outweigh the negative ones.<sup>86</sup> (This case does not say that beneficial impacts should not be considered for the preliminary assessment, nor does it say that beneficial impacts are never a factor.) Earlier cases interpreting NEPA held that beneficial impacts should be a consideration in the rulemaking process.<sup>87</sup>

Several agencies have taken issue with the Office of Advocacy’s interpretation of significant economic impact. However, the Office of Advocacy believes that its interpretation is consistent with the legislative history and overall purposes of the RFA. The Office of Advocacy does not dispute that the RFA intends for agencies to “minimize the significant economic impact.”<sup>88</sup> However, the Office of Advocacy’s interpretation does not necessarily mean that agencies should minimize beneficial impacts—that certainly would be contrary to the purposes of the RFA. Instead, Advocacy believes that it is often possible to analyze beneficial impacts with minimal effort and without necessarily triggering the need for an IRFA. Moreover, analyzing beneficial impacts lends credibility to the alternatives selected by the agency.

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

## **What adequate and inadequate certifications look like**

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

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<sup>85</sup> *Friends of Fiery Gizzard v. Farmers Home Admin.*, 61 F.3d 501, 505 (6th Cir. 1995).

<sup>86</sup> *Id.* at 505.

<sup>87</sup> See *Hiram Clarke Civic Club v. Lynn*, 476 F.2d 421, 426-27 (5th Cir. 1973), (Considering only negative impacts “raises serious questions about the adequacy of the investigatory basis underlying the HUD decision not to file an EIS.”); *Environmental Defense Fund v. Marsh*, 651 F.2d 983, 993 (5th Cir. 1981), stating “[A] beneficial impact must nevertheless be discussed in an EIS, so long as it’s significant. NEPA is concerned with all significant environmental effects, not merely adverse ones.”

<sup>88</sup> 5 U.S.C. Chapter 6, Congressional Findings and Declaration of Purpose.

## ***An example of an adequate certification***

The following example of an adequate certification by the U.S. Small Business Administration is from the proposed rule on small business investment companies.

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to “prepare and make available for public comment an initial regulatory flexibility analysis” which will “describe the impact of the proposed rule on small entities.” (5 U.S.C. §. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

This proposed rule directly affects all SBICs, of which there are currently 432. SBA estimates that approximately 75 percent of these SBICs are small entities. Therefore, SBA has determined that this proposed rule will have an impact on a substantial number of small entities.

However, SBA has determined that the impact on entities affected by the proposed rule will not be significant. The effect of the proposed rule will be to allow SBICs the flexibility to choose the optimal structure for their investments without having to notify or seek approval from SBA. SBA expects the impact of the proposed rule will be a reduction in the paperwork burden for SBICs. SBA asserts that the economic impact of the reduction in paperwork, if any, will be minimal and entirely beneficial to small SBICs. Accordingly, the Administrator of the SBA hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. SBA invites comment from members of the public who believe there will be a significant impact either on SBICs, or on companies that receive funding from SBICs.<sup>89</sup>

## ***Examples of inadequate certifications***

Following are examples of inadequate certifications that were effectively challenged and refuted through formal comments to the agency or through the courts.<sup>90</sup>

**Shark Protection.** *Southern Offshore Fishing Association v. Daley*<sup>91</sup> offers a landmark legal decision recognizing the failure of an agency to adequately examine the market to determine whether there was a significant impact on a substantial number of small entities. On December 20, 1996, the National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA) published the proposed rule for the

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<sup>89</sup> 67 Fed. Reg. 35,055, at 35,056 (May 17, 2002). Note that although this certification addressed beneficial impacts, the agency acknowledged that even those impacts would be minimal and therefore correctly certified the rule.

<sup>90</sup> For another example of an improper certification, see Chapter 5 under the discussion of *North Carolina Fisheries v. Daley*.

<sup>91</sup> *Southern Offshore Fishing Ass’n v. Daley*, 995 F. Supp. 1411 (M.S. Fla. 1998).

Atlantic Shark Fisheries: Quotas, Bag Limits, Prohibitions, and Requirements.<sup>92</sup> The proposed rule, among other things, reduced the commercial quotas for sharks by 50 percent. NMFS prepared a certification in lieu of an IRFA for the proposal. As the basis for the certification NMFS stated, in part:

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

Advocacy submitted comments asserting that the certification was inappropriate. In its comments, Advocacy pointed out that under NMFS's own criteria for assessing regulatory impact, the proposal would have a significant economic impact on a substantial number of small entities.<sup>93</sup> NMFS's regulatory impact review stated that the majority of the participants in the fishing industry are small businesses and that there were 326 fisherman, 134 of which qualified for direct permits in the shark fishery. Approximately 41 percent of the shark fishery consisted of fishermen who only fished for sharks. The remaining fishermen were pelagic longline fishermen who also primarily fished for tuna and swordfish. Advocacy, therefore, concluded that the rule would have an impact on a substantial number of small entities.

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

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

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<sup>92</sup> 61 Fed. Reg. 67,295.

<sup>93</sup> At that time, NMFS criteria provided that a rule had a significant impact on a substantial number of small entities if 20 percent of those engaged in the fishery had either a reduction in gross revenues by more than 5 percent, an increase in total costs of production by more than 5 percent, or a 10 percent increase in compliance costs; or if 2 percent of small business entities were forced to cease business operations. NMFS no longer uses these criteria. Advocacy was pleased with NMFS's decision to abandon these criteria and institute new guidelines for determining economic impact on the fishing industry.

could amount to approximately 18 percent of the business's gross revenues, which would also be a significant economic impact.<sup>94</sup>

The members of the fishing industry successfully challenged NMFS's RFA compliance in *Southern Offshore Fishing Association v. Daley*.<sup>95</sup> The court found that the agency certified without making a "reasonable, good-faith effort," prior to issuance of the final rule, to inform the public about the potential adverse effects of its proposals and about less harmful alternatives.

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

Congress knew about the tendency of agencies to impose "one-size-fits-all" regulations and specifically rejected it. As Congress states, one-size-fits-all regulations are unnecessary and disproportionately burdensome to small businesses.... Because of the disparity of the impact of governmental regulations, the agency cannot certify a rule on the basis that all entities have the same regulatory obligations.<sup>96</sup>

**Offshore Oil and Gas Well Operations.** One of the responsibilities of the Minerals Management Service (MMS) of the Department of the Interior is to ensure safety in offshore oil and gas well operations. In February 1998, MMS proposed a rule to update and clarify MMS regulations on postlease operations. MMS prepared a certification in lieu of an IRFA for the proposal. As a basis for the certification, MMS stated:

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

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<sup>94</sup> U.S. Small Business Administration, Office of Advocacy comment letter to NMFS and NOAA dated February 6, 1997. See <http://archive.sba.gov/advo/laws/comments/noaa2-6.html>.

<sup>95</sup> Southern Offshore Fishing. This case is also discussed in Chapter 5 of this guide.

<sup>96</sup> See [http://archive.sba.gov/advo/laws/comments/rus02\\_0308.pdf](http://archive.sba.gov/advo/laws/comments/rus02_0308.pdf).



Advocacy submitted comments<sup>97</sup> asserting that the certification was based on generalizations and unsubstantiated assumptions. In its comments, Advocacy identified databases and a means for a threshold analysis to help determine whether the agency should have certified, finding that the MMS had not provided sufficient information to document a rational basis for its decision to certify the rule. Advocacy stated:

For the purposes of its analysis, the Office of Advocacy referred to SIC 1381, Drilling Oil and Gas Wells. While Advocacy acknowledges that SIC 1381 may include more than drilling on the outer Continental Shelf, Advocacy submits the numbers for the sake of argument in an effort to point out the inherent weaknesses in MMS's certification.

According to this SIC data, there are a total of 1,380 firms that drill oil and gas wells. Of that 1,380 firms, 1,341 or 97% qualify as small firms in that they have fewer than 500 employees; 654 firms have 1-4 employees. The 654 firms constitute 47 percent of all firms large and small. Needless to say, 47 percent of an industry represents a substantial number of firms and suggests that certification of this rulemaking may be improper.

In the 1-4 employee sector, the estimated receipts for a firm are \$46,774, with an annual payroll of \$32,187. The estimated cost of the proposed rule is \$7,350 (\$2,350 per application and \$5,000 for the rental) per year. The \$7,350 amounts to approximately 16 percent of the annual receipts for that sector. Although there are no hard rules for defining significant economic impact on a substantial number of small entities, a proposal that will impose on 47 percent of an industry an additional cost of 16 percent of annual receipts should at least raise a warning sign for a regulatory agency that the proposal could interfere with profits and company survival. It should also indicate to the agency that certification may be improper under the RFA.

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<sup>97</sup> It should be noted that in the comments, Advocacy also commended MMS for the improvement that it made in its certification process. Instead of an unsupported allegation of no significant economic impact on a substantial number of small entities, MMS did provide a basis for the certification. MMS has continued to work with Advocacy to improve its RFA compliance.

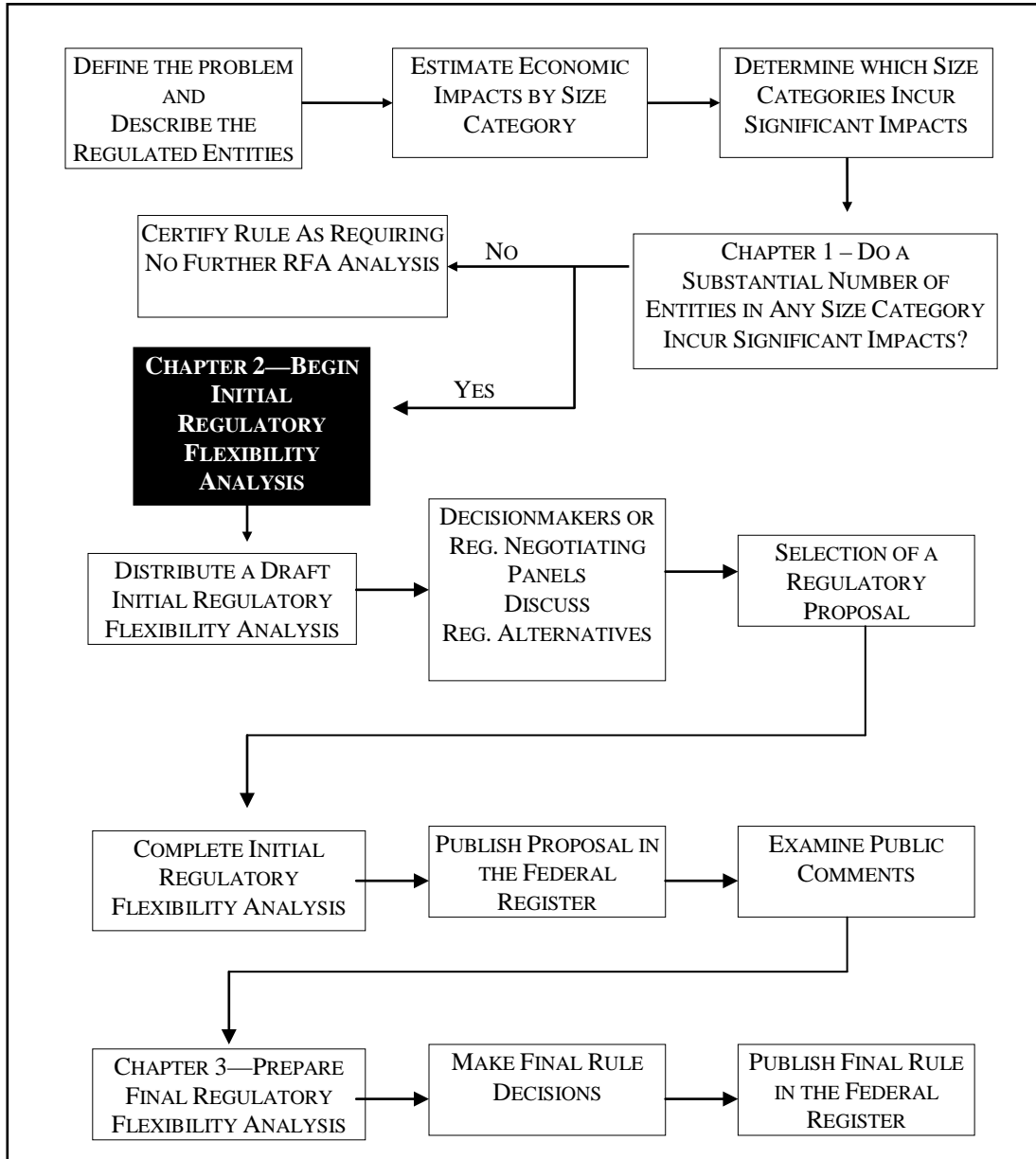
## Certification checklist

1. Request for comment on proposed rules	<p>Look for:</p> <ul style="list-style-type: none"> <li>√ A request for comment on the certification; and,</li> <li>√ A request for comment on the threshold economic analysis and its underlying assumptions.</li> </ul>
2. Description and estimate of number of small entities to which the rule applies	<p>Look for:</p> <ul style="list-style-type: none"> <li>√ The North American Industry Classification System (NAICS codes) categories for those entities subject to the regulation;</li> <li>√ A breakdown of each industry by several entity sizes, which should include the SBA size standard for each industry;</li> <li>√ Any alternative operational size definition used to tier requirements under the rule;</li> <li>√ For each size category in each industry, information on revenues, profit or other measures of economic sustainability.</li> </ul>
3. Estimate of economic impacts on small entities	<p>Look for:</p> <ul style="list-style-type: none"> <li>√ A set of tables, charts and discussion for a typical entity in each size category in each industry:</li> <li>√ Estimates of the cost impacts of the proposal;</li> <li>√ Estimates of the beneficial impacts of the proposal.</li> </ul>
4. Criteria for “significant economic impacts”	<p>The best analyses will not use a preset criterion, but instead will examine one or more of the following:</p> <ul style="list-style-type: none"> <li>√ <i>Long-term insolvency</i>, measured as regulatory costs significantly reducing typical profits for the size category;</li> <li>√ <i>Short-term insolvency</i>, measured as increased operating expenses or new debt larger than cash reserves and cash flow can support, causing nonmarginal firms to close;</li> <li>√ <i>Disproportionality</i>, based on whether regulations place small entities at a significant competitive disadvantage;</li> <li>√ <i>Inefficiency</i> based on whether the social costs imposed on small entities outweigh the social benefits of regulating them.</li> </ul> <p>Look for a cogent explanation underlying any conclusionary statements about preset “criteria.”</p>
5. Criteria for substantial number	<p>Look for:</p> <ul style="list-style-type: none"> <li>√ The North American Industry Classification System (NAICS codes) of those regulated;</li> <li>√ A stratification of each industry by size, which should include the SBA size standard for each industry;</li> <li>√ Any alternative operational size definition used to tier requirements under the rule;</li> </ul>

	<ul style="list-style-type: none"> <li>√ Description of size categories demonstrating all entities within the category share similar economic characteristics;</li> <li>√ Whether a ‘percentage of entities significantly affected’ approach is used;</li> <li>√ Whether a ‘minimum number’ approach is used. (This is usually arbitrary and probably capricious);</li> <li>√ Justification of whatever criterion is used.</li> </ul> <p>Typically, if an industry is properly segmented, analysis of a typical entity within the segment will indicate whether most or few will be significantly affected, as all within the segment should have similar economic characteristics.</p>
6. Examination of industry segments with significant economic impacts	<p>Look for:</p> <ul style="list-style-type: none"> <li>√ An estimate of how many segments within an industry will experience significant impacts: if even one significant segment will, an IRFA is needed;</li> <li>√ An estimate of entities experiencing significant impacts. Other entities with similar economic characteristics should also be experiencing adverse impacts, and finding any with such adversely impacts tends to imply there is a segment that deserves special attention. The resulting IRFA should materially address the problems in that segment, recognizing the rest have few, if any impacts.</li> </ul>
7 Disclosure of assumptions	<p>Look for:</p> <ul style="list-style-type: none"> <li>√ A discussion on how sensitive underlying assumptions are to conclusions on whether there is no significant economic impact on a substantial number of small entities;</li> <li>√ A discussion on the uncertainty associated with the most significant underlying assumptions;</li> <li>√ A presentation on the range of potential findings, as reflects the underlying uncertainty in assumptions.</li> </ul>
8. Certification statement by the head of the agency	<p>Look for:</p> <ul style="list-style-type: none"> <li>√ A finding under 5 U.S.C. § 605, the Regulatory Flexibility Act, that “the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.”</li> </ul>

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

### The RFA decision process



During the preparation of a proposed rule, an agency must prepare an initial regulatory flexibility analysis (IRFA) if it determines that a proposal may impose a significant economic impact on a substantial number of small entities.<sup>98</sup> (If the agency determines that the proposed rule does not have such an impact, it should certify the rule as discussed in Chapter 1 of this guide.)

The RFA requires agencies to publish the IRFA, or a summary thereof, in the *Federal Register* at the same time it publishes the proposed rulemaking.<sup>99</sup> The IRFA must include a discussion of each element required by section 603 of the RFA, and the agency must also send a copy of the IRFA to the Chief Counsel for Advocacy.<sup>100</sup> Agencies are required to notify Advocacy when they submit a draft proposed or final rule to the Office of Information and Regulatory Affairs (OIRA) under Executive Order 12866, or at a reasonable time prior to publication of the rule by the agency.<sup>101</sup> Moreover, the earlier a copy of the IRFA is provided to Advocacy, the more opportunity exists for constructive involvement and feedback to the agency. If an agency is preparing a series of closely related rules, it may, to avoid duplicative action, consider them one rule for the purposes of complying with the IRFA requirement.<sup>102</sup>

## Issues to be addressed in the analysis

Section 603 of the RFA requires agencies to perform a detailed analysis of the potential impact of the proposed rule on small entities.<sup>103</sup> In order to perform this analysis, an agency must enumerate the objectives and goals of the rule, as well any additional reasons the agency is pursuing the rule.

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

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<sup>98</sup> For a full discussion of "significant economic impact on a substantial number of small entities," and the requirements of a proper certification statement, see Chapter 1 of this guide.

<sup>99</sup> 5 U.S.C. § 603(a).

<sup>100</sup> *Id.*

<sup>101</sup> Exec. Order No. 13,272, § 3(b).

<sup>102</sup> 5 U.S.C. § 605(c).

<sup>103</sup> *Id.* at § 603(b)-(c).

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

- Should the agency redefine “small entity” for purposes of the IRFA?
- Which small entities are affected the most? Are all small entities in an industry affected equally or do some experience disparate impacts such that aggregation of the industry would dilute the magnitude of the economic effect on specific subgroups?<sup>104</sup>
- Are all the required elements of an IRFA present, including a clear explanation of the need for and objectives of the rule?<sup>105</sup>
- Has the agency identified and analyzed all major cost factors?
- Has the agency identified all significant alternatives that would allow the agency to accomplish its regulatory objectives while minimizing the adverse impact or maximizing the benefits to small entities?
- Can the agency use other statutorily required analyses to supplement or satisfy the IRFA requirements of the RFA?
- Are there circumstances under which preparation of an IRFA may be waived or delayed?
- What portion of the problem is attributable to small businesses (i.e., is regulation of small businesses needed to satisfy the statutory objectives)?
- Does the proposed solution meet the statutory objectives in a more cost-effective or cost-beneficial manner than any of the alternatives considered?

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

The agency must balance the thoroughness of an analysis and practical limits of an agency's capacity to carry out the analysis with the significance of the rule and the expected economic impacts. Agencies should consult available information on how to conduct an economic analysis, such as the guidelines in OMB's *Economic Analysis of Federal Regulations under Executive Order 12866* and should review small business data, including data referenced in Appendices C and D.

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

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<sup>104</sup> See discussion of this issue in Chapter 1.

<sup>105</sup> An agency may want to avoid repeating relevant text by cross-referencing the needs and objectives of the rule in its IRFA.

## Elements of an IRFA

The preparation of an IRFA should be coordinated with the development of the data and analysis the agency will use in preparing the proposed rule under the requirements of the Administrative Procedure Act. In doing so, the agency should be mindful of the requirements of the RFA and collect data based on size. The development of a rational rule will require the acquisition of data that describe the scope of the problem, the entities affected, and the extent of those effects on the entities and the problem being addressed. Without such information, the agency will be unable to develop a rational rule.<sup>106</sup>

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

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

Section 603(c) is the key provision of the IRFA. It requires an agency to include a description of any significant alternatives to the proposed rule that minimize significant economic impacts on small entities while accomplishing the agency's objectives. The approach an agency takes while developing an IRFA depends on such factors as the quality and quantity of available information and the anticipated severity of a rule's impacts on small entities subject to the rule and the benefits yielded by each significant alternative. Section 607 of the RFA requires agencies to develop a quantitative analysis of the effects of a rule and its alternatives using available data. If quantification is not practicable or reliable, agencies may provide general descriptive statements regarding the rule's effects.<sup>107</sup> This second option is a last resort when it is not practicable for the agency to complete a significant quantitative analysis.

The new Section 603(d) of the RFA requires the CFPB to include a description of any projected increase in the cost of credit for small entities, as well as a description of significant alternatives which, while accomplishing the stated objectives, minimize any such increase, and the advice and recommendations of small entities with respect to these

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<sup>106</sup> *Bowen v. AHA*, 476 U.S. 610, 643 (1986); *National Ass'n of Home Health Agencies v. Schweiker*, 690 F.2d 932, 949 (D.C. Cir. 1982); *Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1098, 1103 (4<sup>th</sup> Cir. 1985).

<sup>107</sup> 5 U.S.C. § 607.

cost-of-credit issues.<sup>108</sup> The CFPB is required to identify small entity representatives in consultation with the Office of Advocacy and collect advice and recommendations about these cost-of-credit issues in addition to the issues raised by the proposed regulation.

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

### ***Reasons action is being considered***

For the first element of the IRFA, the agency must discuss the reasons it is considering the proposed rule.<sup>109</sup> The agency should list any issue to be addressed in the rulemaking and should be thorough in listing its reasons, as this section provides insight into the need for the rule.

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

### ***Objectives of the proposed rule***

For the second element of the IRFA, the agency must list the objectives of the proposed rule.<sup>110</sup> Again, the agency should be thorough when discussing its objectives, as this discussion conveys to the public the goals of the rulemaking and why the agency is taking specific actions contained within the proposed rule. This section provides the justification for the agency's actions, balancing the burden of the compliance requirements against the need for the rule. Such a discussion should include how the rule is achieving the statutory objectives. Compliance with this requirement should not be difficult since agencies are required to explain their proposed actions and the reasons underlying those proposed actions in order to elicit comment from the public as required by section 553 of the APA.<sup>111</sup>

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

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<sup>108</sup> 5 U.S.C. § 603(d), added to the RFA by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Pub. Law 111-203 § 1100G(d)(1). This law also added the CFPB to the list of covered agencies—previously EPA and OSHA—that are required to hold small business review panels.

<sup>109</sup> *Id.* at § 603(b)(1).

<sup>110</sup> *Id.* at § 603(b)(2).

<sup>111</sup> See *Spartan Radiocasting v. FCC*, 619 F.2d 314, 321 (4<sup>th</sup> Cir. 1980).



### ***Description and estimate of the number of small entities***

The third element of the IRFA requires the agency to identify the classes of small entities affected by the proposed rule and provide an estimate of the number of small entities in each of those classes.<sup>112</sup> In particular, the agency should pay special attention to small entities expected to face disproportionate impacts relative to other entities in the industry, whether those entities are large or small. Classification requires the development of a profile for the affected industry or industries and categorization by various size classes within each affected industry. It is crucial that the agency list all industry classes affected by the rule. Specifically, if the agency imposes a compliance requirement on a class of small entities, it must identify that class of small entities in this section of the IRFA. As a default, section 601 of the RFA requires agencies to use size standards set by the SBA in determining whether businesses are small businesses. SBA's Office of Size Standards set these standards using NAICS.<sup>113</sup> Agencies must identify each of the affected classes according to their NAICS code. Once the agency has identified all the affected industries by code, it can use the NAICS code in combination with the U.S. Census data<sup>114</sup> to gain an estimate of the number of entities in each class. To help agencies with this element of the IRFA, the Office of Advocacy provides a listing of NAICS codes along with links to the U.S. Census data for each class on its web page.<sup>115</sup>

If the agency determines that the existing SBA size standards for small businesses are not appropriate for RFA analysis purposes, the RFA permits the agency, after notice and comment, to establish one or more alternative definitions of a small entity that are appropriate for the rule.<sup>116</sup> The RFA requires an agency to consult with the Office of Advocacy when performing an RFA analysis using a different small business size standard than that provided by the SBA.<sup>117</sup>

### ***Estimating compliance requirements***

For the fourth element of the IRFA, the agency must describe and estimate the compliance requirements of the proposed rule.<sup>118</sup> This is one of the two most important elements in the IRFA, because the alternatives the agency examines in the IRFA will be designed to minimize these compliance burdens. Provision of a list in the IRFA enables small entities to more easily identify potential burdens and tailor their comments in the rulemaking process to those burdens that most affect them without wading through many *Federal Register* pages.

As stated by the RFA, some of the costs the agency must describe in the IRFA include the costs of any recordkeeping; professional expertise, such as lawyer, accountant, or engineering, needed to comply with recordkeeping; and reporting requirements. Section

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<sup>112</sup> 5 U.S.C. § 603(b)(3).

<sup>113</sup> See <http://www.sba.gov/size/>.

<sup>114</sup> See <http://www.census.gov/>.

<sup>115</sup> Office of Advocacy, Research and Statistics, <http://www.sba.gov/advocacy>.

<sup>116</sup> See the size standard discussion in Chapter 1.

<sup>117</sup> 5 U.S.C. § 601(3).

<sup>118</sup> *Id.* at § 603(b)(4).

603 also requires that the agencies examine other compliance requirements, which may include, for example, the following: (a) capital costs for equipment needed to meet the regulatory requirements; (b) costs of modifying existing processes and procedures to comply with the proposed rule; (c) lost sales and profits resulting from the proposed rule; (d) changes in market competition as a result of the proposed rule and its impact on small entities or specific submarkets of small entities; (e) extra costs associated with the payment of taxes or fees associated with the proposed rule; and (f) hiring employees dedicated to compliance with regulatory requirements.

Since all rules are different and impose different compliance requirements, the RFA contemplates that agencies will prepare analyses to determine all significant long- and short-term compliance costs. Agencies should list the compliance requirements separately to provide greater transparency.

The IRFA should also, to the extent practicable, compare the costs of compliance for small and large entities to determine whether the proposed rule affects small entities disproportionately, to analyze the ability of small entities to pass on these costs in the form of price increases or user fees, and to assess the effects on firms' profitability or their ability to provide services. This should be done in conjunction with an estimation of the costs of compliance relative to changes in market structure and the competitive status of various subclasses of small entities as well as the competitive positions of small entities in comparison with larger entities.<sup>119</sup>

### ***Significant alternatives considered***

The keystone of the IRFA is the description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize the rule's economic impact on small entities.<sup>120</sup> The development and adoption of these alternatives provide regulatory relief to small entities.

Analyzing alternatives establishes a process for the agency to evaluate proposals that achieve the regulatory goals efficiently and effectively without unduly burdening small entities, erecting barriers to competition, or stifling innovation. This process provides an

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<sup>119</sup> Competitive status is not relevant when the small entities regulated by the proposed rule are not-for-profit organizations or governmental jurisdictions. In regulations that are limited to nonprofits or governmental jurisdictions, changes in regulatory costs should not affect the competitive status of the entities. However, there are certain nonprofit and governmental jurisdictions that do compete with for-profit enterprises, such as electric cooperatives. In preparing an IRFA, the agency must be mindful of the type of small entity regulated and tailor its analytical requirements to those entities.

<sup>120</sup> 5 U.S.C. § 603(c). Since the RFA is an economically neutral statute, the IRFA should examine alternatives to ensure that the proposed rule is maximizing any beneficial impact on small entities. In the case of a rule that has a significant beneficial effect, the failure to consider alternatives that enhance the beneficial effect means that the agency has not examined alternatives that "minimize" the economic impact of the proposed rule. For example, if a rule increases revenue to a small entity by \$100 and an alternative exists that meets the statutory objective of the agency and increases revenue by \$200, then the agency has not complied with the RFA if it did not examine the second alternative. The failure to provide the small entity with a potential extra \$100 in revenue in essence does not minimize the economic impact on small entities.

additional filter by which the agency conducts rational rulemaking mandated by the APA. Rather than focus on the overall costs and benefits of a particular regulation (as might be required by statute, such as the best achievable control technology, or by the regulatory analysis requirements of E.O. 12866), the RFA requires the agency to undertake an analysis in order to discover less costly methods of attaining the statutory objectives of the rulemaking agency. Instead of analyzing the impacts of its regulatory actions on all relevant sectors of the economy, the IRFA narrows the scope of the particular review to small entities. The premise underpinning the IRFA is that, everything else being equal, the most rational alternative is often the one that achieves the objective of the agency at the lowest cost. Since small entities typically constitute the vast majority of entities in a particular industry under the SBA size standards, it often makes the most economic sense to adopt the regulatory strategy that imposes the least cost on small entities because that generally would represent the most cost-effective strategy meeting the agency's statutory objectives.

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

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

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

Agencies are not limited to alternatives that minimize burdens only for small entities. As EPA's 1992 RFA guidance recognized, cost-effective alternatives for small entities often are cost-effective for all entities.<sup>121</sup> Agencies should identify regulatory alternatives at the earliest stage of rulemaking and not wait until after the proposed rule is finished to develop alternatives. This is crucial because otherwise the agency may have already bought into one particular regulatory solution without considering alternatives. Such predeterminations by the agency violate the basic tenet of rational rulemaking under the APA by making the notice and comment process irrelevant. Interpretations of the notice and comment provisions of the APA contemplate a dialogue between the agency and the regulated community.<sup>122</sup> An agency already predisposed to only one way of thinking undermines the notice and comment procedure, thereby leaving itself open to a finding by a court that the agency action was arbitrary, capricious, or otherwise not in accordance with the law under section 706 of the APA.<sup>123</sup> Thus, the development of alternatives in the RFA demonstrates to the court that an agency did not in the proposed rule have a predisposition to rule in a manner that eviscerates the notice and comment process. If an agency is unable to analyze small business alternatives separately, then alternatives that reduce the impact for businesses of all sizes must be considered.

In the memorandum on regulatory flexibility that accompanied President Obama's E.O. 13563, the president expanded the existing requirement for an agency to document the decision to reject an alternative that may reduce regulatory burdens on small entities. The RFA had required agencies to explain in the final regulatory flexibility analysis accompanying final rules why significant alternatives were not selected.<sup>124</sup> President Obama directed that a similar explanation be provided for proposed rules.<sup>125</sup>

Consistent with an agency's obligations under section 609 of the RFA, agencies should perform outreach to interested groups to help develop regulatory solutions. In doing so, agency personnel should recognize that different sectors of an industry may have very different perspectives on a particular regulatory approach. The agency, before adopting one approach, should ensure that it contacts small entities and their representatives as well as large entities and their representatives. This type of communication is not prohibited by the APA and will help the agency focus on potential benefits and costs of various approaches to small businesses. In practice, the best proposed rules have been developed through a robust pre-proposal exchange of specific rulemaking concepts with the stakeholders including small businesses.<sup>126</sup>

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<sup>121</sup> See *Revised Interim Guidance for EPA Rulewriters*, p. 18.

<sup>122</sup> See *Chocolate Mfrs. Ass'n v. Block*, 755 f.2d 1098, 1103 (4<sup>th</sup> Cir. 1985).

<sup>123</sup> See *McLouth Steel Prods. v. EPA*, 838 F.2d 1317, 1324 (D.C. Cir. 1988); *Levesque v. Block*, 723 F.2d 175, 187 (1<sup>st</sup> Cir. 1983); *United States Steel Corp. v. EPA*, 595 F.2d 207, 214 (5<sup>th</sup> Cir. 1979).

<sup>124</sup> 5 U.S.C. § 604(a)(6).

<sup>125</sup> Memorandum for the Heads of Executive Departments and Agencies, "Regulatory Flexibility, Small Business, and Job Creation" (76 Fed. Reg. 3827, January 21, 2011).

<sup>126</sup> Executive Order 13,563 restates the value of pre-proposal input from affected firms. Section 2(c) states: "Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking."

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

### ***Duplicative, overlapping, and conflicting rules***

The sixth element of the IRFA is to identify any duplicative, overlapping, and conflicting federal rules.<sup>127</sup> Rules are duplicative or overlapping if they are based on the same or similar reasons for the regulation, the same or similar regulatory goals, and if they regulate the same classes of industry. Rules are conflicting when they impose two conflicting regulatory requirements on the same classes of industry.<sup>128</sup>

This section of the IRFA requires the agency to examine the potential conflicting and duplicative rules that can unnecessarily add cumulative regulatory burdens on small entities without any gain in regulatory benefits. By identifying overlapping, duplicative, or inconsistent regulations, the agency might be able to avoid adding an additional regulatory burden (even one as simple as an additional report that is already filed elsewhere).<sup>129</sup>

Because of the breadth and volume of federal regulations, a review of all existing rules on a particular industry group can be an onerous task for a federal agency. Nevertheless, it is important that the agency try to identify potential conflicting, duplicative, and overlapping regulations. The IRFA should include a request for comments identifying such rules. At the very least, the agency should review its own rules and identify any rules that cover the same subject matter and affect the same classes of industry. In fact, the law already requires such a review under section 610 of the RFA.<sup>130</sup>

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<sup>127</sup> 5 U.S.C. § 603(b)(5).

<sup>128</sup> For example, under the repealed ergonomics rule, OSHA would have forced skilled nursing facilities to acquire mechanical lifts to move patients. On the other hand, regulations promulgated by the Centers for Medicare and Medicaid Services (CMS) mandated that patients have a right not to be moved using mechanical lifts. Thus, the OSHA and CMS regulations would have been at cross purposes with respect to providing ergonomic protection for employees.

<sup>129</sup> In 1999, EPA relieved hundreds of thousands of facilities—facilities that were already filing federal underground storage tank forms for gasoline and diesel fuel with local authorities—from filing very similar reports for the same fuels under the federal community right-to-know law.

<sup>130</sup> See Chapter 6 for more information on compliance with Section 610 of the RFA.

## Using other analyses to satisfy the IRFA requirements

The RFA permits agencies to prepare IRFAs in conjunction with, or as a part of, other analyses required by law as long as the RFA's requirements are satisfied.<sup>131</sup> Agencies need to exercise caution when relying on other analyses to satisfy the RFA, as they may not necessarily be a complete substitute for a regulatory flexibility analysis. In fact, these other analyses will prove far more useful as sources for data to be used in the IRFA than as substitutes for an IRFA. For major rules that require the preparation of a regulatory impact analysis (RIA) under Executive Orders 12866 and 13563, agencies may prepare the RIA and the regulatory flexibility analyses together. Nevertheless, the agency must keep in mind that the RIA is a much broader analysis of benefits and costs and does not necessarily focus on the cost effectiveness of regulatory compliance for small entities. Thus, the focus of the RIA under the executive orders is not a substitute for the IRFA. Agencies can coordinate their preparation of regulatory flexibility analyses with any other analyses accompanying a rule.<sup>132</sup> In doing so, however, agencies should ensure that such analyses describe explicitly how the requirements of the Regulatory Flexibility Act are satisfied. Similarly, agencies can develop evaluations of administrative burdens associated with reporting and recordkeeping requirements in concert with the paperwork burden analysis prepared under the Paperwork Reduction Act. However, Paperwork Reduction Act analysis is not a substitute for RFA compliance analysis.

## When an IRFA may be waived or delayed

Section 608 of the RFA provides that an agency may waive or delay the completion of some or all the requirements of section 603 regarding preparation of IRFAs if the agency is promulgating the rule in response to an emergency that makes compliance with the RFA impracticable.<sup>133</sup> Promulgating agencies must publish the waiver or delay in the *Federal Register* no later than the date of publication of the final rule. If a true emergency exists, the agency must explain clearly why the circumstances constitute an emergency.

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

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<sup>131</sup> 5 U.S.C. § 605(a).

<sup>132</sup> Many requirements of Exec. Order No. 12,866 parallel those in the RFA. See a discussion in the Introduction. Executive Order 12,866 directs agencies to “assess both the costs and the benefits of the intended regulation....[and] propose or adopt a regulation only upon a reasoned determination that the benefits...justify the costs.” Further, E.O. 12,866 requires agencies to develop and analyze regulatory alternatives, including, where appropriate, small business alternatives that achieve statutory objectives. Thus, it is often most effective to coordinate or combine analytic products used to satisfy both the E.O. and the RFA.

<sup>133</sup> 5 U.S.C. § 608(a).

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

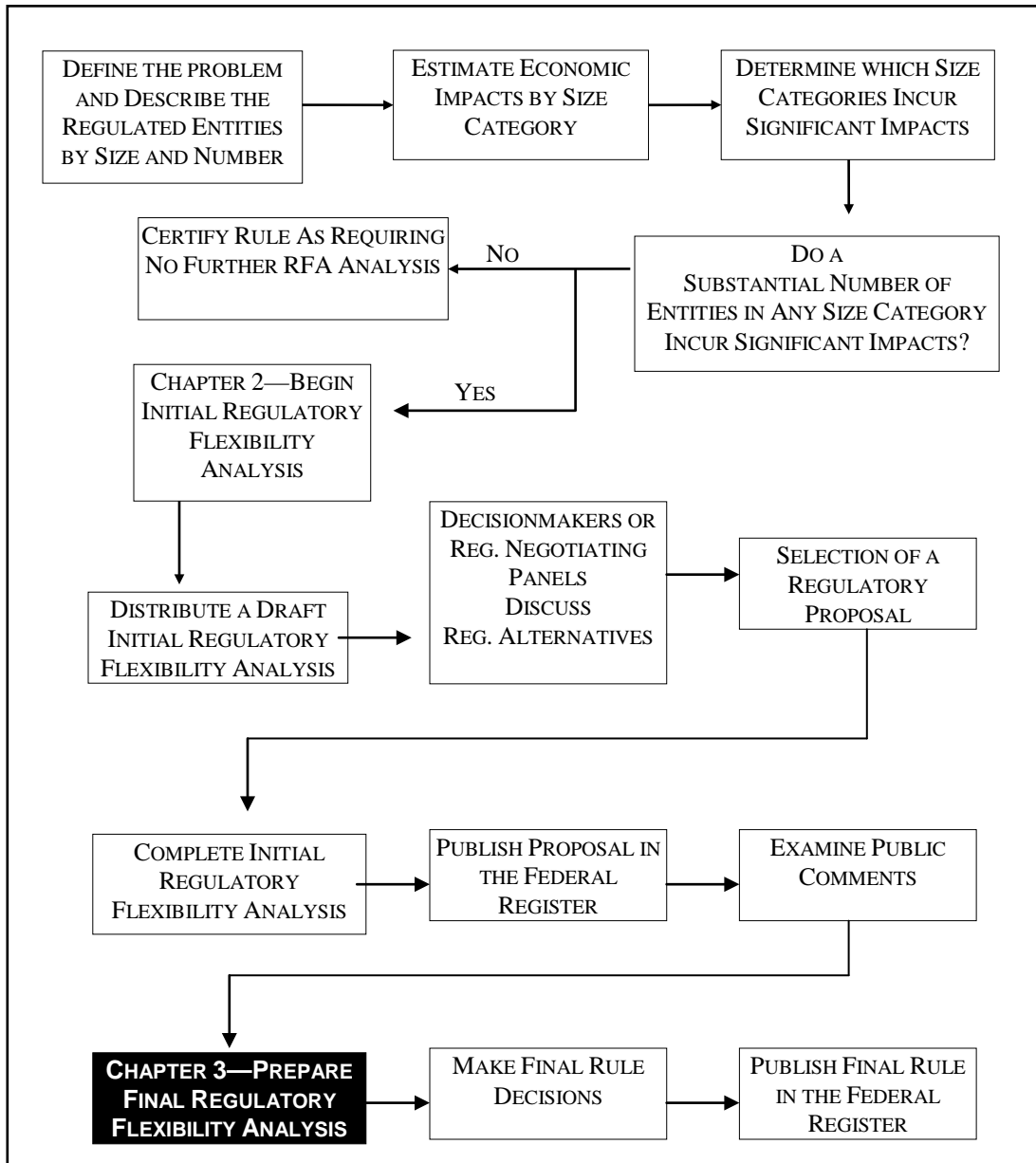
In Appendix J, a satisfactory IRFA by the Environmental Protection Agency contains the elements required by the RFA and a thorough analysis of the regulation's potential impact on small entities when insufficient data are available on cost or impact.<sup>134</sup>

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<sup>134</sup> For an example of a satisfactory IRFA when cost/impact data are available, see the CMS proposed rule on Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar 2003, 67 Fed. Reg. 43,846 (June 28, 2002), 43,865 ff. For another example, see U.S. Department of Transportation (DOT) proposed rule on Regulatory Assessment for Changes in Vessel and Facility Response Plans: 2003 Response Requirements, 67 Fed. Reg. 63,331, where DOT properly analyzed alternatives to the rule.

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

## The RFA decision process





When promulgating a final rule, agencies must prepare a final regulatory flexibility analysis (FRFA) unless the agency finds that the final rule will not have a significant economic impact on a substantial number of small entities or the final rule is issued under the APA provision allowing for good cause to forego notice and comment rulemaking.<sup>135</sup> When the agency publishes its final rule, it must also publish the FRFA, or a summary of the FRFA, in the *Federal Register*.<sup>136</sup> Draft final rules that are not certified must be submitted to Advocacy before publication in the *Federal Register*.<sup>137</sup> The FRFA must include the agency's response to any comments filed by the Chief Counsel for Advocacy, including a detailed statement of any changes made to the proposed rule in the final rule as a result of such comments.<sup>138</sup> The agency must also make copies of the FRFA available to the public. These published FRFAs are then subject to judicial review.<sup>139</sup>

The RFA mandates that agencies revise their initial regulatory flexibility analysis based on the public comments received. Agencies routinely create a summary of the public's comments to be published along with the final rules. In developing this summary, the agency should specifically summarize comments from small entities even if the comments of the small entities do not relate to the RFA. This will help the agency prepare a more accurate FRFA or demonstrate support for a certification. Once the agency determines that it cannot certify the final rule under section 605(b), the agency must prepare a FRFA. If the agency determines that the rulemaking will not result in a significant economic impact on a substantial number of small entities, the head of the agency may so certify under section 605(b) of the RFA, and provide a copy of the certification to the Chief Counsel for Advocacy.<sup>140</sup>

## Issues to be addressed in the analysis

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

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<sup>135</sup> 5 U.S.C. § 604 and 605(b). The APA provision is found in 5 U.S.C. § 553 (b)(B).

<sup>136</sup> *Id.* at § 604(b). Since the actual FRFA usually more accurately informs the public of the agency's efforts to analyze costs and alternatives, it is good practice to include the actual FRFA in the final rule preamble as published in the *Federal Register*.

<sup>137</sup> Exec. Order No. 13,272, 67 Fed. Reg. 53,462 (Aug. 16, 2002).

<sup>138</sup> 5 U.S.C. § 604(3).

<sup>139</sup> 5 U.S.C. § 611.

<sup>140</sup> As indicated earlier in the discussion concerning certifications, RFA § 605(b) requires that the certification appear in either the proposed or final rule. Although it is fairly clear that the certification must appear in the final rule if there is no certification in the proposed rule, it is not clear whether the certification must be duplicated in the final rule if it already appears in the proposed rule. The Office of Advocacy believes that, given the emphasis in the law on public notice, the certification should also appear in the final rule even though there may have already been a certification in the proposed rule. Doing so will help demonstrate the continued validity of the certification after receipt of public comments. In addition, significant changes between the proposed and final rule could warrant a change in the agency's certification evaluation for the final rule. For a more detailed discussion of certifications, see Chapter 1 of this guide.

The requirements for a FRFA are somewhat different from those for an IRFA. The requirements for the FRFA are very similar to the requirements that the courts impose on the development of a statement of basis and purpose for a final rule under section 553 of the APA.<sup>141</sup> The only additional requirements are those that relate to ensuring the items in the FRFA are easily identifiable to small entities without having to search the entire *Federal Register* notice. The agency should coordinate the preparation of the FRFA with development of the basis and purpose statement in the preamble. The preparation of a basis and purpose statement is not a substitute for a FRFA or for robust consideration of significant alternatives that are more cost-effective to small entities but still achieve the objectives of the agency. The requirements, outlined in seven provisions in section 604(a)(1)–(6), are highlighted in italics below:

- 1) *A statement of the need for, and objectives of, the rule.* The agency can cross-reference to a similar statement in the supplementary information if the cross reference enables small entities to easily identify the need for and objectives of the rule.
- 2) *A statement of the significant issues raised by the public comments in response to the IRFA, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.* Under the APA, agencies are required to respond to comments addressing relevant statutory considerations.<sup>142</sup> Since the RFA constitutes a relevant statutory consideration, the agency is obligated under the APA to respond to comments on the RFA and relate how it changed the proposal, if at all, in response to the comments.
- 3) *The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.*<sup>143</sup>
- 4) *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.*
- 5) *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.*

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<sup>141</sup> *E.g.*, *Troy Corp. v. Browner*, 120 F.3d 277, 289 (D.C. Cir. 1997); *Lloyd Noland Hosp. v. Heckler*, 762 F.2d 1561, 1566-67 (11<sup>th</sup> Cir. 1985); *United States v. Nova Scotia Foods*, 568 F.2d 240, 252 (2d Cir. 1977); *Portland Cement Ass’n v. Ruckelshaus*, 486 F.2d 375, 393 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974); *Automotive Parts & Accessories Ass’n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968).

<sup>142</sup> *Id.*

<sup>143</sup> The Small Business Jobs Act of 2010, Pub. Law 111-240 added this provision.

6) *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 of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected. Again this requirement already is mandated by the rational rulemaking requirements of the APA.*<sup>144</sup>

6) *For a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities.*<sup>145</sup>

As noted in the third provision above, section 1601 of the Small Business Jobs Act<sup>146</sup> further amended the final regulatory flexibility analysis (FRFA) section of the RFA by requiring agencies to respond to any comments filed by the Chief Counsel for Advocacy in response to a proposed rule and a detailed statement of any changes made in response to the comments.

## **Additional questions to be addressed in a FRFA**

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

### ***Have all significant issues been assessed?***

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

### ***Has the number of small entities been estimated?***

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

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<sup>144</sup> See *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 539-41 (1981).

<sup>145</sup> The numbering is as shown—two paragraphs (6) were enacted. The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Pub. Law 111-203, added this provision.

<sup>146</sup> Public Law 111-240.

entities, as in the case of a regulation affecting an emerging industry about which little is known.

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

### ***Has the adverse economic impact on small entities been minimized?***

Agencies must consider, and may adopt, one or more significant alternatives to minimize the rule's burden on small entities.<sup>147</sup> Some of the traditional alternatives may include lengthening the time for compliance; tiering the compliance requirements based on the size of the business or degree to which small entities contribute to the problem; providing for exemptions for parts of the rule or the entire rule for small entities; timing compliance to correspond with other statutory deadlines with related requirements; allowing for increased flexibility in the methods used for achieving the agency's objectives (for example, using a performance standard instead of requiring a specific technology); making requirements less prescriptive; etc. Such alternatives also include providing regulatory relief to all regulated entities, such as lowering the overall stringency of a standard or changing the regulatory threshold. In the first instance, it remains the obligation of the agency to develop significant alternatives pursuant to the RFA. Otherwise the agency is transferring its statutory RFA mandate to those entities that can least afford or have the least expertise in rulemaking processes to craft alternatives—small entities. Even after the agency has crafted alternatives, it should, as a matter of course, in the proposed rule and IRFA, specifically request whether any other alternatives exist that the agency has not considered. Small entities may be able to provide additional alternatives based on the analysis already performed by the agency, i.e., the analysis may spark ideas that small entities may not have thought of absent such analysis. Adoption of this procedure will ensure that agencies have met their obligation to consider alternatives to the final regulatory solution as mandated by the RFA.

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<sup>147</sup> The outcome of a rulemaking would be superior if the agency adopted a standard that achieves its objectives but reduces burdens or increases benefits to small entities. Development of regulations that have small entity orientation will be beneficial in the long run to the agency. Since most regulated entities are small, rules that have a small entity orientation will likely garner greater support from that community, increased compliance, reduced penalties, and quicker achievement of the agency's statutory objective. A regulation that does not have such small entity orientation will face resistance from the regulated community, force the agency to increase enforcement, and delay accomplishment of whatever goal the agency was attempting to reach. For example, if the OSHA ergonomics rule had gone into effect in 2001, it is unlikely that many small entities could have complied. The Department of Labor would have expended scarce resources to obtain compliance without accomplishing the goal of increasing worker safety.

## ***Have all significant alternatives been reviewed?***

Has the statement of factual, policy, and legal reasons for selecting the alternative adopted in the final rule, and the reasons for rejecting other significant alternatives, been included or appropriately cross-referenced for easy identification by small entities? The Small Business Regulatory Enforcement Fairness Act (SBREFA)<sup>148</sup> made significant changes to this section of the RFA with respect to compliance requirements. Prior to 1996, an agency needed only state the alternatives and the reason (or reasons) for rejecting a particular alternative. As a result of the amendments, an agency must now include a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule. This explanation already is required under the APA, and the FRFA will help the agency demonstrate compliance with the APA's rulemaking procedures through the clarification of the reasons for selecting or rejecting particular alternatives. In addition to educating the courts, the rationales might spur action by Congress to correct a flaw that the agency identified. Thus, the FRFA, if done correctly, can play a key role in the development of public policy. The agency must also detail for the public record why each of the other significant alternatives was rejected; again, this is a requirement of APA rulemaking requiring the agency to explain how it considered all relevant statutory criteria including those mandated by the RFA. The changes indicate that agencies were not providing specific explanations of their final actions. There should be significant articulable and supportable reasons for rejecting alternatives. President Obama reaffirmed the principle of documenting a decision to reject an alternative that may reduce regulatory burden for small entities.<sup>149</sup> The development and consideration of alternatives is subject to judicial review.<sup>150</sup>

## **Permissible delays in publication; provision for lapse of final rule**

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

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<sup>148</sup> 5 U.S.C. § 604(a)(6).

<sup>149</sup> Memorandum for the Heads of Executive Departments and Agencies, "Regulatory Flexibility, Small Business, and Job Creation" (76 Fed. Reg. 3827, January 21, 2011).

<sup>150</sup> See *National Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33 (D.D.C. 2000), in which the court ordered HHS to complete a FRFA that discussed less burdensome alternatives considered and rejected in order to comply with the RFA.

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

In Appendix K is an example of a satisfactory FRFA released by the Environmental Protection Agency. This FRFA contains each of the elements required by the RFA and presents a thorough analysis of the regulation's impact on small entities.<sup>151</sup>

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<sup>151</sup> For an additional example of a satisfactory FRFA, see the Environmental Protection Agency final rule for Effluent Guidelines and Standards for the Organic Chemicals, Plastics, and Synthetic Fibers Industry, 58 Fed. Reg. 36,872 (July 9, 1993).

## CHAPTER 4 SBREFA PANELS

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

In July 2010, the United States Congress passed the Dodd-Frank Wall Street Reform and Consumer Protection Act (Act).<sup>152</sup> Section 1011 of the act establishes the Consumer Financial Protection Bureau to supervise certain activities of financial institutions. Section 1100G, titled “Small Business Fairness and Regulatory Transparency,” amends 5 U.S.C. § 609(d), to require the CFPB to comply with the SBREFA panel process, making it the third agency with this responsibility, along with the Environmental Protection Agency and the Occupational Safety and Health Administration.

In addition to the regular requirements of the initial regulatory flexibility analysis (IRFA) found in 5 U.S.C. § 603, a CFPB IRFA must include “a description of (A) any projected increase in the cost of credit for small entities; (B) any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any increase in the cost of credit for small entities; and (C) advice and recommendations of representatives of small entities relating to issues described in subparagraphs (A) and (B) and subsection (b).” When the Bureau produces a final regulatory flexibility analysis, it must include “a description of the steps the agency has taken to minimize any additional cost of credit for small entities.”

### Who must hold SBREFA panels?

The statute requires that EPA, CFPB, and OSHA evaluate their regulatory proposals to determine whether SBREFA panels should be convened.<sup>153</sup> The requirement for SBREFA panels may appear to impose additional steps for these agencies in their rulemaking processes. However, the panel process only formalizes the outreach requirements and analyses that the Administrative Procedure Act and the RFA already mandate for all new rules that affect small businesses. Any additional work that may be needed in this special early outreach effort should be offset by time saved at the other end of the regulatory process. When problems are resolved before a proposed rule is published, objections from the public are reduced. Experience has shown that the panel process results in better rules, better compliance, and reduced litigation. In at least two instances, EPA withdrew a regulatory proposal based on work performed in connection with the panel process.<sup>154</sup>

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<sup>152</sup> Public Law 111-203.

<sup>153</sup> 5 U.S.C. § 609(d)(2).

<sup>154</sup> See EPA’s Effluent Limitations Guidelines for Industrial Laundries; 64 Fed. Reg. 45071 (Dec. 12, 1997), withdrawn by EPA on August 18, 1999, Effluent Limitations Guidelines for Construction and Development, 67 Fed. Reg. 42644 (June 24, 2002), withdrawn April 26, 2004.

## How is the decision to hold a SBREFA panel made?

For each proposed rule, the RFA requires that an agency either certify that the proposal has no significant economic impact on a substantial number of small entities, or prepare an IRFA on the proposal.<sup>155</sup> Whenever EPA, CFPB, or OSHA determines that a regulatory proposal may have a significant economic impact on a substantial number of small entities, the law further requires that the agency convene a review panel. SBREFA panels are required for all EPA, CFPB, and OSHA rules for which an IRFA is required. Panel outreach must take place before the publication of the proposed rule. However, the Chief Counsel for Advocacy may waive the panel requirement upon the request of EPA, CFPB, or OSHA under certain conditions. To waive the panel requirement, the Chief Counsel must find that convening a panel would not advance the effective participation of small entities in the rulemaking process. Section 609(e) of the RFA lays out several factors in making this determination, including consideration of whether small entities have already been consulted in the rulemaking process and whether special circumstances warrant the prompt issuance of a rule.

## How does a SBREFA panel work?

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

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

The law requires that a SBREFA panel be convened and complete its report with recommendations within a 60-day period. The formal panel process begins with the convening of the panel by the rulemaking agency. The date is normally fixed after consultation with both Advocacy and OIRA. Before convening, the three agencies work together to discuss regulatory alternatives and their advantages and disadvantages. The agencies also discuss what data, information, and regulatory alternatives will be presented to the SERs so that they can provide informed advice. As EPA advises in its SBREFA panel guidance, the agency “need(s) to describe in sufficient detail, including some analysis of the impact on small entities and environmental benefits, each significant regulatory alternative you have identified that accomplishes the statutory mandate.”<sup>156</sup> With this information, the small entity representatives will be able to provide informed advice to the panel. The rulemaking agency usually has preliminary discussions with small entities about its draft proposal before the panel is formally convened. These

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<sup>155</sup> See Chapter 1 for a detailed discussion of how to certify a proposed rule and Chapter 2 on how to prepare an initial regulatory flexibility analysis.

<sup>156</sup> 2006 EPA Final Guidance, section 5.8.2. See section 5.8.2 for more guidance on what information should be provided to the panel and the small entity representatives.



preparations ensure that the panel process can be completed during the statutorily specified 60-day period.

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

The purpose of the panel process is threefold. First, the panel process ensures that small entities that would be affected by a regulatory proposal are consulted about the pending action and offered an opportunity to provide information on its potential effects. Second, a panel can develop, consider, and recommend less burdensome alternatives to a regulatory proposal when warranted. Finally, the rulemaking agency has the benefit of input from both real-world small entities and the panel's report and analysis prior to publication.<sup>157</sup>

## **Suggested SBREFA panel timeline**

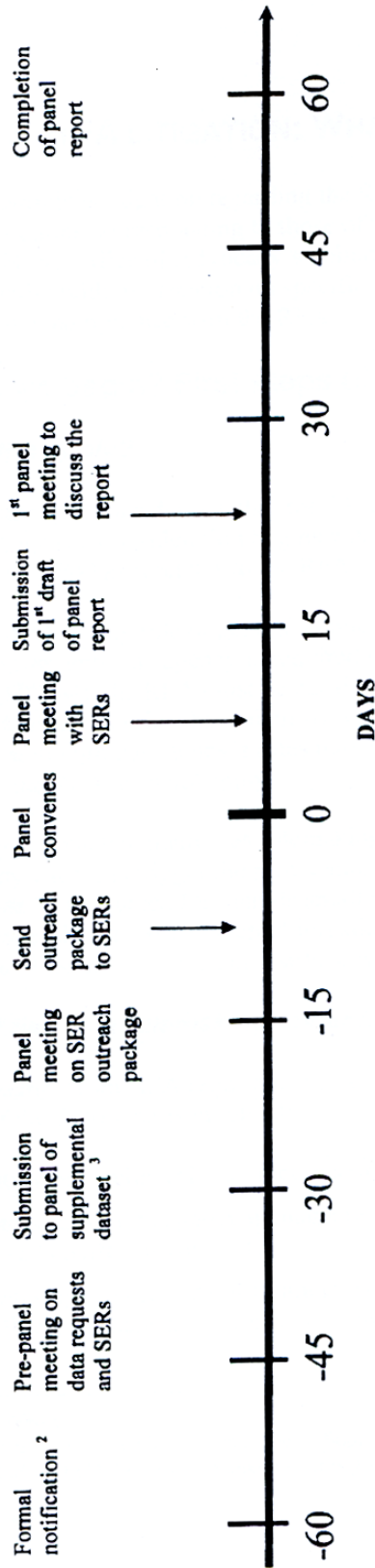
The RFA provides that the formal panel process must be concluded within 60 days from the formal convening of the panel to the completion of its report. Experience has shown that the panel process works best if agencies and panel members accomplish as much preliminary work as possible before the formal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

The EPA procedure is to hold two meetings with the SERs, one preceding and one following the formal convening of the panel. There are two opportunities for oral exchanges with the panel members, followed by two opportunities for written comments 15 days after the meetings. The two sessions facilitate a robust discussion of the issues, and give the agency the ability to further refine its draft regulatory alternatives in light of the initial round of written SER comments. The timeline on the next page is based on the OSHA practice of a single SER meeting after convening; however, the OSHA practice is to start with a fully developed draft proposed rule and preamble.

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<sup>157</sup>2006 EPA Final Guidance, Chapter 5, is a good source for effective panel procedures implementation, <http://www.epa.gov/rfa/documents/Guidance-RegFlexAct.pdf>.

Suggested panel timeline<sup>1</sup>



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

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

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

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

## CHAPTER 5 RFA LITIGATION: WHAT THE COURTS HAVE SAID

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

### Where do we begin? First steps of RFA rule analysis

#### *Does the RFA apply?*

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

If, under the APA or any rule of general applicability governing federal grants to state and local governments, the agency is required to publish a general notice of proposed rulemaking (NPRM), the RFA must be considered.<sup>158</sup> Significantly, some agencies, such as the Rural Utilities Service, have their own administrative rules that require notice and comment even though the agency’s rules may be exempt from the APA. If an NPRM is not required, the RFA does not apply.<sup>159</sup> Pursuant to RFA section 601(2), the term “rule” does not include a rule of particular applicability to rates, wages, corporate or financial structures or reorganization thereof, prices, facilities, appliances, services, or allowances.

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<sup>158</sup> 5 U.S.C. § 604(a). See also *National Association of Home Builders v. Army Corps of Engineers*, 417 F.3d 1272 (D.C. Cir. 2005) where the plaintiffs challenged nationwide permits issued under the Clean Water Act by the Corps as violating, *inter alia*, the RFA, because the Corps did not conduct a flexibility analysis as required by the RFA. The Army Corps of Engineers argued that its permitting action did not constitute a “rule.” It was an “order” because “order” included a “licensing” disposition and a “license” included a “permit.” The court considered the argument an “elaborate statutory construction” and rejected it for a more straightforward one. The court found that the permitting action fit within the APA’s definition of “rule” because each permit was a legal prescription of general and prospective applicability which the Corps issued to implement permitting authority that Congress entrusted to it pursuant to the Clean Water Act. As such, the action constituted a rule because it was an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. In addition, the court found that the Army Corps of Engineers action was a legislative rule because the permits authorized the discharge of certain materials, granted rights, imposed obligations, produced other significant effects on private interests. Accordingly, it was subject to the notice and comment requirements of the APA and to the requirements of the RFA.

<sup>159</sup> *In Roche v. Evans*, 249 F. Supp. 2d 47 (D. Mass. 2003), the New England Fishery Management Council (Council) adopted an adjustment to the existing Northeast Multispecies Fisheries Management Plan (FMP) mandating that certain fishing areas would be closed to fishing for varying lengths of time. The court stated that the RFA does not apply to the adoption of such a framework adjustment to an FMP because, under the abbreviated framework adjustment procedure permitted under 50 C.F.R. § 648.90, there is no requirement that the Council “publish a general notice of proposed rulemaking.” The court noted, “the whole purpose of the framework adjustment procedure is to dispense with that requirement.” 249 F.Supp.2d at 57. With the trigger of notice and comment lacking, the court granted summary judgment in favor of the agency.

Further, only actions that qualify as rulemaking under the APA that affect small entities or small entity concerns trigger the protections of the RFA.<sup>160</sup> Small entities whose concerns must be accounted for include small businesses, small not-for-profit organizations, and small governmental jurisdictions—cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.<sup>161</sup>

### ***What qualifies as a rulemaking under the APA?***

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

1. Military or foreign affairs functions of the United States.<sup>162</sup>
2. Matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.<sup>163</sup>

Also exempt from the APA requirement for notice and comment rulemaking are interpretative rules.<sup>164</sup> Interpretative rules generally require no judgments and little by the agency on implementation, but rather interpret the language or intent expressed by Congress. Legislative rules require judgments and great discretion; an example is setting a clean air standard for the nation.

### ***Exemptions under the APA***

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

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<sup>160</sup> *Atlantic Fish Spotters Association v. Evans*, 206 F. Supp. 2F.d 81, 93 (D. Mass. 2002).

<sup>161</sup> 5 U.S.C. § 601(3)-(5). See also Chapter 1 of this guide for a discussion of what qualifies as a small entity. *State v. Centers for Medicare & Medicaid Services*, 2010 WL 1268090 (M.D. Ala. 2010) (memorandum and order) where the court held that the State of Alabama did not have standing as a small entity; *La Gloria Oil & Gas Co. v. United States*, 56 Fed. Cl. 211 (2003), the court declined to address the plaintiff's arguments concerning alleged violation of the RFA because plaintiff was not a small business; *Williams Alaska Petroleum v. United States*, 57 Fed. Cl. 789 (2003), the plaintiff was precluded from asserting a claim under the RFA because the plaintiff was not a small entity; *Navajo Refining Co. v. United States*, 58 Fed. Cl. 200 (2003), the court declined to address the plaintiffs' arguments concerning the defendant's alleged violation of the RFA because they were not small businesses and lacked standing to challenge the defendant's compliance with the RFA.

<sup>162</sup> APA [§ 553\(a\)\(1\)](#) exempts from notice and comment rulemaking those rules involving “a military or foreign affairs function of the United States.” The legislative history of [§ 553\(a\)\(1\)](#) indicates the exception should be construed narrowly to include only those “ ‘affairs’ which so affect relations with other governments that, for example, public rulemaking provisions would clearly provoke definitely undesirable international consequences.” S.Rep. No. 752, 79th Cong., 1st Sess. 13 (1945). *Jean v. Nelson*, 711 F.2d 1455 (11<sup>th</sup> Circuit 1983).

<sup>163</sup> 5 U.S.C. § 553(a).

<sup>164</sup> SBREFA amended the RFA to bring certain interpretative rulemakings of the Internal Revenue Service within coverage of the RFA. The law now applies to those IRS rules published in the *Federal Register* that would normally be exempt from the RFA as interpretative rules, but that impose a “collection of information” requirement on small entities. For a more detailed discussion, see Chapter 1.

**Military or foreign affairs functions of the United States.** In reviewing the early RFA case, *In re Sealed Case*,<sup>165</sup> the D.C. District Court held that regulations such as those delineating the products subject to the ban on importation into the United States of uranium ore, uranium oxide, textiles, and coal from South Africa, fell under the foreign affairs function of the United States; thus, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking and opportunity for public participation were inapplicable. Because a notice of proposed rulemaking is not required for this rule, the Regulatory Flexibility Act, 5 U.S.C. §601 *et seq.*, did not apply.<sup>166</sup>

**Interpretative rules.** In *National Association for Home Care v. Shalala*,<sup>167</sup> the plaintiffs argued that the Department of Health and Human Services failed to consider alternatives to the proposed rule as required by the RFA. The agency, however, asserted that the Balanced Budget Act (BBA) did not grant the Secretary any discretion in implementing the Interim Payment System (IPS). The court agreed, holding that the BBA was an interpretative rather than substantive rule, given its high degree of specificity regarding the implementation of the IPS. As an interpretative rule, the BBA need not comply with the RFA. The court stated generally that the RFA does not apply to interpretative rules which merely clarify or explain existing laws or regulations.<sup>168</sup>

**Publications not subject to the APA and rate exemptions.** In *American Moving and Storage Association, Inc., v. DOD*,<sup>169</sup> the D.C. District Court examined a notice published in the *Federal Register* by the Department of Defense announcing a significant change in procurement policy regarding its source for distance calculations for payments and audits in its transportation programs from a previously used official mileage table to a new computer software program. The plaintiffs asserted that the change would have a significant economic impact on small carriers, requiring RFA compliance. DOD asserted that the policy change was not a “rule” as defined by the RFA, and therefore it did not have to comply with the RFA. The court agreed with the agency and held that the procurement policy change was not a “rule” for RFA purposes. The court further found that even if the RFA definition of a rule included some procurement policy changes, the calculations for payments and audits were exempt from the definition by the APA exception relating to rates.<sup>170</sup> As a result, the RFA did not apply.<sup>171</sup>

**Good Cause.** In *Oregon Trollers Association v. Gutierrez*,<sup>172</sup> the Ninth Circuit upheld the lower court’s decision regarding NMFS’s invocation of the good cause exception to the APA’s notice and comment provisions in an action involving the management of the Chinook salmon season. The plaintiffs argued that NMFS failed to prepare the economic analyses required by the RFA. The RFA applies to any rule requiring notice and

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<sup>165</sup> *In re Sealed Case*, 666 F. Supp. 231, 236 (D.D.C. 1987).

<sup>166</sup> *Id.* See also Jean V. Nelson, 711 F.2d 1455.

<sup>167</sup> *National Association for Home Care v. Shalala*, 135 F. Supp. 2d 161, 165 (D.D.C. 2001).

<sup>168</sup> *Id.* See also, *Cent. Tex. Tel. Coop. v. F.C.C.*, 402 F.3d 205 (D.C. Cir. 2005); *Broadgate, Inc. v. United States Citizenship & Immigration Services*, 730 F. Supp. 2d 240 (D.D.C. 2010).

<sup>169</sup> *American Moving and Storage Association v. DOD*, 91 F. Supp. 2d 132, 136 (D.D.C. 2000).

<sup>170</sup> 5 U.S.C. § 553(b) (1996).

<sup>171</sup> *Id.* at 136.

<sup>172</sup> *Oregon Trollers Association v. Gutierrez*, 452 F.3d 1104 (9th Cir. 2006).

comment under section 553(b) of the APA. The court held that NMFS’s invocation of the “good cause” exception to the RFA requirement was valid because the NMFS gave season-specific reasons for the exception. NMFS explained that management measures are based on data from the prior season, which are not available until January. Because the new season opens on May 1, the 60-day comment period is infeasible. The court added that as long as the NMFS provides fresh reasoning related to the season in which the exception applies, repeated invocation of the exception is not a problem.

## The certification statement

### *The decision process*

An agency may certify that no regulatory flexibility analysis is necessary when it determines that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule. However, an agency must provide a factual basis for the certification. A mere statement that there will be no effect is not sufficient. The agency must conduct an analysis demonstrating that it has considered the potential effects of the regulation.<sup>173</sup>

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

In *Northwest Mining Association v. Babbitt*,<sup>174</sup> the Bureau of Land Management (BLM) published a final rule in February 1997 that would impose a bonding requirement on hardrock mining. The rule was originally proposed in 1991. While the original proposal would have set a limit on bonding requirements, the final rule contained burdensome provisions not included in the proposal—provisions on which the public, therefore, had no opportunity to comment. The BLM certified that the rule would not have a significant economic impact on a substantial number of small entities. However, the agency failed to substantiate its conclusions. In remanding the rule, the court stated that the final rule’s certification violated the RFA because the factual basis for the certification that the agency provided failed to incorporate the correct definition of small entity.<sup>175</sup>

In *North Carolina Fisheries Association v. Daley*,<sup>176</sup> the District Court for the Eastern District of Virginia found that NMFS violated the RFA when it certified that there would not be a significant economic impact on a substantial number of small entities, because the fishing quota would remain unchanged. The court remanded the matter to NMFS with instructions to perform a proper analysis because even though the quota was the same, the agency provided no data to show that the quota was still valid.<sup>177</sup>

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<sup>173</sup> North Carolina Fisheries Association v. Daley, 16 F. Supp. 2d 647, 652 (E.D. Va. 1997).

<sup>174</sup> Northwest Mining Association v. Babbitt, 5 F. Supp. 2d 9, 14 (D.D.C. 1998).

<sup>175</sup> *Id.* at 652.

<sup>176</sup> North Carolina Fisheries Association v. Daley, 16 F. Supp. 2d 647 (E.D. Va. 1997).

<sup>177</sup> See additional discussion of this case later in this chapter.

In *Harlan Land Co. v. United States Department of Agriculture*,<sup>178</sup> the District Court for the Eastern District of California found the certification analysis performed by the Animal and Plant Health Inspection Services (APHIS) of the U.S. Department of Agriculture (USDA) was inadequate. APHIS had published a final rule allowing the importation of lemons, grapefruit, and oranges from various areas in Argentina. APHIS prepared an economic analysis of the rule and determined that the rule would not have a significant economic impact on a substantial number of small entities. Based on that determination, APHIS did not prepare an RFA analysis.<sup>179</sup> Citrus growers brought suit against the USDA and APHIS, arguing that the agency violated both the APA and the RFA in issuing the rule. The economic analysis in the final rule focused on the impact that the Argentine imports would have on the supply and prices of citrus fruit in the United States and the resulting costs and benefits to domestic growers, etc. The analysis failed to consider what the costs would be if Argentine plant pests were introduced into U.S. citrus orchards. The court found that APHIS's determination of a lack of significant economic impact on a substantial number of small entities was based on its conclusion that there was a negligible risk of pest introduction. The court considered the risk assessment to be flawed and thus remanded the final rule to the defendants for consideration of the economic impact that the importation of Argentine citrus will have on small businesses.

In *American Federation of Labor v. Chertoff*,<sup>180</sup> the Department of Homeland Security (DHS) promulgated a final rule titled Safe-Harbor Procedures for Employers Who Receive a No-Match Letter. Under the rule, an employer who received a "no-match letter" (indicating that an employee's name and social security number did not match) could take certain actions to avoid liability. The plaintiffs (union and business representatives) sought a preliminary injunction to bar enforcement of the rule, asserting that it was arbitrary and capricious in violation of the APA, and that promulgation of the rule violated the RFA. In promulgating the rule, DHS certified that the rule would not have a significant impact on small entities. However, in briefing, DHS claimed that an RFA analysis was unnecessary because the rule was voluntary, and that the RFA does not apply to interpretative rules. The court did not consider the post-rule rationalization that the rule was interpretive, focusing instead on DHS's first argument, which was that there was no impact on small entities because the rule was voluntary. The court was persuaded by the plaintiff's declarations that the rule could have significant costs, noting the potential costs of hiring human resources staff to track and solve mismatches, hiring legal services help, and training staff. The court decided that there were "serious questions [about] whether DHS violated the RFA," and granted the plaintiff's motion for preliminary injunction.<sup>181</sup>

**Where the court found that certification was appropriate.** In other cases, courts found that agencies properly certified rules.

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<sup>178</sup> *Harlan Land Co. v. United States Dept. of Agriculture*, 186 F. Supp. 2d 1076 (E.D. Cal. 2001).

<sup>179</sup> *Id.* at 1097.

<sup>180</sup> *American Federation of Labor v. Chertoff*, 552 F.Supp.2d 999, ( N.D.Cal., 2007).

<sup>181</sup> *Id.* at 1013.

In *Associated Builders and Contractors, Inc., v. Herman*, the Department of Labor suspended a revised class of employees called “helpers” on federal construction sites in 1993 and reinstated former helper regulations pursuant to a congressional mandate.<sup>182</sup> Regarding the RFA, the Department of Labor certified that the rule would not have a significant economic impact on a substantial number of small entities. The court upheld the certification, because the rule preserved the status quo, and DOL estimated few firms would have taken advantage of the helper classifications during the interim period pending final rulemaking.<sup>183</sup>

In *Environmental Defense Center. v. E.P.A.*,<sup>184</sup> EPA issued a rule, pursuant to the Clean Water Act, to control pollutants introduced into the nation’s waters by storm sewers. The rule mandated that discharges from small municipal storm sewers and construction sites sized 1-5 acres be subject to the permitting requirements of the National Pollutant Discharge Elimination System (NPDES). The EPA certified that the rule would not yield “significant impacts.” The plaintiffs argued that the EPA’s certification was erroneous because the EPA mislabeled significant costs as “not significant,” failed to account for the costs of all affected small entities, and failed to account for all significant costs to small entities. The Ninth Circuit agreed with the Natural Resources Defense Council’s view that “plain language of § 605(b) sets out a three-component test indicating that EPA need not perform a regulatory flexibility analysis if it finds that the proposed rule will not have: (1) “a significant economic impact” on (2) “a substantial number” of (3) “small entities.”<sup>185</sup> The Ninth Circuit determined that the EPA complied with the RFA and reasonably certified that the rule would not have a significant economic impact, but did not explain clearly its reasoning, beyond stating the legal test described above.

The court also noted that any procedural defect was harmless error because the EPA had already conducted the economic analyses the petitioners sought when they convened a small business advocacy review panel before publishing notice of the proposed rule. The EPA had followed the advice and recommendations of the panel and included provisions designed to minimize impacts on such entities, such as alternative compliance and reporting mechanisms responsive to the resources of small entities, simplified procedures, performance rather than design standards, and waivers. The court noted that “...the analyses required by RFA are essentially procedural hurdles; after considering the relevant impacts and alternatives, an administrative agency remains free to regulate as it sees fit.”<sup>186</sup>

In *Cactus Corner v. U.S.D.A.*,<sup>187</sup> USDA promulgated a rule allowing and setting conditions for resumption of the importation of Spanish clementines, following a ban after the discovery of live Mediterranean fruit fly (Medfly) larvae. Domestic fruit growers and packers sought declaratory and injunctive relief to set aside and hold the rule

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<sup>182</sup> *Associated Builders and Contractors, Inc., v. Herman*, 976 F. Supp. 1 (D.D.C. 1997).

<sup>183</sup> *Id.*

<sup>184</sup> *Environmental Defense Center. v. E.P.A.*, 344 F.3d 832 (9th Cir. 2003).

<sup>185</sup> *Id.* at 879-880.

<sup>186</sup> 344 F.3d at 879.

<sup>187</sup> *Cactus Corner v. U.S.D.A.*, 346 F. Supp. 2d 1075 (E.D. Cal. 2004).



unlawful, claiming, *inter alia*, that the rule violated the RFA because the agency had failed to prepare an initial or final regulatory flexibility analysis. It also sought to enjoin the defendant from implementing the rule or otherwise allowing the importation of clementines from Spain, and an award of costs, disbursements, and reasonable attorneys' fees. USDA conducted a regulatory impact analysis (RIA), which concluded that the regulatory benefits outweighed the regulatory costs associated with the implementation of the rule. Based on the RIA, the agency determined that the proposed rule would not have a significant economic impact on a substantial number of small entities. The court stated that, because the agency certified that the rule would "likely not have a significant economic impact on a substantial number of small Medfly host crop producers in the United States," initial and final regulatory flexibility analyses were not needed.<sup>188</sup> It further stated that the certification was supported by an analytical statement including factors such as the relatively low percentage of income derived by small wholesalers from clementine sales, and that small importers and wholesalers would likely be "better off" under the proposed regulations when compared with their status under the current ban on the importation of clementines as well as compared with the less strict conditions imposed before the ban.<sup>189</sup> The court stated that the agency relied on other analyses supporting its overall conclusion that the rule itself will result in a sufficiently high probability that Medfly infestation will not occur to conclude that any impact the new rule will have on small entities will be positive rather than negative, negating the need for a regulatory flexibility analysis.<sup>190</sup>

### **Size standards**

It is important that an agency use the size standard contained in the Small Business Administration's small business size standard regulations,<sup>191</sup> promulgated by the SBA under the Small Business Act, or follow the consultation procedures outlined in section 601(3) of the RFA.

**Incorrect size standard.** In *Northwest Mining Association v. Babbitt*, discussed above, the court held that BLM violated the RFA because the agency failed to use the appropriate size standard as defined by the Small Business Administration (SBA). The court noted that "the RFA requires agencies to use the Small Business Administration's definition of small entity."<sup>192</sup> Continuing, the court stated that "section 601 of the RFA sets forth, in relevant part, '[f]or the purposes of this chapter ... the term 'small entity' shall have the same meaning as the term 'small business' ....'"<sup>193</sup> The term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act.<sup>194</sup> The SBA publishes these small business definitions in 13 C.F.R. § 121.201. Division B of section 121.201 provides, in pertinent part, that mining

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<sup>188</sup> *Id.* at 1087.

<sup>189</sup> *Id.* at 1115

<sup>190</sup> *Id.* at 1116.

<sup>191</sup> 13 C.F.R. § 121.201 (1996).

<sup>192</sup> *Northwest Mining Association*, 5 F. Supp. 2d at 15. See Chapter 1 for detail on exceptions to using SBA size standards.

<sup>193</sup> 5 U.S.C. § 601(6).

<sup>194</sup> 15 U.S.C. § 632; 5 U.S.C. § 601(3).

concerns must have 500 or fewer employees to be considered “small.”<sup>195</sup> Therefore, the standard for “small miner” which the BLM must use when performing an initial or final regulatory flexibility analysis or when certifying “no significant impact” is a 500 or fewer employee standard. By using a definition other than the SBA’s, the BLM violated the procedure of law mandated by the statute. The court found that the definitions section of the RFA uses phrases such as “ ‘small entity’ *shall have* the same meaning ...” and “ ‘small business’ *has* the same meaning ...”<sup>196</sup> (emphasis added). The court concluded that words such as those do not leave room for alternate interpretations by the agency. The rule was remanded to the agency.

**Use of Incorrect Size Standard Cured.** In *Small Business in Telecommunications v. the Federal Communications Commission (FCC)*,<sup>197</sup> the FCC adopted its own definition of “small business” regarding its Lower Channel Report and Order concerning a regulatory scheme for specialized mobile radio (SMR) service in the 800 to 900 MHz range. The Court of Appeals for the District of Columbia Circuit held that although the FCC failed to seek approval from the SBA for its definition, the omission did not nullify the entire rulemaking, since SBA did ultimately approve the definition prior to commencement of the lower channel auction.<sup>198</sup> If the agency modifies a small business size standard in the implementation of a rule, it must seek approval from the SBA Administrator.<sup>199</sup>

### ***The agency must conduct an adequate analysis before certifying***

The landmark legal decision recognizing an agency’s failure to adequately examine the impact on affected entities before certification is the 1998 case, *Southern Offshore Fishing Association v. Daley*.<sup>200</sup> In that matter, the National Marine Fisheries Service (NMFS) published a proposed rulemaking to institute a 50 percent reduction in the shark fishing industry. NMFS certified that the rule would not have a significant economic impact on a substantial number of small entities. Although the agency published a FRFA at the time it finalized the rule, the court found that the agency certified without making a “reasonable, good-faith effort,” prior to issuance of the final rule, to inform the public about the potential adverse effects of its proposals and about less harmful alternatives. The agency continued to deny that its proposal would likely have a significant impact on a substantial number of small entities after receiving public comments challenging the certification. The court concluded that the preparing of a FRFA constituted “an attempt to agreeably decorate a stubborn conclusion” that there was no significant impact on a substantial number of small entities. The court remanded the agency’s certification determination, requiring it to “undertake a rational consideration of the economic effects and potential [regulatory] alternatives.”<sup>201</sup>

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<sup>195</sup> *Id.*

<sup>196</sup> 5 U.S.C. § 601.

<sup>197</sup> *Small Businesses in Telecomm. v. FCC*, 251 F.3d 1015, 1025 (D.C. Cir. 2001).

<sup>198</sup> *Id.*

<sup>199</sup> *Id.* at 1025.

<sup>200</sup> *Southern Offshore Fishing*, 995 F. Supp. at 1437.

<sup>201</sup> *Id.*

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

The first case arose in 1997.<sup>202</sup> There, the National Marine Fisheries Service (NMFS) set the 1997 quota for flounder fishing by continuing the quota from the previous year. In doing so, NMFS did not perform a regulatory flexibility analysis. Instead, the agency certified that the rule would not have a significant impact on a substantial number of small businesses because the quota remained the same from 1996 to 1997. There was no record showing that the agency did any comparison between conditions in 1996 and 1997. The court stated that “a simple conclusory statement that, because the quota was the same in 1997 as it was in 1996, there would be no significant economic impact, is not an analysis.”<sup>203</sup> The court remanded the issue to the agency with orders to “undertake enough analysis to determine whether the quota had a significant economic impact on the North Carolina Fishery.”<sup>204</sup> The court further ordered the department to “include in [the] analysis whether the adjusted quota will have a significant economic impact on small entities in North Carolina.”<sup>205</sup>

The issue returned to the court in 1998.<sup>206</sup> The issue before the court on remand was whether the Secretary of Commerce had discharged his responsibilities under the RFA and under National Standard 8 of the Magnuson Act to perform an economic analysis.<sup>207</sup> After review, the court concluded that “the Secretary of Commerce acted arbitrarily and capriciously in failing to give any meaningful consideration to the economic impact of the 1997 quota regulations on North Carolina fishing communities. Instead, the Secretary has produced a so-called economic report that obviously is designed to justify a prior determination.”<sup>208</sup> The court further stated that as part of an adequate analysis before certification, the agency must consider alternatives less burdensome to small entities.<sup>209</sup> The court concluded that “Congress has not intended for administrative agencies to circumvent the fundamental purposes of the RFA by invocation of the certification provision.” The court felt that Secretary Daley’s certification in this instance amounted to an effort to avoid the requirements of the RFA, specifically the requirement to consider alternative ways to minimize economic impacts. Because the court found that the Secretary and the agency did not uphold their responsibilities under the law, it set aside the 1997 summer flounder quota and imposed a penalty against the NMFS.

Court cases have held that the agency must account for the public comments it received challenging the initial determination that no significant economic impact was likely.<sup>210</sup> In

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<sup>202</sup> *North Carolina Fisheries*, 16 F. Supp. 2d at 647.

<sup>203</sup> *Id.* at 653.

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> *North Carolina Fisheries Association v. Daley*, 27 F. Supp. 2d 650 (E.D. Va. 1998).

<sup>207</sup> *Id.* at 660.

<sup>208</sup> *Id.* at 668.

<sup>209</sup> *Id.* at 660.

<sup>210</sup> See generally, *National Truck Equip. Association v. NHTSA*, 919 F.2d 1148 (6th Cir. 1990); *Northwest Mining Association v. Babbitt*, 5 F. Supp. 2d 9 (D.D.C. 1998).

*Northwest Mining Association v. Babbitt*,<sup>211</sup> the court addressed the Bureau of Land Management (BLM) claims that the Northwest Mining Association (NWMA) did not have standing to object to its final rule under either the APA or the RFA because it did not submit comments during the notice and comment period. The NWMA asserted that it did not need to submit comments during the notice and comment period because the BLM's original rule proposal did not properly inform it that its interests were at stake. The court agreed with the NWMA, holding that because there was no way the NWMA could have submitted comments regarding issues on which it was not informed were at stake, the agency must consider even comments not submitted during the formal notice and comment period.<sup>212</sup>

**Bare Certification Not Sufficient.** In *Theiss v. Principi*,<sup>213</sup> the Veteran's Administration promulgated an amendment to define "educational institution," excluding home schools. The court determined that this was a substantive, legislative rule and was invalid for failure to comply with notice-and-comment procedures under the APA. The court warned that any future amendment should comply with the APA as well as with the provisions of the RFA and that a "bare certification" like the one in this case would likely be insufficient because it was not accompanied by a "statement providing the factual basis for such certification."<sup>214</sup>

### ***Direct versus indirect impact on small entities***

**Must the agency consider the indirect effects of the proposed regulation?** It was first held in *Mid-Tex Electric Cooperative, Inc., v. Federal Energy Regulatory Commission (FERC)* that a regulatory flexibility analysis is required when an agency determines that the rule will have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule.<sup>215</sup> In that case, FERC proposed a rule that allowed electric utilities to include in their rate bases amounts equal to 50 percent of their investments in construction work in progress. In response to an argument that FERC "should have considered the impact of the proposed rule on wholesale and retail customers of the jurisdictional entities subject to rate regulation by the Commission," FERC stated that "the RFA does not require the Commission to consider the effect of this rule, a federal rate standard, on nonjurisdictional entities whose rates are not subject to the rule."<sup>216</sup>

The court agreed, reasoning that "Congress did not intend to require that every agency consider every indirect effect that any regulation might have on small businesses in any stratum of the national economy."<sup>217</sup> The court concluded that "an agency may properly certify that no regulatory flexibility analysis is necessary when it determines that the rule

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<sup>211</sup> *Northwest Mining Association*, 5 F. Supp. 2d 9.

<sup>212</sup> *Id.* at 13.

<sup>213</sup> *Theiss v. Principi*, 18 Vet. App. 204 (2004).

<sup>214</sup> *Id.* at 214.

<sup>215</sup> *Mid-Tex Elec. Coop v. FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985).

<sup>216</sup> *Id.* at 341.

<sup>217</sup> *Id.*

will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule.”<sup>218</sup>

In viewing this decision, the same court later held in *United Distribution Companies v. FERC*<sup>219</sup> that an agency is under no obligation to conduct a small entity impact analysis of effects on entities it does not regulate. Because in this case FERC had no jurisdiction to regulate the local distribution of natural gas, it could not be required to conduct a regulatory flexibility analysis for those entities engaged in the local distribution of the gas.<sup>220</sup>

Although *Mid-Tex* occurred prior to the passage of the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, post-SBREFA courts have upheld its reasoning. For example, in *Motor and Equipment Manufacturers Association v. Nichols*,<sup>221</sup> the court found that because the deemed-to-comply rule did not subject any aftermarket businesses to regulation, EPA was not required to conduct a regulatory flexibility analysis as to small aftermarket businesses. It was only obliged to consider the impact of the rule on small automobile manufacturers subject to the rule, and it met that obligation. A number of other cases have held similarly.<sup>222</sup>

Likewise in *American Trucking Associations v. EPA*,<sup>223</sup> EPA established a primary national ambient air quality standard (NAAQS) for ozone and particulate matter. At the time of the rulemaking, EPA certified the rule pursuant to 5 U.S.C. § 605(b). The basis of the certification was that EPA had concluded that small entities were not subject to the rule because the NAAQS only regulated small entities indirectly through the state implementation plans.<sup>224</sup> Although the court remanded the rule to the agency for non-RFA reasons, the court found that EPA had complied with the requirements of the RFA.

Similarly, in *Michigan v. EPA*,<sup>225</sup> EPA certified that its revised NAAQS would not have a significant economic impact within the meaning of the RFA. According to the EPA, the NAAQS itself imposed no regulations upon small entities. Instead, several states regulate small entities through the state implementation plans they are required by the Clean Air Act to develop. Because the NAAQS regulated small entities only indirectly—that is, insofar as it affected the planning decisions of the states—the EPA concluded that small entities were not “subject to the proposed regulation.” The court agreed, stating that states have broad discretion in determining the manner in which they will achieve compliance with the NAAQS. In conclusion, the court stated that “a State may, if it chooses, avoid

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<sup>218</sup> *Id.* at 343.

<sup>219</sup> *United Dist. Cos. v. FERC*, 88 F.3d 1105, 1170 (D.C. Cir. 1996).

<sup>220</sup> *Id.*

<sup>221</sup> *Motor and Equip. Mfrs. Association v. Nichols*, 142 F.3d 449, 467 (D.C. Cir. 1998).

<sup>222</sup> See *American Trucking Associations v. EPA*, 175 F.3d at 1044; *Michigan v. EPA*, 213 F.3d 663, 689 (D.C. Cir. 2000); *Cement Kiln Recycling Coalition v. EPA*, 255 F.3d 855, 868 (D.C. Cir. 2001).

<sup>223</sup> *American Trucking*, 175 F.3d at 1027.

<sup>224</sup> *Id.*

<sup>225</sup> *Michigan v. EPA*, 213 F.3d at 689.

imposing upon small entities any of the burdens of complying with a revised NAAQS.”<sup>226</sup>

The court in *Cement Kiln Recycling Coalition v. EPA*<sup>227</sup> further bolstered the notion that indirect impacts should be disregarded by noting that the RFA is not intended to apply to every entity that may be targeted by the proposed regulation. The fact that the rule will have economic impacts in many sectors of the economy does not change this. The court reasoned that “requiring an agency to assess the impact on all of the nation's small businesses possibly affected by a rule would be to convert every rulemaking process into a massive exercise in economic modeling, an approach we have already rejected.”<sup>228</sup>

An entity can otherwise experience indirect impacts through its dealings with the entity that experiences direct impacts, such as through increased after-market prices or newly required modifications to necessary equipment. Some courts have stated that this impact would likewise not require a regulatory flexibility analysis.<sup>229</sup>

In *White Eagle Cooperative Association v. Conner*,<sup>230</sup> the plaintiffs, a cooperative of milk producers, brought action challenging USDA’s amendment of a regional milk marketing order. The United States District Court for the Northern District of Indiana entered summary judgment in government's favor, and the association appealed. Among other things, plaintiffs asserted that in adopting the amendments to the marketing order, USDA violated the RFA by failing to undertake an analysis and by employing the certification option without sufficient factual support. USDA asserted that plaintiffs could not challenge the agency’s RFA compliance because the order regulates handlers—not producers. Since the plaintiffs are an association of producers, not handlers, USDA argued that plaintiffs lacked standing to challenge the agency’s compliance. The court held that the association did not have standing to raise a challenge under the RFA because the impact was indirect.

**Where an Agency Argued Indirect Impact Unsuccessfully.** In *Aeronautical Repair Station Association v. F.A.A.*<sup>231</sup>, the plaintiff challenged a final rule of the Federal Aviation Administration (FAA) which amended its drug and alcohol testing regulations to expressly mandate that air carriers require drug and alcohol tests of all employees of its contractors, including employees of subcontractors at any tier, who perform safety-related functions such as aircraft maintenance. The plaintiff challenged the rule on the

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<sup>226</sup> *Id.*; see also, *Nat’l Women, Infants, & Children Grocers Association v. Food & Nutr. Serv.*, 416 F. Supp. 2d 92 (D.D.C. 2006) where the court granted summary judgment to the defendant and denied the plaintiffs’ motion for summary judgment, holding the FNS certification proper because the interim rule regulated state agencies—the impact on small businesses was indirect. Furthermore, the court bolstered its reasoning by citing the fact that FNS stated in the *Federal Register* that it planned to use data collected from the interim rule to strengthen its ultimate FRFA.

<sup>227</sup> *Cement Kiln*, 255 F.3d at 868.

<sup>228</sup> *Id.*

<sup>229</sup> See, e.g., *Nichols*, 142 F.3d at 467; *Cement Kiln*, 255 F.3d at 868.

<sup>230</sup> *White Eagle Cooperative Association, et al., v. Charles F. Conner, Acting Secretary, United States Department of Agriculture*, 553 F.3d 467 (7<sup>th</sup> Cir. 2009).

<sup>231</sup> *Aero. Repair Station Association v. F.A.A.* 494 F.3d 161 (D.C. Cir. 2007).

grounds that it impermissibly expanded the scope of employees tested in violation of the unambiguous statutory language of § 45102(a)(1), the Administrative Procedure Act, 5 U.S.C. §§ 701-06, and the Fourth and Fifth Amendments to the United States Constitution. In addition, it challenged the FAA's conclusion that it was not required to conduct a regulatory flexibility analysis. The court upheld the substance of the rule but rejected the FAA's RFA determination.

In the NPRM, the FAA performed a tentative RFA analysis and counted among RFA small entities both air carriers and Part 145 repair stations because it could not determine how many of the 2,412 Part 145 repair stations are considered small entities. In the second NPRM, the FAA determined that the small entity group is considered to be Part 145 repair stations, but it still could not determine how many of the Part 145 repair stations and their subcontractors were considered small entities. The FAA concluded that most, if not all of the noncertificated maintenance contractors would be considered small entities. Based on its calculation of annualized costs of less than 1 percent of annual median revenue, the FAA certified that the proposed action would not have a significant economic impact on a substantial number of small entities.

Although commentators raised RFA issues, in the final rule FAA disagreed and asserted that contractors were not among entities regulated under the testing regulations for the purpose of the RFA. The FAA noted that the directly regulated employers were air carriers operating under 14 CFR Parts 121 and 135, § 135.1(c) operators, and air traffic control facilities not operated by the FAA or under contract to the U.S. military, who must conduct drug and alcohol testing under the FAA regulations. For drug and alcohol testing purposes, certificated repair stations were contractors, and contractors were not regulated employers. Accordingly, the FAA concluded it was not required to conduct an RFA analysis, including considering significant alternatives, because contractors (including subcontractors at any tier) were indirectly regulated entities.

In making its determination, the FAA relied on the *Mid-Tex* case and other cases that held that under the RFA the regulating agency need consider only the economic impact on businesses directly affected and regulated by the subject regulations. The plaintiffs asserted that the FAA's determination was incorrect. The court found that, unlike the parties claiming economic injury in the cited cases, the contractors and subcontractors were directly affected and therefore regulated by the challenged regulations. Although the regulations immediately addressed the employer air carriers which were in fact the parties certified to operate aircraft, the regulations expressly required that the employees of contractors and subcontractors be tested. Thus, the contractors and subcontractors (at whatever tier) were entities subject to the proposed regulation.

The FAA also asserted that it had substantially complied with the RFA because it conducted initial evaluations and a final economic evaluation of the effects on the industry, responding to comments following the proposal. The court found that the final evaluation was not a FRFA because the FAA determined that contractors and subcontractors are not regulated entities for the purpose of the RFA. In addition, the FAA did not consider alternatives as required by the RFA. The court upheld the substance of

the FAA's 2006 final rule and remanded for the limited purpose of conducting the analysis required under the RFA, treating the contractors and subcontractors as regulated entities.

## The initial regulatory flexibility analysis

Because an agency's initial regulatory flexibility analysis cannot be the subject of litigation,<sup>232</sup> case law provides a detailed discussion only for the final regulatory flexibility analysis. It is important to note that although the IRFA is not judicially reviewable, a proper IRFA is necessary to provide the foundation for a good FRFA. An agency cannot develop an adequate FRFA if the IRFA did not lay the proper foundation for eliciting public comments and seeking additional economic data and information on the regulated industry's profile and regulatory impacts. Further, without an adequate IRFA, small entities cannot provide informed comments on regulatory alternatives that are not adequately addressed in the IRFA.<sup>233</sup>

In *Allied Local and Regional Manufacturers Caucus v. EPA*, paint manufacturers and associations of manufacturers and distributors of architectural coatings petitioned for review of EPA's regulations limiting the content of volatile organic compounds (VOCs) in consumer and commercial products such as architectural coatings, including paints.<sup>234</sup> Plaintiffs alleged that EPA failed to comply with the RFA by failing to discuss the economic impact of "stigmatic harm" arising from the agency's suggestion that it may impose more stringent VOCs in the future, and of asset devaluation, in that the coatings rule allegedly will render existing product formulas valueless. The court ruled that section 603 of the RFA, which discusses IRFAs, was not subject to judicial review pursuant to section 611(c). However, the court did have the jurisdiction to determine whether the agency had met the overall requirement that the decisionmaking not be arbitrary and capricious. The court found that the EPA examined alternatives to product reformulation when creating regulations limiting content of VOCs in consumer and commercial products, and that its decisions were neither arbitrary nor capricious. The court, therefore, found that EPA had met its obligations under the RFA.

Similarly, in *U.S. Cellular Corp. v. FCC*,<sup>235</sup> the court noted that an IRFA is not subject to judicial review. There, the FCC adopted an order requiring wireless carriers to bear financial responsibility for enhanced 911 implementation, rather than having local government guarantee costs. Plaintiffs argued that the FCC failed to issue an IRFA and that the FRFA did not contain a description of the steps the agency took to minimize the impact on small businesses, as required by the RFA. The court held that the RFA

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<sup>232</sup> Because § 611 of the RFA does not mention § 603, the IRFA requirement, a court would consider a pre-promulgation challenge unripe.

<sup>233</sup> *Southern Offshore Fishing*, 995 F. Supp. at 1434 and 1436 ("the agency could not possibly have complied with § 604 by summarizing and considering comments on an IRFA that NMFS never prepared").

<sup>234</sup> *Allied Local and Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61 (D.C. Cir. 2000).

<sup>235</sup> *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 89 (D.C. Cir. 2001).



expressly prohibits courts from considering claims of noncompliance with RFA section 603's requirement to issue an IRFA.<sup>236</sup>

## The final regulatory flexibility analysis

### **General content**

Section 604 of the RFA prescribes the content of the FRFA. Courts have found that an agency can satisfy the requirements of section 604 “as long as it compiles a meaningful, easily understood analysis that covers each requisite component dictated by the statute and makes the end product readily available to the public.”<sup>237</sup> For example, in *Associated Fisheries of Maine, Inc., v. Daley*, the court stated that the Secretary of Commerce had complied with FRFA requirements because the Secretary explicitly considered numerous alternatives, exhibited a fair degree of sensitivity concerning the need to alleviate the regulatory burden on small entities within the fishing industry, adopted some salutary measures designed to ease that burden, and satisfactorily explained reasons for adopting others. Similarly, in *Alenco Communications v. FCC*,<sup>238</sup> the court held that the regulatory analysis was compliant with the terms of the RFA where the agency provides a lengthy analysis of the economic impact of the proposed rule on small businesses and responds to comments submitted by the Office of Advocacy and other commenters.<sup>239</sup>

The court addressed the issue in *National Association of Mortgage Brokers v. Board of Governors of the Federal Reserve System*.<sup>240</sup> In that case, the National Association of Independent Housing Professionals, Inc. (NAIHP) and the National Association of Mortgage Brokers (NAMB) “requested the Court to issue a temporary restraining order and preliminary injunction to enjoin the Board of Governors of the Federal Reserve System [Board] from implementing a Final Rule . . . that restricts certain compensation practices of loan originators relating to mortgage loans.” Among other claims, the Plaintiffs argued that the Board failed to comply with the RFA because they “[1] failed to provide a statement of need for or objectives of the rule; [2] failed to meaningfully analyze the Rule’s impact on small businesses; [3] failed to respond to public comments; and [4] failed to analyze alternatives to the proposed regulation.” The court disagreed, finding that the FRFA stated that the rule addressed problems that have been observed in the mortgage market in order to prohibit unfair and deceptive acts and practices in connection with mortgage loans, and recognized that the rule would have a “significant economic impact on a substantial number of small entities but the precise compliance costs were difficult to ascertain. The FRFA also discussed and rejected alternatives from

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<sup>236</sup> *Id.*

<sup>237</sup> *Associated Fisheries of Maine, Inc., v. Daley*, 127 F.3d 104, 115 (1st Cir. 1997); *Grand Canyon Air Tour Coalition v. FAA*, 154 F.3d 455, 470 (D.C. Cir. 1998); *National Propane Gas Association v. DOT*, 43 F. Supp. 2d 665, 681 (N.D. Tex. 1999); *Associated Builders and Contractors, Inc., v. Herman*, 976 F. Supp. 1 (D.D.C. 1997).

<sup>238</sup> *Alenco Communications v. FCC*, 201 F.3d 608 (5th Cir. 2000).

<sup>239</sup> *Id.* at 625.

<sup>240</sup> *National Association of Mortgage Brokers v. Board. Of Governors of the Federal Reserve System*, 773 F. Supp. 2d 151 (D.D.C. 2011).

public comments. The court stated that the Board did not need to address each portion of the rule challenged in the comments because it “addressed the effects of all of the Rule’s prohibitions regarding loan originator compensation collectively, and this satisfies the Board’s obligations under 5 U.S.C. § 604(a).” In making its ruling the court reiterated that the RFA’s requirements are purely procedural and although it directs agents to state, summarize, and describe, the RFA in and of itself imposes no substantive constraints on agency decisionmaking. Moreover, the agency does not need to present its FRFA in any particular mode of presentation, as long as the FRFA compiles a meaningful, easily understood analysis that covers each requisite component dictated by the statute and makes the end product readily available to the public. Finally, the court noted that failure to comply with the RFA may be, but does not have to be, grounds for overturning a rule. Additionally, while making a section 604 challenge, parties may raise the related but distinct claim that an agency did not reasonably address the rule’s impact on small businesses and such challenges are evaluated under the arbitrary and capricious standard of review.<sup>241</sup>

### ***Is a FRFA always required?***

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

However, in the event that the publication of an NPRM is impossible due to the emergency nature of the rule, the requirements of the RFA may be satisfied by publishing a FRFA subsequent to the rulemaking.<sup>242</sup> In *National Propane Gas Association v. DOT*,<sup>243</sup> the Department of Transportation’s Research and Special Programs Administration (RSPA) instituted an emergency interim final rule to address concerns about the transportation of compressed gas on highways. RSPA later modified and adopted the interim final rule as the emergency discharge control regulation for loading or unloading of cargo tank motor vehicles. The regulation required vehicle operators to shut down immediately if they learned of a gas leakage.

Gas companies brought suit alleging various violations of the APA and RFA. Plaintiffs challenged the rule on the grounds that defendants failed to prepare a FRFA, as required by the RFA. RSPA argued that the rule was not subject to the RFA because the RFA applies only to the rules for which an agency is required to publish a notice of proposed rulemaking pursuant to section 553 of the APA. RSPA asserted that the APA did not require a notice of proposed rulemaking here because of the emergency nature of the rule. Nevertheless, RSPA claimed that in preparing preliminary and final regulatory evaluations under Executive Order 12866, the agency did analyze the impact of the interim final rule and the final rule on all affected parties, including small businesses. The court agreed, and found that although the agency did not prepare a FRFA, all of the

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<sup>241</sup> *Id.* at 178.

<sup>242</sup> *National Propane Gas Association*, 43 F. Supp. 2d at 681.

<sup>243</sup> *Id.*

elements of a FRFA were available throughout their summary of such analysis published in the *Federal Register*. The court thus found that RSPA complied with each of the requirements found in the RFA, including responding to comments and consideration of alternatives. The court asserted that a preliminary regulatory evaluation was available in the docket for the public to provide comment, and it also found that to require an additional analysis by the agency would be duplicative.

### ***Considering alternatives to the final rule***

Section 604 of the RFA requires the agency to consider alternatives that would achieve the statutory objectives while lessening the regulatory burden on affected small entities. This involves making a “reasonable, good-faith effort to canvass major options and weigh their probable effects.”<sup>244</sup>

In *AML International, Inc., v. Daley*,<sup>245</sup> the National Marine Fisheries Service implemented a management plan for the spiny dogfish industry that imposed quotas that effectively shut down the industry for the next five years. The plaintiffs asserted that NMFS failed to comply with the RFA because the NMFS failed to consider alternatives. The court found that NMFS’s consideration of alternatives was sufficient. NMFS considered and rejected alternatives because they did not meet the mandate of the Magnuson-Stevens Act or provide long-term economic benefits greater than those of the proposed action.<sup>246</sup>

Similarly, in *Ace Lobster Co. v. Evans*,<sup>247</sup> the Department of Commerce imposed limitations on the number of lobster traps that could be used in a particular area. Lobster fisherman and business owners alleged that the Department of Commerce implemented the regulations in violation of the APA, the Magnuson-Stevens Act, and the RFA. The basis for the assertion was that during the comment period, numerous commenters submitted information about an alternative plan for the lobster fishery, which was approved by the Lobster Conservation and Management Team and submitted for consideration as an alternative. The agency rejected the alternative because it would likely increase the number of lobster traps in offshore waters and increase the lobster mortality rate. Plaintiffs alleged that the defendant did not adequately analyze the selected alternative or consider the alternative that would mitigate the negative economic impacts on offshore fishing fleets, and that the agency’s concern for verification of prior fishing fleets was unfounded.<sup>248</sup> The court stated that under the standard for judicial review of compliance with the RFA, the court reviews only whether the agency conducted a complete IRFA and FRFA in which it described steps to minimize the economic impact of its regulations on small entities and discussed alternatives, providing a reasonable explanation for rejections. The RFA permits the agency to select an alternative that is more economically burdensome if there is evidence that other

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<sup>244</sup> National Association of Psychiatric Health Sys. v. Shalala, 120 F. Supp. 2d 33, 42 (D. D.C. 2000).

<sup>245</sup> *AML Int’l v. Daley*, 107 F. Supp. 2d 90 (D. Mass. 2000).

<sup>246</sup> *Id.* at 105.

<sup>247</sup> *Ace Lobster Co. v. Evans*, 165 F. Supp. 2d 148 (D. R.I. 2001).

<sup>248</sup> *Id.* at 185.

alternatives would not accomplish the objectives of the statute. Because the agency examined the alternative and decided that, while less onerous, it did not achieve the conservation goals, it met its obligations under the RFA. The court further found that there was sufficient analysis and explanation of the other rejected alternatives.<sup>249</sup>

**What kinds of alternatives must the agency consider?** In *Associated Fisheries of Maine*, the court first held that section 604 does not require that a FRFA address every alternative, only significant ones.<sup>250</sup> The RFA does permit the agency to select an alternative that is more economically burdensome if there is evidence that other alternatives would not accomplish the stated objectives of the applicable statutes.<sup>251</sup>

**What is a significant alternative?** This question was clarified by the court in *Little Bay Lobster Co. v. Evans*.<sup>252</sup> There, the court stated that “significant alternatives” are those with potentially lesser impacts on small entities (versus large-scale entities) as a whole, and not those that may lessen the regulatory burden on some particular small entity. Further, the agency is not obligated under the RFA to address alternatives that might have had lesser impacts on some small entities vis-à-vis other similarly affected small entities.<sup>253</sup>

In *Hall v. Evans*,<sup>254</sup> the Department of Commerce determined that the monkfish fishery was overfished. To address the problem, the agency implemented a fishery management plan to prescribe landing limits for vessels holding limited access monkfish permits. The limits allowed categories A and C vessels using trawl gear to land up to 1,500 pounds of monkfish tailweight per day at sea, while vessels using any gear other than trawl or “mobile” gear may land up to 300 pounds of monkfish tailweight per day at sea. The plaintiffs filed suit asserting that the regulations violated the Magnuson Act and the RFA. The plaintiffs asserted that the defendant’s RFA analysis: (1) failed to recognize the costs of forcing closures of the directed monkfishing industry within 4 years, supposedly to allow the industry to receive positive revenue benefits after 20 years; (2) forced particularly harsh consequences on small businesses; and (3) failed to conduct an assessment of meaningful and more gradual restrictions in order to avoid severe costs to small businesses. Plaintiffs asserted that neither the IRFA nor the FRFA provided an assessment of the real economic impact on small entities in that the IRFA failed to assess the number and quality of vessels affected by the regulations and failed to address the disparity in landing allocations between different gear types. Although the regulations were set aside for violation of the Magnuson Act, the court found no violation of the RFA. With respect to the RFA allegations, the court found that there was enough evidence in the IRFA to show that the defendants considered both the economic effect of the fishery plan as a whole upon small entities and less onerous alternatives.<sup>255</sup>

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<sup>249</sup> *Id.*

<sup>250</sup> *Associated Fisheries of Maine*, 127 F.3d at 115; See also *Grand Canyon Air Tour Coalition*, 154 F.3d at 470 and *Blue Water Fishermen’s Association v. Mineta*, 122 F. Supp. 2d 150, 178 (D. D.C. 2000).

<sup>251</sup> *Associated Fisheries of Maine*, 127 F.3d at 114.

<sup>252</sup> *Little Bay Lobster Co v. Evans*, 2002 WL 1005105, Slip. Op. (D. N.H. May 16, 2002).

<sup>253</sup> *Id.* at 25.

<sup>254</sup> *Hall v. Evans*, 165 F. Supp. 2d 114 (D.R.I. 2001).

<sup>255</sup> *Id.* at 147.

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

In *Ashley County Medical Center v. Thompson*,<sup>256</sup> the Department of Health and Human Services imposed upper payment limit (UPL) regulations that would reduce the upper limit on what states could reimburse locally owned public hospitals for services to Medicaid beneficiaries. The plaintiffs alleged that the FRFA failed to describe the steps the agency had taken to minimize the significant economic impact on hospitals, and failed to discuss any affirmative steps the agency had taken or intended to take to mitigate the injury that the 2002 UPL rule would cause to public hospitals. The court, noting that the RFA requires only that the agency describe steps taken and not that the agency take any particular steps, stated that if there were no steps that could have been taken to minimize the impact on small businesses, then the statutory requirement would have been met simply by reporting that information. The court noted that the agency had provided a description of the alternatives considered and rejected in the *Federal Register*, and thus all the requirements of the RFA were clearly satisfied.<sup>257</sup>

Conversely, in *Nat'l Assoc. of Psychiatric Health Sys. v. Shalala*,<sup>258</sup> the plaintiffs challenged an interim final rule promulgated by the Department of Health and Human Services (HHS) that required a face-to-face evaluation of patients within one hour after the patient has been placed in restraints or seclusion. The plaintiffs argued that the Secretary failed to conduct an adequate analysis before adopting the one-hour provision. The court agreed with the plaintiffs, stating that it could not find that the Secretary made a good-faith effort to canvass major alternatives and weigh their probable effects.<sup>259</sup> Specifically, the Secretary did not obtain data or analyze available data on the impact of the final rule on small entities, nor did she properly assess the impact the final rule would have on small entities. The court stated that by these omissions the Secretary totally failed to comply with section 5 of section 604(a) of the RFA.<sup>260</sup> The court thus remanded the matter to HHS for completion of a compliant FRFA.<sup>261</sup>

However, in *Southern Offshore Fishing Ass'n v. Daley*,<sup>262</sup> the court stated that the agency's consideration of alternatives was inadequate. Particularly troublesome to the

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<sup>256</sup> *Ashley County Med. Ctr. v. Thompson*, 205 F. Supp. 2d 1026 (E.D. Ark. May 13, 2002).

<sup>257</sup> *Id.* See also *Nat'l Coal. for Marine Conservation v. Evans*, 231 F. Supp. 2d 119 (D.D.C. 2002) where plaintiffs argued that the Florida Closure violated the RFA, alleging that the DOC's analysis of the economic, social, and environmental effects of the closure as well as alternatives to minimize harm impacts Florida's fishing communities was flawed or superficial. The court held that the DOC considered alternatives, and granted the DOC's motion for summary judgment.

<sup>258</sup> *National Association of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33 (D.D.C. 2000).

<sup>259</sup> *Id.* at 44.

<sup>260</sup> *Id.* Note that because of renumbering resulting from an added provision in the RFA, section 5 is now section 6.

<sup>261</sup> *Id.* at 42.

<sup>262</sup> *Southern Offshore Fishing Association v. Daley*, 995 F. Supp. 1411 (M.D. Fla. 1998).

court was the “agency’s apparently superficial analysis of less restrictive alternatives to the quota reduction. After extensive discussion and summary of its statistical modeling, [the agency’s] report devotes only four of fifty pages to considering potential alternatives.”<sup>263</sup>

Exceptions to the requirement of considering alternatives:

- Where uniform requirements are mandated by statute, a statement to that effect by the implementing agency obviates the need to solicit or consider proposals which include differing compliance standards.<sup>264</sup>
- Where the Secretary is not granted the authority to examine alternatives in implementing the regulation.<sup>265</sup>

### ***Analysis of the economic impact***

**What type of analysis must the agency conduct?** It is now well established that the RFA does not require an economic modeling, per se.<sup>266</sup> Rather, the RFA mandates only that the agency describe the steps it took “to minimize the economic impact on small entities consistent with the stated objectives of applicable statutes.”<sup>267</sup> Neither cost-benefit analysis nor economic modeling is specifically required,<sup>268</sup> as long as the agency compiles a meaningful, easily understood analysis that covers each requisite component dictated by the statute and makes the end product—whatever form it reasonably may take—readily available to the public.<sup>269</sup> However, such an examination may be required by the underlying statute or E.O. 12866, working in concert with the RFA.

An agency can satisfy the requirements of an economic impact analysis by providing either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or more general descriptive statements if quantification is not practicable or reliable.<sup>270</sup> Courts have stated that sufficient analysis and

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<sup>263</sup> Southern Offshore Fishing Association. at 1437.

<sup>264</sup> Greater Dallas Home Care Alliance v. United States, 10 F. Supp. 2d 638, 648 (N.D. Tex. 1998).

<sup>265</sup> Greater Dallas Home Care Alliance v. United States, 36 F. Supp. 2d 765, 769 (N.D. Tex. 1999).

<sup>266</sup> Alenco Communications, 201 F.3d at 625; see also Ashley County Med. Ctr 205 F. Supp. 2d at 1026; and Ace Lobster, 165 F. Supp. 2d at 184.

<sup>267</sup> Alenco Communications, 201 F.3d at 625.

<sup>268</sup> See National Telephone Cooperative Association v. Federal Communications Commission and United States of America, 563 F.3d 536, 385 U.S. App. D.C. 327, 47 Communications Reg. (P&F) 985 (C.A. D.C. 2009), where the court reiterated its previous finding that the RFA’s requirements are “purely procedural.” Though it directs the agencies to state, summarize, and describe, the act in and of itself imposes no substantive constraint on agency decisionmaking. The RFA requires agencies to publish analyses that address certain legally delineated topics. Because the analysis at issue addressed all of the legally mandated subject areas, it complied with the RFA. See also Association of American Physicians & Surgeons v. H.H.S., 224 F. Supp 2d 1115 (S.D. Tex. 2002).

<sup>269</sup> National Association of Mortgage Brokers at 178.

<sup>270</sup> Alenco Communications, 201 F.3d at 625.

explanations for the rejection of alternatives are all that is necessary to satisfy this requirement.<sup>271</sup>

Where the majority of businesses likely to experience impacts are deemed small, it follows that any attempt to reduce the adverse economic impacts of a regulation aimed at them is necessarily an attempt to minimize the negative effects of the regulation on small business.<sup>272</sup>

**What is the relevant economic impact that agencies should consider?** For the purpose of flexibility analysis, the relevant economic “impact” is the impact of compliance.<sup>273</sup>

The RFA requires only that the agency consider the economic effect on the entity, and not the effect on specific revenue earned.<sup>274</sup> This means that the agency need not consider how one particular element of the affected entity’s business is affected. Rather, the agency should evaluate the regulation’s entire effect.

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

It is important that the agency appropriately consider all relevant information. It has been held that although an agency has considerable discretion to act on the basis of less than perfect information when performing the analysis of the rule’s economic impact on small entities, it is not permissible to omit known information in order to skew the results.<sup>275</sup>

In *North Carolina Fisheries Ass’n v. Daley*,<sup>276</sup> the court examined the agency’s economic analysis. In performing the analysis, the Secretary of Commerce utilized criteria employed internally by the National Marine Fisheries Service (NMFS) in evaluating the economic impacts of regulations under the RFA. Thus, the Secretary considered the following criteria:<sup>277</sup>

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

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

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<sup>271</sup> *Ace Lobster*, 165 F. Supp. 2d at 185.

<sup>272</sup> *Associated Fisheries of Maine*, 127 F.3d at 115.

<sup>273</sup> *Mid-Tex*, 773 F.2d at 342.

<sup>274</sup> *Washington v. Daley*, 173 F.3d 1158, 1170 (9th Cir. 1999).

<sup>275</sup> *North Carolina Fisheries*, 27 F. Supp. 2d at 660.

<sup>276</sup> *Id.*

<sup>277</sup> It should be noted that NMFS no longer uses these criteria for its RFA analyses.

Based on the NMFS's internal guidelines, the Secretary found that there would be no significant economic impact on a substantial number of small businesses arising from the 1997 summer flounder quota. In making this determination, the economic analysis used the total number of vessels to be issued moratorium permits as “the universe for the evaluation of impacts.” The small entities or communities studied constituted the whole state of North Carolina. Examining the unadjusted 1997 quota first, the economic analysis stated that it was “possible” that criterion 1 would be triggered by reducing the income of more than 20 percent of the entire North Carolina fleet by more than 5 percent. The economic analysis next considered the NMFS's criterion under the initial 1997 quota adjustment. Under the adjustment, the economic analysis determined that 57 percent of the vessels with home ports in North Carolina are projected to have revenue reductions of greater than 5 percent. The economic analysis further maintained that an additional 43 percent of North Carolina's flounder fleet may have reduced revenues by 25 percent or more. Despite this assessment, the economic analysis concluded that there were no significant economic impacts and asserted that any adverse effects arising from the initial 1997 quota adjustment were offset by previous revenues the fishermen had earned from overfishing.<sup>278</sup> The court concluded that the Secretary prepared an economic analysis utterly lacking in compliance with the requirements of the RFA. In the first place, the Secretary did not consider a community any smaller than the entire state of North Carolina. In the second place, the Secretary completely ignored readily available data that would have shown the number of fishing vessels likely to experience the impacts of the agency's regulatory actions. The agency's economic analysis indicating that there would be no significant economic impact on a substantial number of small entities was the result of impermissibly considering too large a community and ignoring readily available data.<sup>279</sup>

### **Public comments**

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

**Must an agency always seek public comment?** An agency need not seek comment on information that is supplementary to the decision. That is to say, an agency is entitled to rely on information not exposed to comment only as long as it is not substantially related to the agency's rationale.<sup>280</sup> Any information relied on in the analytical process at all, however, must be included in the IRFA.

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<sup>278</sup> North Carolina Fisheries, 27 F. Supp. 2d at 660.

<sup>279</sup> *Id.*

<sup>280</sup> National Mining Association v. Chao, 160 F. Supp. 2d 47, 88 (D.D.C. 2001).



## Judicial review

The 1996 SBREFA amendment provides, for the first time, for judicial review of agency action under the RFA and allows the Chief Counsel for Advocacy to file as *amicus curiae* (friend of the court) in regulatory appeals. “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.”<sup>281</sup> The standard of review is whether the agency acted in a manner that was arbitrary and capricious.<sup>282</sup>

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<sup>281</sup> 5 U.S.C. § 612(b).

<sup>282</sup> National Association of Mortgage Brokers v. Board of Governors at 178.

## CHAPTER 6 SECTION 610 REVIEW OF EXISTING RULES

Section 610 of the Regulatory Flexibility Act<sup>283</sup> requires federal agencies to review regulations that have a significant economic impact on a substantial number of small entities<sup>284</sup> within 10 years of their adoption as final rules. In Executive Orders 13563 and 13579, President Obama reaffirmed the need for agencies to carry out retrospective analyses of existing rules.<sup>285</sup> For example, Executive Order 13563 says that:

Within 120 days of the date of this order, each agency shall develop and submit to the Office of Information and Regulatory Affairs a preliminary plan, consistent with law and its resources and regulatory policies, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.<sup>286</sup>

Executive Order 13579 reiterates the provisions relating to retrospective analyses of existing rules, noting that independent agencies should, within 120 days of the date of the order, develop and release to the public a plan as described in E.O. 13563.<sup>287</sup> President Obama issued a memorandum with the executive order, asking the independent agencies to reassess their regulations and to follow the principles of E.O. 13563.

These periodic rule reviews are a mechanism for agencies to assess the impact of existing rules on small entities and to determine whether the rules should be continued without change, or should be amended or rescinded, consistent with the objectives of applicable statutes. Agency compliance with section 610's periodic review requirement has varied substantially from agency to agency since 1980.<sup>288</sup> While some agencies systematically review all of their existing rules, other agencies review few, if any, of their current rules. Agencies also vary considerably in the amount of public involvement they allow, and the amount of information they provide to the public about their reviews.

Statements made during the 1980 debate on the Regulatory Flexibility Act demonstrate that Congress intended for section 610 to be a mechanism that requires agencies to

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<sup>283</sup> 5 U.S.C. § 610 (2000).

<sup>284</sup> "Small entities" include small businesses that meet the Small Business Administration size standard for small business concerns at 13 C.F.R. § 121.201, small governmental jurisdictions with a population of less than 50,000, and small organizations that are independently owned not-for-profit enterprises and which are not dominant in their field. See 5 U.S.C. §§ 601(3)-(5).

<sup>285</sup> Exec. Order No. 13,563 § 6 and Exec. Order No. 13,579 § 2.

<sup>286</sup> Exec. Order No. 13,563 § 6(b).

<sup>287</sup> Exec. Order No. 13,579 § 2(b).

<sup>288</sup> See, for example, Government Accountability Office, *Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews* (GAO-07-791), July 2007; General Accounting Office, *Regulatory Flexibility Act: Agencies' Interpretations Vary* (GAO/GGD-99-55) April 1999. See also Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement – and Current Proposals to Invigorate the Act*, 33 *Fordham Urb. L.J.* 1199-1255 (2006).

periodically re-examine the regulatory burden of their rules vis-à-vis small entities, considered in the light of changing circumstances.<sup>289</sup> This view was also reflected in Advocacy's initial 1982 guidance explaining the then-new RFA, which stated that

The RFA requires agencies to review all existing regulations to determine whether maximum flexibility is being provided to accommodate the unique needs of small businesses and small entities. Because society is not static, changing environments and technology may necessitate modifications of existing, anachronistic regulations to assure that they do not unnecessarily impede the growth and development of small entities.<sup>290</sup>

## **RFA section 610 review**

The objective of a section 610 review is like the goal of many other retrospective rule reviews:<sup>291</sup> to determine whether an existing rule is actually working as it was originally intended and whether revisions are needed. Has the problem the rule was designed to address been solved? Are regulated entities (particularly small entities) able to comply with the rule as anticipated by the agency? Are the costs of compliance in line with the agency's initial estimates? Are small businesses voicing continuing concerns about the difficulty they have complying with the rule? The section 610 review is an excellent way to address these questions.

### ***Review of rules that were originally certified***

In some cases, even if an agency was originally able to certify properly under section 605 of the RFA that a rule would not have a significant economic impact on a substantial number of small entities,<sup>292</sup> changed conditions may mean that the rule now does have a significant impact and therefore should be reviewed under section 610. For

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<sup>289</sup> House Debate on the Regulatory Flexibility Act, 142 Cong. Rec. H24,575, H24,583-585 (daily ed. Sept. 8, 1980) (“At least once every 10 years, agencies must assess regulations currently on the books, with a view toward modification of those which unduly impact on small entities.” (Statement of Rep. McDade)) (“[A]gencies must review all regulations currently on the books and determine the continued need for any rules which have a substantial impact on small business.” (Statement of Rep. Ireland)). Similarly, the section-by-section analysis of the periodic review provision of S. 299, which became the RFA, notes that the required factors in a section 610 review mirror the evaluative factors in President Carter's Executive Order 12,044, *Improving Government Regulations*. Exec. Order 12,044, 43 Fed. Reg. 12,661 (March 24, 1978). Pursuant to that Executive Order, President Carter issued a Memorandum to the Heads of Executive Departments and Agencies in 1979, further instructing federal agencies: “As you review existing regulatory and reporting requirements, take particular care to determine where, within statutory limits, it is possible to tailor those requirements to fit the size and nature of the businesses and organizations subject to them.” President Jimmy Carter, Memorandum to the Heads of Executive Departments and Agencies, November 16, 1979.

<sup>290</sup> Office of Advocacy, *The Regulatory Flexibility Act* (October 1982).

<sup>291</sup> Typical agency-initiated retrospective regulatory reviews include post-hoc validation studies, reviews conducted pursuant to petitions for rulemaking or reconsideration, paperwork burden reviews, and reviews undertaken to advance agency policies.

<sup>292</sup> See 5 U.S.C. § 605(b).

example, many more small businesses may be subject to the rule now than when the rule was promulgated. The cost of compliance with a current rule may have increased sharply because of a required new technology. If there is evidence (such as new cost or burden data) that a rule is now having a significant economic impact on a substantial number of small entities, including small communities or small nonprofit organizations, Advocacy believes that the agency should conduct a section 610 review.

Advocacy is aware that some agencies interpret section 610 not to require the periodic review of rules that were originally certified when they were promulgated as having no significant economic impact on a substantial number of small entities. This narrow interpretation of the section 610 review requirements discounts several important considerations. First, evidence of significant current impacts to small entities from an existing rule may call into question the accuracy of the original determination that the rule would have no significant impact. Second, as time passes and the agency (along with regulated small entities) is better able to measure and understand the impacts of a regulation, it benefits the agency to use the periodic review process to update their rules and perform regulatory “housekeeping.” Third, limiting section 610 reviews only to rules that were found to have a significant economic impact on a substantial number of small entities at the time of promulgation would severely undercut the intent of section 610. EPA and OSHA, for example—which between them determine that at most one or two rules each year will have such an impact—will exclude from section 610 review each of the hundreds of other rules promulgated annually that may now have a significant impact on small entities. Given the legislative history of section 610, it is very difficult to believe that Congress intended this outcome. Finally, a reading of the plain language of section 610 supports Advocacy’s interpretation. If Congress meant to limit periodic reviews, it would have simply required agencies to review rules that originally had a significant impact, rather than rules that now have a significant impact.

An agency may learn about the current impacts of an existing rule through complaints from small entities or petitions for a section 610 or other retrospective review of the rule. If these complaints and/or petitions are founded on reliable cost and impact data, the agency will have a clear indication that the rule is now having an impact on small entities.

### ***Scope of the review***

Once an agency has determined that an existing rule has a significant economic impact on a substantial number of small entities at the present time, the agency’s section 610 review should, at a minimum, address each of the five factors listed in section 610(b)(1)-(5):

- Whether or not there a continuing need for this rule, consistent with the stated objectives of the applicable statutes;
- Whether the public has ever submitted comments or complaints about this rule;
- The degree of complexity of this rule;
- Whether some other federal or state requirement accomplishes the same regulatory objective as this rule; and

- The length of time since the agency has reviewed this rule, and/or the extent to which circumstances have changed which may affect regulated entities.

Particular attention should be paid to changes in technology, economic circumstances, competitive forces, and the cumulative burden faced by regulated entities. Has the impact of the rule on small entities remained the same?

Section 610(b) requires an agency to evaluate and minimize “any significant economic impact of a rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes.” To accomplish this, agencies may want to use an economic analysis similar to the initial regulatory flexibility analysis (IRFA) under section 603 of the RFA, taking into account the limitations on data availability and limited agency resources.<sup>293</sup> Agencies have the discretion to place significant weight on other relevant factors, in addition to the types of economic data required by an IRFA. These other factors include an agency’s experience in implementing the rule, as well as the views expressed over time by the public, regulated entities, and Congress. With the benefit of actual experience with a rule, the agency and other interested parties should be in a good position to evaluate potential improvements to the rule. Several factors deserve attention here, such as the benefits achieved by the regulation, unintended market effects and market distortions, unusually high firm mortality rates in specific industry sub-sectors, and widespread noncompliance with reporting and other paperwork requirements. Thus, a useful review should go beyond obvious measures such as ensuring that regulatory requirements are expressed in plain language and that paperwork can be filed electronically. The analysis should be aimed at understanding and reducing burdens that unnecessarily have a significant impact on small entities.

As a matter of good practice, the section 610 analysis should be based on relevant data, public comments, and agency experience. The agency should make use of available information and data supplied by the public, and indicate the sources of the data. To the extent that an agency relies on specific data to reach a conclusion about the continuing efficacy of a rule, the agency should be able to provide that data. The agency should explain its assumptions so that stakeholders can understand its analysis.

### ***Timing of the review***

The language of section 610 specifies that the review should take place within 10 years after the date a rule is promulgated. While agencies need to gain some experience with a rule before undertaking a retrospective review, the review may take place prior to the 10-year mark. If an agency substantially revises a rule after its initial promulgation, it is

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<sup>293</sup> See 5 U.S.C. § 603. The legislative history of S.299, which became the RFA, notes that “[i]n reviewing existing rules, agencies should follow the procedures described in sections 602-609 [of the RFA] to the extent appropriate.” 142 Cong. Rec. H24,575, H24,583-585 (daily ed. Sept. 8, 1980). In the context of a section 610 review, the elements of an IRFA analysis that should be present include: a discussion of the number and types of small entities affected by the rule, a description of the compliance requirements of the rule and an estimate of their costs, identification of any duplicative or overlapping requirements, and a description of possible alternative regulatory approaches.

arguable whether the 610 review may be delayed to correspond to the revision date. Advocacy would not likely object to a revision of the date, but agencies should seek input from Advocacy on this point.

Section 610 does not specifically set a limit on the amount of time for a rule review. Some agencies have reported that they spend more than a year on each section 610 review. It is within an agency's discretion to determine how much time it needs to spend on retrospective rule reviews. Advocacy recognizes that section 610 reviews may take more than a year in order to permit adequate time to gather and analyze data, to allow public comment, and to consider those comments in the review. Of course, some reviews could take less time, based on the complexity of the issues and the nature of the regulated industry.

Agencies may wish to take advantage of the opportunity afforded in section 605(c) of the RFA to consider a series of "closely related rules" as one rule for periodic review purposes. An agency can accomplish a comprehensive section 610 review of closely related rules, satisfying the requirements of the RFA while potentially reducing the agency resources required.

### ***Outreach to regulated small entities***

Section 610(c) of the RFA requires agencies to publish in the *Federal Register* a list of the rules they plan to review in the upcoming year. Agencies use the *Unified Regulatory Agenda* for this purpose.<sup>294</sup> This listing requirement is intended to give small entities early notice of the section 610 reviews so that they will be ready and able to provide the agency with comments about the rule under review. As a practical matter, however, agencies often give stakeholders no other information about the ongoing status of a section 610 review, what factors an agency is considering in conducting the review, how comments can be submitted to the agency, or the factual basis on which the agency made its section 610 review findings.

Agencies should communicate with interested entities about the status of ongoing section 610 reviews, as well as those they have completed, to enhance transparency. This information may be most efficiently communicated via an agency website or other electronic media, and should inform interested parties of their ability to submit comments, as well as the agency's commitment to consider those comments. Several agencies already utilize web-based communications as an outreach tool during section 610 reviews.<sup>295</sup>

Insights about an existing regulation received from regulated entities and other interested parties should be a key component of a retrospective rule review. By making the review process transparent and accessible, agencies are more likely to identify improvements that will benefit all parties at the conclusion of the review. Advocacy can help agencies who wish to communicate with small entity stakeholders by hosting roundtables, working

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<sup>294</sup> The *Unified Regulatory Agenda* can be accessed at <http://www.reginfo.gov>.

<sup>295</sup> See, e.g., [www.osha.gov](http://www.osha.gov), [www.epa.gov](http://www.epa.gov), and [www.dot.gov](http://www.dot.gov) and search for "RFA section 610."

through trade groups, and getting a specific message to a targeted audience. Advocacy is ready to assist agencies in their outreach efforts.

### ***Using other agency reviews to satisfy section 610***

Agencies that undertake retrospective rule reviews to satisfy other agency objectives may also be able to satisfy the periodic review requirement of section 610, as long as the rule reviews are functionally equivalent. For example, agencies that evaluated a current regulation pursuant to Executive Order 13563<sup>296</sup>, or earlier, the Office of Management and Budget's 2002 publicly nominated rule reform process<sup>297</sup> or OMB's manufacturing rule reform process<sup>298</sup> could qualify as section 610 reviews, if they otherwise met the criteria for section 610 review. Similarly, agencies that undertook retrospective reviews of their regulatory programs because of complaints or petitions from regulated entities could qualify as section 610 reviews – as long as the review includes the minimum factors required by section 610. The best way for agencies to get “credit” for a section 610 review in these circumstances is to communicate adequately with stakeholders, and with Advocacy.

### **Examples of successful retrospective rule reviews**

**Federal Railroad Administration's Section 610 Review of Railroad Workplace Safety.** On December 1, 2003, the Department of Transportation's Federal Railroad Administration (FRA) completed a section 610 review of its railroad workplace safety regulations. After determining that the workplace safety regulations had a significant economic impact on a substantial number of small entities, the FRA examined the rules in light of section 610's review factors. Although the FRA did not recommend any regulatory change as a result of this review, they provided a good description of its analysis of the workplace safety regulations under each review factor and the agency's conclusions.<sup>299</sup>

**EPA's RCRA Review.** As a result of public nominations for reforms to the Environmental Protection Agency's hazardous waste management program under the Resource Conservation and Recovery Act (RCRA), EPA evaluated the program and identified duplicative requirements, such as forcing filers to submit reports to multiple locations when one location is adequate. By reducing or eliminating these procedures

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<sup>296</sup> See, for example, p. 61 of 2011 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities (2011) available at [http://www.whitehouse.gov/sites/default/files/omb/inforeg/2011\\_cb/2011\\_cba\\_report.pdf](http://www.whitehouse.gov/sites/default/files/omb/inforeg/2011_cb/2011_cba_report.pdf).

<sup>297</sup> See Table 9, “New Reforms Planned or Underway – Regulations” and Table 10, “New Reforms Planned or Underway – Guidance Documents” in *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (September 2003) at 26-34; available at [http://yosemite.epa.gov/SAB/sabcvpress.nsf/0/5143268e911789ba85256db900562c4b/\\$FILE/2003\\_cost-ben\\_final\\_rpt.pdf](http://yosemite.epa.gov/SAB/sabcvpress.nsf/0/5143268e911789ba85256db900562c4b/$FILE/2003_cost-ben_final_rpt.pdf).

<sup>298</sup> See Regulatory Reform of the U.S. Manufacturing Sector (2005) at [http://georgewbush-whitehouse.archives.gov/omb/inforeg/reports/manufacturing\\_initiative.pdf](http://georgewbush-whitehouse.archives.gov/omb/inforeg/reports/manufacturing_initiative.pdf).

<sup>299</sup> See [http://www.fra.dot.gov/downloads/safety/railroad\\_workplace\\_safety.pdf](http://www.fra.dot.gov/downloads/safety/railroad_workplace_safety.pdf).

after public notice and comment, EPA enabled regulated entities to collectively save up to \$3 million per year while preserving the protections of the RCRA program. The retrospective review was successful because it involved a detailed review of the program's requirements and their costs, based on years of practical experience. The agency considered technical changes such as computerization that have made some of the older paperwork requirements redundant, and found ways to modernize the program to reflect current realities.<sup>300</sup>

**OSHA Excavations Standard.** In March 2007, the Occupational Safety and Health Administration completed a section 610 review of its rules governing excavations and trenches. These standards had been in place since 1989, and were designed to ensure that trenches do not collapse on workers and that excavated material does not fall back into a trench and bury workers. In the review, OSHA did a good job of seeking public input on how and whether the rule should be changed. While the agency ultimately decided that no regulatory changes to the standard were warranted, it did determine that additional outreach and worker training would help continue the downward trend of fewer deaths and injuries from trench and excavation work. OSHA concluded that its current excavations standard has reduced deaths from approximately 90 per year to about 70 per year.<sup>301</sup>

**FCC Section 610 Review of 1993-1995 Rules.** In May 2005, the Federal Communications Commission undertook a section 610 review of rules the Commission adopted in 1993, 1994, and 1995 which have, or might have, a significant economic impact on a substantial number of small entities. The FCC solicited public comment on the rules under review, explained the criteria it was using to review the rules, and gave instructions on where to file comments. This approach was transparent because the agency allowed adequate time for comments (three months) and gave interested parties sufficient information to prepare useful comments.<sup>302</sup>

## **Section 610 assistance from the Office of Advocacy**

The Office of Advocacy is ready to assist agencies that are planning a retrospective review of their regulations, to ensure that the review fully meets the requirements of section 610. Discussions with the Office of Advocacy are confidential interagency communications, and the Advocacy staff is ready to assist. For more information about this guidance, or for other questions about compliance with section 610, contact Advocacy at (202) 205-6533.

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<sup>300</sup> 71 Fed. Reg. 16,862 (April 4, 2006).

<sup>301</sup> 72 Fed. Reg. 14,727 (March 29, 2007).

<sup>302</sup> 70 Fed. Reg. 33,416 (June 8, 2005).



## CHAPTER 7 ADDITIONAL RFA AND SBREFA REQUIREMENTS

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

### Semi-annual regulatory agenda

Section 602 of the RFA requires federal agencies to publish a regulatory flexibility agenda in the *Federal Register* during April and October of each year.<sup>303</sup> Each agency is required to list all rules it expects to propose or promulgate that are likely to have a significant economic impact on a substantial number of small entities. To be useful to small entities, the regulatory flexibility agenda should include a realistic assessment of the regulations under consideration by the agency for development in the coming year. Agencies generally prepare and publish their regulatory flexibility agenda with the unified regulatory agenda required by Executive Order 12866.<sup>304</sup>

The regulatory flexibility agenda must contain:

- A brief description of the subject area of any rule the agency expects to propose or promulgate that is likely to have a significant economic impact on a substantial number of small entities. (See Chapter 1 of this guide for a discussion of how to certify a rule.)
- A summary of the nature of each such rule under consideration, the objectives and the legal basis for issuing each rule, and an approximate schedule for completing action on any rule for which an agency has issued a general notice of proposed rulemaking.
- The name and telephone number of an agency official knowledgeable about the rule.

The RFA requires agencies to endeavor to provide direct notification of the agenda to small entities or their representatives, or to publish the agenda in publications that small entities are likely to receive, and to invite comments in the agenda.<sup>305</sup>

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<sup>303</sup> 5 U.S.C. § 602(a).

<sup>304</sup> Exec. Order 12,866 § 4(b).

<sup>305</sup> See § 609 of the RFA regarding the outreach to small entities to obtain needed comment during agency rulemaking. An example of a useful outreach tool is the U.S. Department of Transportation's Docket Management System (DMS). DMS offers a service (listserv) to which a small entity can subscribe and tailor to receive notification when certain documents reach the DMS.

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

## **Small entity compliance guides**

For each rule (or related series of rules) requiring a final regulatory flexibility analysis, section 212 of SBREFA requires the agency to publish one or more small entity compliance guides.<sup>306</sup> Agencies are required to publish the guides with publication of the final rule, post them to websites, distribute them to industry contacts, and report annually to Congress.<sup>307</sup>

Agency compliance with this requirement is varied.<sup>308</sup> In other words, unless the agency is going to certify that the rule will not have a significant economic impact on a substantial number of small entities, the agency must issue a small entity compliance guide, and designate it as such. As appropriate to the rule, Advocacy urges agencies to write the small entity compliance guide in plain and simple language. It should be readily understandable from the perspective of small entities subject to the rule. The guide is to inform a small entity of its obligations and responsibilities under the rule. It may be appropriate to prepare separate guides for different classes or groups of small entities. The guides may cover federal and state requirements affecting the small entities subject to the rule.<sup>309</sup>

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

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<sup>306</sup> Small Business Regulatory Enforcement Fairness Act, Pub. Law 104-121 § 212.

<sup>307</sup> The Small Business and Work Opportunity Act of 2007 added these additional requirements for agency compliance to SBREFA.

<sup>308</sup> See generally Regulatory Reform: Compliance Guide Requirement Has Had Little Effect on Agency Practices (GAO-02-172, December 2001).

<sup>309</sup> See § 215 of the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 857 (codified at 5 U.S.C. § 601 et seq.).

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

Although the compliance guide requirement under SBREFA is not specific in many regards as to what agencies are required to do, Advocacy has noted several instances in which agencies have failed to meet even the most basic requirements of the statute. For instance, the Federal Acquisition Regulation (FAR) Council<sup>310</sup> published a list of rules for which a FRFA was prepared. This is not a compliance guide.

Compliance guides issued pursuant to section 212 are not subject to judicial review under SBREFA; however, the content of the compliance guide may serve as evidence of the reasonableness or appropriateness of any proposed fines, penalties, or damages in a civil or administrative action against a small business for a violation.<sup>311</sup>

## **Informal compliance assistance**

Section 213 of SBREFA acknowledges the importance of compliance assistance and directs agencies that regulate small entities to establish a practice of answering inquiries from small entities. Agencies are to provide information and advice about compliance, helping small entities interpret and apply the law to specific facts provided by the small entity making the inquiry. As with the content of the compliance guides, guidance given by agencies on how the law is to be applied to a specific factual situation provided by the small entity may be considered evidence of the reasonableness or appropriateness of proposed fines, penalties, or damages imposed on the small entity. Under this section, and using existing resources as practicable, agencies are to institute a practice of providing informal compliance assistance. Agencies were required to establish a program to provide informal compliance assistance within one year of SBREFA's enactment in 1996 and to report to Congress on their programs no later than two years after enactment.<sup>312</sup>

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<sup>310</sup> The (FAR Council prepares and issues revisions to the uniform policies and procedures for acquisition by all executive agencies. The FAR Council does this in conjunction with the Defense Acquisition Regulations (DAR) Council and the Civilian Agency Acquisition (CAA) Council. 48 C.F.R § 1 (2000).

<sup>311</sup> Sections 231–233 of SBREFA amended the Equal Access to Justice Act (EAJA). These provisions expanded the ability of parties in litigation with the government to recover attorney fees under that law. In administrative and judicial proceedings, if the government's demand to enforce a party's compliance with a statutory or regulatory requirement is unreasonable when compared with the judgment or decision, the party may be entitled to attorney fees and other expenses related to defending against the action. SBREFA increased the allowable attorney fees from \$75 per hour to \$125 per hour.

<sup>312</sup> The Committee on Small Business and the Committee on Governmental Affairs of the U.S. Senate and the Committee on Small Business and the Committee on the Judiciary of the U.S. House of Representatives were to receive agency reports required under sections 213 and 223 of SBREFA.

## Regulatory enforcement fairness

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

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

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

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

## Penalty reduction policies

Agencies regulating activities of small entities are required, under section 223 of SBREFA, to establish a policy or program to provide for the reduction (and, under appropriate circumstances, the waiver) of civil penalties for violations of a statutory or regulatory requirement by a small entity. SBREFA grants agencies broad discretion with respect to the scope of their penalty reduction and waiver policies.<sup>313</sup> Agencies were to implement their small entity penalty reduction and waiver programs within one year of the enactment of SBREFA in 1996 and to report on their programs to Congress one year later.<sup>314</sup> Under appropriate circumstances, an agency may consider the ability to pay as a factor in determining penalty assessments on small entities.

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

- Requiring a small entity to correct the violation within a reasonable period of time.

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<sup>313</sup> See generally *Regulatory Reform: Implementation of Selected Agencies' Civil Penalty Relief Policies for Small Entities* (GAO-01-280, February 2001). The Office of Advocacy maintains that agencies should define small entities in accordance with section 601 of the RFA.

<sup>314</sup> Approximately 22 of the 77 agencies that assess penalties submitted a report pursuant to section 223 of SBREFA. House of Representatives Report 106-8, Part I, pp. 5-6.

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

## Congressional review

The Congressional Review Act, Section 251 of the Contract with America Advancement Act of 1996 (which also includes SBREFA), requires agencies to provide Congress with notice of final agency rulemaking actions and the opportunity to review a “major rule” before it becomes effective.<sup>315</sup> Before a final rule can become effective, the agency promulgating the rule must submit a report to the House of Representatives, the Senate, and the Comptroller General of the U.S. Government Accountability Office (GAO).<sup>316</sup> The report must contain the following information:

- A copy of the rule.
- A concise general statement about the purpose of the rule, including whether it is a “major rule.”<sup>317</sup>
- The proposed effective date of the regulation.

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

- A copy of the cost-benefit analysis of the rule, if any.
- The agency's actions relevant to sections 603, 604, 605, 607, and 609 of the RFA.
- The agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995.<sup>318</sup>

Major rules cannot take effect until the end of a 60-legislative-day period beginning on the latter of: (1) the date Congress receives the agency’s report or (2) the date of the

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<sup>315</sup> Codified at Chapter 8 of title 5, United States Code.

<sup>316</sup> 5 U.S.C. § 801. The GAO’s website, <http://www.gao.gov>, includes information on major rules, including a form for submitting a rule under the Congressional Review Act (<http://www.gao.gov/decisions/majrule/fedrule2.pdf>).

<sup>317</sup> A “major rule” is a rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) finds has resulted or is likely to result in an annual impact on the economy of \$100 million or more; have a major impact on an industry, government, or consumers; or have an effect on competition, productivity, or international trade. 5 U.S.C. § 804(2).

<sup>318</sup> 2 U.S.C. § 1501.

rule's publication in the *Federal Register*. Congress may disapprove or rescind a rule by a joint resolution of disapproval, subject to a presidential veto.<sup>319</sup>

## CONCLUSION

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

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

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

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<sup>319</sup> This congressional authority was first used in S. J. Res. 6, introduced in accordance with 5 U.S.C. § 802, passed the House and Senate, and was signed into law on March 20, 2001 to prevent an ergonomics regulation issued by the Occupational Safety and Health Administration from going into effect.

## 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), the Dodd-Frank Wall Street Reform and Consumer Protection Act (P.L. 111-203), and the Small Business Jobs Act of 2010 (P.L. 111-240).

### 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
- § 602 Regulatory agenda
- § 603 Initial regulatory flexibility analysis
- § 604 Final regulatory flexibility analysis
- § 605 Avoidance of duplicative or unnecessary analyses
- § 606 Effect on other law
- § 607 Preparation of analyses
- § 608 Procedure for waiver or delay of completion
- § 609 Procedures for gathering comments
- § 610 Periodic review of rules
- § 611 Judicial review
- § 612 Reports and intervention rights

### **§ 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.

(d) (1) For a covered agency, as defined in section 609(d)(2), each initial regulatory flexibility analysis shall include a description of—

(A) any projected increase in the cost of credit for small entities;

(B) any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any increase in the cost of credit for small entities; and

(C) advice and recommendations of representatives of small entities relating to issues described in subparagraphs (A) and (B) and subsection (b).

(2) A covered agency, as defined in section 609(d)(2), shall, for purposes of complying with paragraph (1)(C)—

(A) identify representatives of small entities in consultation with the Chief Counsel for Advocacy of the Small Business Administration; and

(B) collect advice and recommendations from the representatives identified under subparagraph (A) relating to issues described in subparagraphs (A) and (B) of paragraph (1) and subsection (b).

#### **§ 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 statement of the need for, and objectives of, the rule;

(2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement 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) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;

(4) 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;

(5) 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;

(6) 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;

(6)<sup>1</sup> for a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

(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..

<sup>1</sup>So in original. Two paragraphs (6) were enacted.

#### **§ 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 advance notice of proposed rulemaking, if issued, of a statement that the proposed rule may have a significant economic effect on a substantial number of small entities;

(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

(1) the Environmental Protection Agency,

(2) the Consumer Financial Protection Bureau of the Federal Reserve System; and

(3) 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 RFA RECENT DEVELOPMENTS

January 31, 2011

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Winslow Sargeant, Ph.D  
Chief Counsel for Advocacy, U.S. Small Business Administration

SUBJECT: Regulatory Flexibility Act: Recent Developments

As required by Executive Order 13272<sup>1</sup>, I am writing to advise you of recent activity related to the Regulatory Flexibility Act (RFA) and provide additional guidance related to these changes.

Since 2007, several amendments to the RFA have become law, and this memorandum describes these changes. President Obama has also recently expressed his renewed commitment to regulatory review and regulatory relief. On January 18, 2011, President Obama issued Executive Order 13563, "Improving Regulation and Regulatory Review,"<sup>2</sup> and a Memorandum on Regulatory Flexibility, Small Business, and Job Creation.<sup>3</sup>

The Office of Advocacy strongly endorses these principles and policies and is ready to assist you and your agencies in compliance with the RFA, Executive Order 13563, and the President's memorandum. The Office of Advocacy provides RFA training to agencies as required by Executive Order 13272. Requests for training should be directed to Claudia Rodgers, Deputy Chief Counsel for Advocacy, [Claudia.Rodgers@sba.gov](mailto:Claudia.Rodgers@sba.gov).

### **The Small Business and Work Opportunity Act of 2007 requires timely publication of small entity compliance guides.**

Congress enacted additional requirements for agency compliance guides in 2007, as part of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007.<sup>4</sup> This statute requires an agency to:

- Publish one or more „small entity compliance guides" for any rule for which it must prepare a Final Regulatory Flexibility Analysis;<sup>5</sup>

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<sup>1</sup> Executive Order 13272, signed August 13, 2002 (67 Fed. Reg. 53,461 (August 16, 2002)). Section 2(a) requires the Chief Counsel for Advocacy to "notify agency heads from time to time of the requirements of the [Regulatory Flexibility] Act."

<sup>2</sup> 76 Fed. Reg. 3821 (January 21, 2011).

<sup>3</sup> Memorandum for the Heads of Executive Departments and Agencies, "Regulatory Flexibility, Small Business, and Job Creation" (76 Fed. Reg. 3827 (January 21, 2011)).

<sup>4</sup> Pub. Law 110-28 (May 27, 2007). See Title VI, Subtitle B, sec. 7005.

<sup>5</sup> See 5 U.S.C. 604 for the requirements for a Final Regulatory Flexibility Analysis.



- Publish these guides with publication of the final rule, if possible, but before the effective date of the rule;
- Post these guides to its website and distribute to known industry contacts; and
- Report annually to Congress.

The statute also describes generally what should be included in a compliance assistance guide.

**The Dodd-Frank Wall Street Reform and Consumer Protection Act requires Small Business Advocacy Panels for CFPB rulemakings.**

The Dodd-Frank Wall Street Reform and Consumer Protection Act,<sup>6</sup> passed July 2010, establishes the Consumer Financial Protection Bureau (CFPB) to supervise certain activities of financial institutions. This Act requires the CFPB to comply with the RFA section 609 panel process, making it the third agency with this responsibility, joining EPA and OSHA.<sup>7</sup> The Office of Advocacy looks forward to working with this new agency.

**The Small Business Jobs Act of 2010 requires Final Regulatory Flexibility Analyses to be more detailed and to respond to Advocacy comments.**

On September 27, 2010, President Obama signed into law the Small Business Jobs Act of 2010.<sup>8</sup> This act amended the RFA by making the following three changes to the requirements for Final Regulatory Flexibility Analyses.

- It struck the word “succinct” from the requirement for “a succinct statement of the need for, and objectives of, the rule.”<sup>9</sup>
- It replaced the word “summary” with the word “statement” in the requirement for “a summary statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary statement 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.”<sup>10</sup>
- It added a new paragraph to require “the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.”<sup>11</sup>

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<sup>6</sup> Pub. Law 111-203 (July 21, 2010).

<sup>7</sup> *Id.*, Sec. 1100G. *See* 5 U.S.C. § 609(d).

<sup>8</sup> Pub. Law 111-240 (September 27, 2010).

<sup>9</sup> *Id.*, Sec. 1601(1), amending 5 U.S.C. § 604(a)(1).

<sup>10</sup> *Id.*, Sec. 1601(2), amending 5 U.S.C. § 604(a)(2).

<sup>11</sup> *Id.*, Sec. 1601(3), inserting 5 U.S.C. § 604(a)(3). This codifies the requirement from E.O. 13272, Sec. 3(c) without an exemption for a public interest.

**Executive Order 13563 requires consultation with affected entities and reviews of existing regulations.**

Executive Order 13563, Improving Regulation and Regulatory Review,<sup>12</sup> reaffirms the principles of Executive Order 12866, including the consideration of alternatives, cost-benefit analysis, and the consideration of distributional and cumulative economic impacts. These principles reinforce the agencies' obligations under the RFA.

This new Executive Order instructs agencies to seek the views of affected entities prior to proposed rulemaking.<sup>13</sup> The Office of Advocacy strongly urges agencies to ensure their consultations include small entities. We are available to assist you in arranging these consultations or identifying appropriate small entities with which to consult.

The Executive Order also calls on agencies to engage in periodic reviews of existing regulations.<sup>14</sup> Agencies already have an existing obligation to periodically review regulations under the RFA.<sup>15</sup> In your development of plans for reviews of existing regulations, I strongly encourage you to consider your obligations under the RFA and integrate the two efforts. The Office of Advocacy is available to consult with you on your agency's plans.

**The President's Memorandum on Regulatory Flexibility, Small Business, and Job Creation reaffirms the purposes of the RFA.**

On January 18, 2011, President Obama signed a memorandum<sup>16</sup> to you in which he stated:

My Administration is firmly committed to eliminating excessive and unjustified burdens on small businesses, and to ensuring that regulations are designed with careful consideration of their effects, including their cumulative effects, on small businesses.

He emphasized the importance of compliance with the RFA and its purposes. The President also expanded the existing requirement for an agency to document its decision to reject an alternative that may reduce regulatory burdens on small entities. The RFA currently requires agencies to explain in the Final Regulatory Flexibility Analysis accompanying final rules why significant alternatives were not selected.<sup>17</sup> The President has directed that a similar explanation be provided for proposed rules as well.<sup>18</sup>

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<sup>12</sup> 76 Fed. Reg. 3821 (January 21, 2011).

<sup>13</sup> E.O. 13563, Sec. 2(c).

<sup>14</sup> *Id.*, Sec. 6.

<sup>15</sup> *See* 5 U.S.C. § 610.

<sup>16</sup> Memorandum for the Heads of Executive Departments and Agencies, "Regulatory Flexibility, Small Business, and Job Creation" (76 Fed. Reg. 3827 (January 21, 2011)).

<sup>17</sup> *See* 5 U.S.C. § 604(a)(5) ("... 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.")

<sup>18</sup> *See* 76 Fed. Reg. 3827 ("I further direct that whenever an executive agency chooses, for reasons other than legal limitations, not to provide such flexibility in a proposed or final rule that is likely to have a significant economic

I remind you that alternatives include, but are not limited to, the flexible approaches described in section 4 of E.O. 13563, and the alternatives enumerated in the RFA19 and the President's memorandum. Alternatives under the RFA may include reasonable regulatory alternatives that relieve burden on all affected entities, not just small entities. I encourage agencies to consider all reasonable regulatory alternatives that impact small entities in their RFA analyses.

**Regulatory Flexibility Analyses should be readily available to and easily identified by the public.**

In light of the President's renewed commitment to the principles of Executive Order 12866 and the RFA, and in the spirit of transparency in decisionmaking, I want to remind you that Regulatory Flexibility Analyses must be available to the public at the same time as the proposed or final rule.<sup>20</sup> While Advocacy generally encourages agencies to publish Regulatory Flexibility Analyses or summaries in a separate RFA section within the rule preamble for transparency purposes, your agency is not required to prepare a wholly separate analysis to comply with the RFA.<sup>21</sup> However, your agency should make sure that those sections of the preamble or other supporting documents intended to demonstrate compliance with the RFA are labeled as such. For example, in responding to public comments filed by the Chief Counsel for Advocacy, I recommend you separately identify Advocacy comments and label your response as being presented in compliance with the RFA.

If you have any questions about this memorandum or your agency's compliance with the RFA, please contact Charles Maresca, Director of Interagency Affairs, SBA Office of Advocacy, at (202) 205-6978 or [Charles.Maresca@sba.gov](mailto:Charles.Maresca@sba.gov).

cc: Cass R. Sunstein, Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget

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impact on a substantial number of small entities, it should explicitly justify its decision not to do so in the explanation that accompanies that proposed or final rule.”)

<sup>19</sup> See § 603(c).

<sup>20</sup> See 5 U.S.C. § 603(a) and § 604(c).

<sup>21</sup> See 5 U.S.C. § 605(a).

## APPENDIX C SMALL BUSINESS BY THE NUMBERS

### Frequently Asked Questions About Small Business

#### What is a small business?

The Office of Advocacy defines a small business as an independent business having fewer than 500 employees. (The definition of “small business” used in government programs and contracting varies by industry; see <http://www.sba.gov/size>.)

#### How important are small businesses to the U.S. economy?

##### Small firms:

- Represent 99.7 percent of all employer firms.
- Employ about half of all private sector employees.
- Pay 43 percent of total U.S. private payroll.
- Have generated 65 percent of net new jobs over the past 17 years.
- Create more than half of the nonfarm private GDP.
- Hire 43 percent of high tech workers (scientists, engineers, computer programmers, and others).
- Are 52 percent home-based and 2 percent franchises.
- Made up 97.5 percent of all identified exporters and produced 31 percent of export value in FY 2008.
- Produce 16.5 times more patents per employee than large patenting firms.

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

#### How many small businesses are there?

**In 2009, there were 27.5 million businesses in the United States, according to Office of Advocacy estimates.** The latest available Census data show that there were 5.9 million firms with employees in 2008 and 21.4 million without employees in 2008. Small firms with fewer than 500 employees represent 99.9 percent of the total (employers and nonemployers), as the most recent data show there were 18,469 large businesses in 2008.

Source: Office of Advocacy estimates based on data from the U.S. Dept. of Commerce, Census Bureau, and trends from the U.S. Dept. of Labor, Bureau of Labor Statistics, Business Employment Dynamics.

#### What is small firms' share of employment?

**Small businesses employ about half of U.S. workers.** Of the 120.9 million nonfarm private sector workers in 2008, small firms employed 59.7 million and large firms employed 61.2 million. About half of small firm employment is in second-stage companies (10-99 employees), and half is in firms that are 15 years or older. Small firms' share of employment in rural areas is slightly higher than in urban areas; their share of part-time workers (22 percent) is similar to large firms' share (19 percent). Small firms' employment share remains steady since some small firms grow into large firms over time.

Source: U.S. Dept. of Commerce, Census Bureau: Statistics of U.S. Businesses, Current Population Survey, and Business Dynamics Statistics; and the Edward Lowe Foundation (<http://youreconomy.org>).

#### What share of net new jobs do small businesses create?

**Small firms accounted for 65 percent (or 9.8 million) of the 15 million net new jobs created between 1993 and 2009.** Much of the job growth is from fast-growing high-impact firms, which represent about 5–6 percent of all firms and are on average 25 years old.

Source: U.S. Dept. of Labor, Bureau of Labor Statistics, Business Employment Dynamics; Advocacy-funded research by Zoltan Acs, William Parsons and Spencer Tracy, 2008 (<http://archive.sba.gov/advo/research/rs328tot.pdf>).

## How many businesses open and close each year?

An estimated 552,600 new employer firms opened for business in 2009, and 660,900 firms closed. This amounts to an annual turnover of about 10 percent. Nonemployer firms have turnover rates three times as high, mostly because it is much easier for them to go into business and cease operations.

Category	2005	2006	2007	2008	2009
Births	644,122	670,058	668,395	626,400e	552,600e
Closures	565,745	599,333	592,410	663,900e	660,900e
Bankruptcies	39,201	19,695	28,322	43,546	60,837

Notes: e = Advocacy estimate. Bankruptcies include nonemployer firms.

Source: U.S. Dept. of Commerce, Census Bureau; Administrative Office of the U.S. Courts; U.S. Dept. of Labor, Business Employment Dynamics (BED).

Estimates based on Census data and BED trends.

## What is the survival rate for new firms?

**Seven out of 10 new employer firms survive at least 2 years, half at least 5 years, a third at least 10 years, and a quarter stay in business 15 years or more.** Census data report that 69 percent of new employer establishments born to new firms in 2000 survived at least 2 years, and 51 percent survived 5 or more years. Survival rates were similar across states and major industries. Bureau of Labor Statistics data on establishment age show that 49 percent of establishments survive 5 years or more; 34 percent survive 10 years or more; and 26 percent survive 15 years or more.

Source: U.S. Dept. of Commerce, Census Bureau, Business Dynamics Statistics; U.S. Dept. of Labor, Bureau of Labor Statistics, BED.

## How are credit conditions for small firms?

**Credit conditions are improving.** In mid-2010, commercial banks began to ease the tight lending conditions on small businesses that had begun in early 2007. And credit has continued to flow, as loans under \$1 million totaled \$695 billion in FY 2009. Also, after declining over the past few years, venture capital investment dollars increased in mid-2010.

Source: Federal Reserve Board, Senior Loan Officer Opinion Survey and Call Report data; National Venture Capital Association.

## How are small businesses financed?

**Small businesses rely heavily upon owner investment and bank credit, averaging about \$80,000 a year for young firms.** Startups rely about equally on the owners' cash injections into the business and bank credit; young firms receive about three-quarters of their funds from banks via loans, credit cards, and lines of credit. One-tenth of startups and about a third of young firms do not use capital injections.

Source: Kauffman Foundation, *An Overview of the Kauffman Firm Survey: Results from the 2004–2008 Data*, (Alicia Robb, E.J. Reedy, Janice Ballou, David DesRoches, Frank Potter, Zhanyun Zhao), May 2010.

## Whom do I contact about regulations?

To learn about pending regulation, visit Advocacy's Regulatory Alerts webpage, <http://www.sba.gov/advocacy/815>; to comment on pending regulations, email [advocacy@sba.gov](mailto:advocacy@sba.gov). To report unfair regulatory enforcement, contact SBA's National Ombudsman at [ombudsman@sba.gov](mailto:ombudsman@sba.gov)

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

Of the 27.1 million nonfarm businesses in 2007, women owned 7.8 million businesses, which generated \$1.2 trillion in revenues, employed 7.6 million workers, and paid \$218 billion in payroll. Another 4.6 million firms were 50 percent women owned. Minorities owned 5.8 million firms, which generated \$1 trillion in revenues and employed 5.9 million people. Hispanic Americans owned 8.3 percent of all U.S. businesses; African Americans, 7.1 percent; Asian Americans, 5.7 percent; American Indians and Alaska Natives, 0.9 percent; and Native Hawaiian or other Pacific Islanders, 0.1 percent. Veterans owned 2.4

million businesses in 2007, generating \$1.2 trillion in receipts; another 1.2 million firms were 50 percent veteran owned. About 7 percent of veteran business owners had service-connected disabilities in 2002.

In 2008, the overall rate of self-employment (unincorporated and incorporated) was 9.8 percent, and the rate was 7.1 percent for women, 7.2 percent for Hispanic Americans, 4.7 percent for African Americans, 9.7 percent for Asian Americans and Native Americans, and 13.6 percent for veterans. Service-disabled veterans had lower self-employment rates than non-service-disabled veterans.

Source: U.S. Dept. of Commerce, Census Bureau, Survey of Business Owners; Advocacy-funded research by Open Blue Solutions, 2007 (<http://archive.sba.gov/advo/research/rs291tot.pdf>), and Office of Advocacy: *The Small Business Economy* (<http://www.sba.gov/advocacy/849>).

### **At what rates are the self-employed taxed?**

Of the 15.5 million individuals whose primary occupation was self-employment (incorporated and unincorporated), the median personal marginal federal tax rate was 10 percent in 2008. Only 4.1 percent of the self-employed were in the marginal tax bracket of 33 percent or more.

Source: U.S. Dept. of Commerce, Census Bureau, Current Population Survey, March Supplement (special tabulation).

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

A Kaiser Family Foundation study confirmed the connection between firm size and offering health insurance. The survey shows that almost 60 percent of businesses with 3–9 workers offer health benefits to their employees. The ratio grows to more than three-fourths for firms with 10–24 employees, to 92 percent for firms with 25–49 employees, and to 99 percent for firms with 200 employees or more. Almost two-thirds of workers take health insurance coverage when offered. Overall in 2009, small firm employees were almost twice as likely as large firm employees to be uninsured (27.2 percent vs. 14.7 percent, respectively).

Source: Kaiser Family Foundation and the Health Research and Educational Trust, *Employer Health Benefits 2010 Annual Survey*; Employee Benefit Research Institute, *Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 2010 Current Population Survey*.

### **How can I get more information?**

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

- Economic research: <http://www.sba.gov/advocacy/847>.
- Firm size data: <http://www.sba.gov/advocacy/849>.
- Lending: <http://www.sba.gov/advocacy/852>.
- Small firm data resources: [http://www.sba.gov/sites/default/files/Small\\_Business\\_Data\\_Resources.pdf](http://www.sba.gov/sites/default/files/Small_Business_Data_Resources.pdf)
- Small business profiles by state and territory: <http://www.sba.gov/advocacy/848>.
- *The Small Business Advocate* newsletter: <http://www.sba.gov/advocacy/810>.

For email delivery of Advocacy's newsletter, press, regulatory news, and research, visit <http://web.sba.gov/list>. Direct questions to (202) 205-6533 or [advocacy@sba.gov](mailto:advocacy@sba.gov).

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

### **Is there a PDF version of the FAQ?**

Yes. The pdf version is located at: <http://www.sba.gov/sites/default/files/files/sbfaq.pdf>.

Updated January 2011

## APPENDIX D SMALL BUSINESS STATISTICS FOR REGULATORY ANALYSIS

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

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

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

### Definitions

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

**Establishment:** an establishment is the smallest unit in which business activity is conducted and on which statistical information is collected. The establishment concept does not refer to either ownership or taxpaying status. Establishments may be branches of larger firms and may therefore differ in purchasing power, advertising coverage, management and control systems, technical resources, and access to capital and credit from separately owned and operated businesses of similar size. (Most very small businesses are single establishments.)

**Enterprise:** the enterprise or firm concept refers to all establishments owned by a “parent” company. For instance, an enterprise may own subsidiaries, branches, and unrelated establishments. In most instances, it is necessary to use the enterprise concept

to study the characteristics of small firms since the ownership issue is critical for assessing the impact of a given policy.

## **Advocacy Economic Research on Small Businesses**

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

### **Census-Based Small Business Database**

Beginning in late 1991, the SBA's Office of Advocacy contracted with the Economic Surveys Division of the Bureau of the Census to produce linked longitudinal data files on an enterprise basis. (To see these data, go to the Office of Advocacy's website at <http://www.sba.gov/advocacy/849>.) The Office of Advocacy's data files generally include the number of establishments, firms, payroll per firm, and receipts per firm for various size classes based on firm employment size. The data are also broken out by location and/or industry.

Data are generally available at the six-digit North American Industry Classification System (NAICS) code level of industrial detail. (The NAICS system replaced the previous Standard Industrial Classification (SIC). The data can be accessed through the Office of Advocacy's website.

## **Other Federal Agency Data on Small Firms**

### **Current Population Survey**

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

Data from the Current Population Survey can be used to describe the businesses' sources of capital, their profitability, employment, major industry, and home-based status of women and minority business owners. This data source provides some information on potential regulatory impacts on very small firms, particularly their ability to absorb the burden of federal regulation.



## Characteristics of Business Owners Survey<sup>320</sup>

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

### Statistics of Income

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

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

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<sup>320</sup> U.S. Department of Commerce, Bureau of the Census, *Characteristics of Business Owners: 1992*, CBO-1 (Washington, D.C.: U.S. Government Printing Office, 1997).

## **APPENDIX E EXECUTIVE ORDER 12866**

### **Regulatory Planning and Review**

#### **Public Papers of the Presidents**

**September 30, 1993**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

William J. Clinton

The White House, September 30, 1993.

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

## APPENDIX F EXECUTIVE ORDER 13272

Title 3--  
The President

Executive Order 13,272 of August 13, 2002

Proper Consideration of Small Entities in Agency Rulemaking

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE WHITE HOUSE,

August 13, 2002.



## APPENDIX G EXECUTIVE ORDER 13563 AND MEMORANDA

### Improving Regulation and Regulatory Review

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve regulation and regulatory review, it is hereby ordered as follows:

Section 1. General Principles of Regulation. (a) Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.

(b) This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(c) In applying these principles, each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

Sec. 2. Public Participation. (a) Regulations shall be adopted through a process that involves public participation. To that end, regulations shall be based, to the extent feasible and consistent with law, on the open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole.

(b) To promote that open exchange, each agency, consistent with Executive Order 12866 and other applicable legal requirements, shall endeavor to provide the public with an opportunity to participate in the regulatory process. To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days. To the extent feasible and permitted by law, each agency shall also provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov, including relevant scientific and technical findings, in an open format that can be easily searched and downloaded. For proposed rules, such access shall include, to the extent feasible and permitted by law, an opportunity for public comment on all pertinent parts of the rulemaking docket, including relevant scientific and technical findings.

(c) Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.

Sec. 3. Integration and Innovation. Some sectors and industries face a significant number of regulatory requirements, some of which may be redundant, inconsistent, or overlapping. Greater coordination across agencies could reduce these requirements, thus reducing costs and simplifying and harmonizing rules. In developing regulatory actions and identifying appropriate approaches, each agency shall attempt to promote such coordination, simplification, and harmonization. Each agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation.

Sec. 4. Flexible Approaches. Where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include warnings, appropriate default rules, and disclosure requirements as well as provision of information to the public in a form that is clear and intelligible.

Sec. 5. Science. Consistent with the President's Memorandum for the Heads of Executive Departments and Agencies,

"Scientific Integrity" (March 9, 2009), and its implementing guidance, each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions.

Sec. 6. Retrospective Analyses of Existing Rules. (a) To facilitate the periodic review of existing significant regulations, agencies shall consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data, should be released online whenever possible.

(b) Within 120 days of the date of this order, each agency shall develop and submit to the Office of Information and Regulatory Affairs a preliminary plan, consistent with law and its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.

Sec. 7. General Provisions. (a) For purposes of this order, "agency" shall have the meaning set forth in section 3(b) of Executive Order 12866.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to a department or agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

THE WHITE HOUSE,  
January 18, 2011.

The White House

Office of the Press Secretary

For Immediate Release

January 18, 2011

## **Presidential Memoranda - Regulatory Flexibility, Small Business, And Job Creation**

### **Memorandum for the Heads of Executive Departments and Agencies**

**Subject: Regulatory Flexibility, Small Business, and Job Creation**

Small businesses play an essential role in the American economy; they help to fuel productivity, economic growth, and job creation. More than half of all Americans working in the private sector either are employed by a small business or own one. During a recent 15-year period, small businesses created more than 60 percent of all new jobs in the Nation.

Although small businesses and new companies provide the foundations for economic growth and job creation, they have faced severe challenges as a result of the recession. One consequence has been the loss of significant numbers of jobs.

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612, establishes a deep national commitment to achieving statutory goals without imposing unnecessary burdens on the public. The RFA emphasizes the importance of recognizing "differences in the scale and resources of regulated entities" and of considering "alternative regulatory approaches . . . which minimize the significant economic impact of rules on small businesses, small organizations, and small governmental jurisdictions." 5 U.S.C. 601 note.

To promote its central goals, the RFA imposes a series of requirements designed to ensure that agencies produce regulatory flexibility analyses that give careful consideration to the effects of their regulations on small businesses and explore significant alternatives in order to minimize any significant economic impact on small businesses. Among other things, the RFA requires that when an agency proposing a rule with such impact is required to provide notice of the proposed rule, it must also produce an initial regulatory flexibility analysis that includes discussion of significant alternatives. Significant alternatives include the use of performance rather than design standards; simplification of compliance and reporting requirements for small businesses; establishment of different timetables that take into account the resources of small businesses; and exemption from coverage for small businesses.

Consistent with the goal of open government, the RFA also encourages public participation in and transparency about the rulemaking process. Among other things, the statute requires

agencies proposing rules with a significant economic impact on small businesses to provide an opportunity for public comment on any required initial regulatory flexibility analysis, and generally requires agencies promulgating final rules with such significant economic impact to respond, in a final regulatory flexibility analysis, to comments filed by the Chief Counsel for Advocacy of the Small Business Administration.

My Administration is firmly committed to eliminating excessive and unjustified burdens on small businesses, and to ensuring that regulations are designed with careful consideration of their effects, including their cumulative effects, on small businesses. Executive Order 12866 of September 30, 1993, as amended, states, "Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations."

In the current economic environment, it is especially important for agencies to design regulations in a cost-effective manner consistent with the goals of promoting economic growth, innovation, competitiveness, and job creation.

Accordingly, I hereby direct executive departments and agencies and request independent agencies, when initiating rulemaking that will have a significant economic impact on a substantial number of small entities, to give serious consideration to whether and how it is appropriate, consistent with law and regulatory objectives, to reduce regulatory burdens on small businesses, through increased flexibility. As the RFA recognizes, such flexibility may take many forms, including:

- extended compliance dates that take into account the resources available to small entities;
- performance standards rather than design standards;
- simplification of reporting and compliance requirements (as, for example, through streamlined forms and electronic filing options);
- different requirements for large and small firms; and
- partial or total exemptions.

I further direct that whenever an executive agency chooses, for reasons other than legal limitations, not to provide such flexibility in a proposed or final rule that is likely to have a significant economic impact on a substantial number of small entities, it should explicitly justify its decision not to do so in the explanation that accompanies that proposed or final rule.

Adherence to these requirements is designed to ensure that regulatory actions do not place unjustified economic burdens on small business owners and other small entities. If regulations are preceded by careful analysis, and subjected to public

comment, they are less likely to be based on intuition and guesswork and more likely to be justified in light of a clear understanding of the likely consequences of alternative courses of action. With that understanding, agencies will be in a better position to protect the public while avoiding excessive costs and paperwork.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Nothing in this memorandum shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

The Director of the Office of Management and Budget is authorized and directed to publish this memorandum in the *Federal Register*.

BARACK OBAMA

The White House

Office of the Press Secretary

For Immediate Release

January 18, 2011

## PRESIDENTIAL MEMORANDA - REGULATORY COMPLIANCE

### Memorandum for the Heads of Executive Departments and Agencies

**Subject: Regulatory Compliance**

My Administration is committed to enhancing effectiveness and efficiency in Government. Pursuant to the Memorandum on Transparency and Open Government, issued on January 21, 2009, executive departments and agencies (agencies) have been working steadily to promote accountability, encourage collaboration, and provide information to Americans about their Government's activities.

To that end, much progress has been made toward strengthening our democracy and improving how Government operates. In the regulatory area, several agencies, such as the Department of Labor and the Environmental Protection Agency, have begun to post online (at [ogesdw.dol.gov](http://ogesdw.dol.gov) and [www.epa-echo.gov](http://www.epa-echo.gov)), and to make readily accessible to the public, information concerning their regulatory compliance and enforcement activities, such as information with respect to administrative inspections, examinations, reviews, warnings, citations, and revocations (but excluding law enforcement or otherwise sensitive information about ongoing enforcement actions).

Greater disclosure of regulatory compliance information fosters fair and consistent enforcement of important regulatory obligations. Such disclosure is a critical step in encouraging the public to hold the Government and regulated entities accountable. Sound regulatory enforcement promotes the welfare of Americans in many ways, by increasing public safety, improving working conditions, and protecting the air we breathe and the water we drink. Consistent regulatory enforcement also levels the playing field among regulated entities, ensuring that those that fail to comply with the law do not have an unfair advantage over their law-abiding competitors. Greater agency disclosure of compliance and enforcement data will provide Americans with information they need to make informed decisions. Such disclosure can lead the Government to hold itself more accountable, encouraging agencies to identify and address enforcement gaps.

Accordingly, I direct the following:

First, agencies with broad regulatory compliance and administrative enforcement responsibilities, within 120 days of this memorandum, to the extent feasible and permitted by law, shall develop plans to make public information concerning their regulatory compliance and enforcement activities accessible, downloadable, and

searchable online. In so doing, agencies should prioritize making accessible information that is most useful to the general public and should consider the use of new technologies to allow the public to have access to real-time data. The independent agencies are encouraged to comply with this directive.

Second, the Federal Chief Information Officer and the Chief Technology Officer shall work with appropriate counterparts in each agency to make such data available online in searchable form, including on centralized platforms such as data.gov, in a manner that facilitates easy access, encourages cross-agency comparisons, and engages the public in new and creative ways of using the information.

Third, the Federal Chief Information Officer and the Chief Technology Officer, in coordination with the Director of the Office of Management and Budget (OMB) and their counterparts in each agency, shall work to explore how best to generate and share enforcement and compliance information across the Government, consistent with law. Such data sharing can assist with agencies' risk-based approaches to enforcement: A lack of compliance in one area by a regulated entity may indicate a need for examination and closer attention by another agency. Efforts to share data across agencies, where appropriate and permitted by law, may help to promote flexible and coordinated enforcement regimes.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Nothing in this memorandum shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

The Director of OMB is authorized and directed to publish this memorandum in the *Federal Register*.

BARACK OBAMA



## APPENDIX H MEMORANDUM ON CUMULATIVE IMPACTS

EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

ADMINISTRATOR  
OFFICE OF  
INFORMATION AND  
REGULATORY  
AFFAIRS

March 20, 2012

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Cass R. Sunstein  
Administrator

SUBJECT: Cumulative Effects of Regulations

On January 18, 2011, the President issued Executive Order 13563, “Improving Regulation and Regulatory Review,” which states that to the extent permitted by law, each agency must take into account “among other things, and to the extent practicable, the costs of cumulative regulations.” Executive Order 13563 emphasizes that some “sectors and industries face a significant number of regulatory requirements, some of which may be redundant, inconsistent, or overlapping,” and it directs agencies to promote “coordination, simplification, and harmonization.” Executive Order 13563 also states that to the extent permitted by law, each agency shall “propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs.”

Executive Order 13563 directs that regulations “shall be adopted through a process that involves public participation,” including an “open exchange of information and perspectives.” Public participation can and should be used to evaluate the cumulative effects of regulations, for example through active engagement with affected stakeholders well before the issuance of notices of proposed rulemaking. The President’s Council on Jobs and Competitiveness has emphasized the need for a smart and efficient regulatory system and has drawn particular attention to the cumulative effects of regulation. Cumulative burdens can create special challenges for small businesses and startups.

Consistent with Executive Order 13563, and to the extent permitted by law, agencies should take active steps to take account of the cumulative effects of new and existing rules and to identify opportunities to harmonize and streamline multiple rules. The goals of this effort should be to simplify requirements on the public and private sectors; to ensure against unjustified, redundant, or excessive requirements; and ultimately to increase the net benefits of regulations.

To promote consideration of cumulative effects, and to reduce redundant, overlapping, and inconsistent requirements, agencies should carefully consider the following steps, where appropriate and feasible, and to the extent permitted by law:

- Early consultation with, advance notice to, and close engagement with affected stakeholders to discuss potential interactions between rulemakings under consideration and existing regulations as well as other anticipated regulatory requirements;
- Early engagement with state, tribal, and local regulatory agencies to identify opportunities for harmonizing regulatory requirements, reducing administrative costs, avoiding unnecessary or inconsistent requirements, and otherwise improving regulatory outcomes;
- Use of Requests for Information and Advance Notices of Proposed Rulemaking to obtain public input on potentially overlapping rulemakings and on rulemakings that may have significant cumulative effects;
- Specific consideration of the cumulative effects of regulations on small businesses and start-ups;
- Identification of opportunities to increase the net benefits of regulations and to reduce administrative and other costs, while meeting policy goals and legal requirements;
- Careful consideration, in the analysis of costs and benefits, of the relationship between new regulations and regulations that are already in effect;
- Identification of opportunities to integrate and simplify the requirements of new and existing rules, so as to eliminate inconsistency and redundancy;
- Coordination of timing, content, and requirements of multiple rulemakings that are contemplated for a particular industry or sector, so as to increase net benefits; and
- Consideration of the interactive and cumulative effects of multiple regulations affecting individual sectors as part of agencies' retrospective analysis of existing rules, consistent with Executive Order 13563.

Where appropriate and feasible, agencies should consider cumulative effects and opportunities for regulatory harmonization as part of their analysis of particular rules, and should carefully assess the appropriate content and timing of rules in light of those effects and opportunities. Consideration of cumulative effects and of opportunities to reduce burdens and to increase net benefits should be part of the assessment of costs and benefits, consistent with the requirement of Executive Order 13563 that, to the extent permitted by law, agencies must “select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits.” Agencies should avoid unintentional burdens that could result from an exclusive focus on the most recent regulatory activities. As noted, the cumulative effects on small businesses and start-ups deserve particular attention.

This guidance is effective immediately.

# APPENDIX I EXECUTIVE ORDER 13579

## Regulation and Independent Regulatory Agencies

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve regulation and regulatory review, it is hereby ordered as follows:

Section 1. Policy. (a) Wise regulatory decisions depend on public participation and on careful analysis of the likely consequences of regulation. Such decisions are informed and improved by allowing interested members of the public to have a meaningful opportunity to participate in rulemaking. To the extent permitted by law, such decisions should be made only after consideration of their costs and benefits (both quantitative and qualitative).

(b) Executive Order 13563 of January 18, 2011, "Improving Regulation and Regulatory Review," directed to executive agencies, was meant to produce a regulatory system that protects "public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." Independent regulatory agencies, no less than executive agencies, should promote that goal.

(c) Executive Order 13563 set out general requirements directed to executive agencies concerning public participation, integration and innovation, flexible approaches, and science. To the extent permitted by law, independent regulatory agencies should comply with these provisions as well.

Sec. 2. Retrospective Analyses of Existing Rules. (a) To facilitate the periodic review of existing significant regulations, independent regulatory agencies should consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data and evaluations, should be released online whenever possible.

(b) Within 120 days of the date of this order, each independent regulatory agency should develop and release to the public a plan, consistent with law and reflecting its resources and regulatory priorities and processes, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.

Sec. 3. General Provisions. (a) For purposes of this order, "executive agency" shall have the meaning set forth for the term "agency" in section 3(b) of Executive Order 12866 of September 30, 1993, and "independent regulatory agency" shall have the meaning set forth in 44 U.S.C. 3502(5).

(b) Nothing in this order shall be construed to impair or otherwise affect:

- (i) authority granted by law to a department or agency, or the head thereof; or
- (ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

THE WHITE HOUSE,  
July 11, 2011.

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## SECTION NINE

### INITIAL REGULATORY FLEXIBILITY ANALYSIS

#### 9.1 THE REGULATORY FLEXIBILITY ACT (RFA) AS AMENDED BY THE SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT (SBREFA)

This section considers the effects that the proposed CAFO regulations may have on small livestock and poultry operations as required by the Regulatory Flexibility Act (RFA, 5 U.S.C et seq., Public Law 96-354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The purpose of the RFA is to establish as a principle of regulation that agencies should tailor regulatory and informational requirements to the size of entities, consistent with the objectives of a particular regulation and applicable statutes. The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a “significant impact on a substantial number of small entities.”<sup>1</sup> Small entities include small businesses, small organizations, and governmental jurisdictions.

For this proposed rulemaking, EPA could not conclude that costs are sufficiently low to justify “certification.” Instead, EPA complied with all RFA provisions and conducted outreach to small businesses, convened a Small Business Advocacy Review (SBAR) panel, and prepared an initial regulatory flexibility analysis (IRFA).<sup>2</sup> This analysis is detailed in this section and represents EPA’s assessment of the impacts of the proposed CAFO regulations on small businesses in the livestock and poultry sectors. Section 9.2 outlines EPA’s initial assessment of small businesses in the sectors affected by the proposed regulations. Section 9.3 presents EPA’s analysis (IRFA) and summarizes the steps taken by EPA to comply with the RFA. Section 9.4 presents the data, methodology, and results of EPA’s analysis of impacts to small businesses for this rulemaking.

#### 9.2 INITIAL ASSESSMENT

EPA guidance on implementing RFA requirements suggests the following must be addressed in an initial assessment (USEPA, 1999i). First, EPA must indicate whether the proposal is a rule subject to notice-and-comment rulemaking requirements. EPA has determined

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<sup>1</sup> The preparation of an IRFA for a proposed rule does not legally foreclose certifying no significant impact for the final rule (USEPA, 1999i).

<sup>2</sup>This analysis or a summary of the analysis must be published in the *Federal Register* at the time of publication of a proposal.

that the proposed CAFO regulations are subject to notice-and-comment rulemaking requirements. Second, EPA should develop a profile of the affected small entities. EPA has developed a profile of the livestock and poultry sectors, which includes all affected operations as well as small businesses. This information is provided in Section 2 and also in Sections 6, 7, and 8 of this EA. Much of the profile information covered in these sections of this report applies to small businesses. Additional information on small businesses in the livestock and poultry sectors is provided in Sections 9.2 and 9.3. Third, EPA's assessment needs to determine whether the rule would affect small entities and whether the rule would have an adverse economic impact on small entities.

Section 9.2.1 reviews the SBA definitions of small entities in the livestock and poultry industry and discusses a rationale for using an alternative definition of small business in one sector. Section 9.2.2 then uses the definitions of small entities laid out in Section 9.2.1 to estimate the number of operations that meet this small business definition. Finally, using the information developed in Sections 9.2.1 and 9.2.2, Section 9.2.3 presents the results of EPA's initial assessment. This assessment provides a first level screen of potential impacts to small CAFO businesses and serves as a signal for additional analysis.

### **9.2.1 Definition of Small CAFO Businesses**

The RFA defines a "small entity" as a small not-for-profit organization, small governmental jurisdiction, or small business. There are no small governmental operations that operate CAFOs. There may be a few not-for-profit organizations that operate CAFOs, but complete information is not available to warrant inclusion of not-for-profit organizations in this analysis. This analysis therefore focuses only on small businesses that are defined or designated as CAFOs. (Section 3 describes the circumstances under which an AFO is defined or designated as a CAFO and is subject to the proposed regulations.)

The RFA requires, with some exception, that EPA define small businesses according to its size standards. SBA sets size standards for defining small businesses by number of employees or amount of revenues for specific industries. These size standards vary by North American Industry Classification System (NAICS) code. CAFOs are listed under NAICS 112, Animal Production.<sup>3</sup>

SBA's size standards differ from the revenue cutoff generally recognized by USDA, which has defined \$250,000 in gross sales as its cutoff between small and large family farms (USDA, 1998).

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<sup>3</sup> In September, 2000, SBA updated the basis for its size standard to NAICS codes from Standard Industrial Classification (SIC) codes (USGPO, 2000). By SIC code, these industries are listed under SIC 02, Livestock and Animal Specialties. The actual size standards for each sector, specified as an annual revenue threshold, did not change as a result of this update.

Table 9-1 shows SBA size standards by SIC code for each of the six livestock and poultry sectors, which are expressed in terms of average “annual receipts” (revenue). With one exception, current SBA standards define a “small business” within each of the main livestock and poultry sectors as an operation that generates average revenues ranging from less than \$0.5 million per year (for the hog, dairy, broiler, and turkey sectors) to less than \$1.5 million per year (for the beef feedlot sector), averaged over the most recent three fiscal years (USGPO, 1996; SBA, 1998). The exception is the revenue threshold for a small chicken egg operation (layer sector), which SBA has defined as a business that generates up to \$9 million annually.

**Table 9-1. SBA Revenue Size Standards for Small Livestock and Poultry Operations**

NAICS Code (SIC Code)	NAICS Industry Description	SBA Size Standard <sup>a/</sup>	EPA-Proposed Revenue Cutoff
112112 (0211)	Cattle Feedlots	\$1.5 million	same as SBA
11221 (0213)	Hog and pig farming	\$0.5 million	same as SBA
11212 (0241)	Dairy cattle and milk production	\$0.5 million	same as SBA
11232 (0251)	Broilers and other meat-type chickens	\$0.5 million	same as SBA
11231 (0252)	Chicken egg production	\$9.0 million	\$1.5 million
11233 0253	Turkey production	\$0.5 million	same as SBA

Source: SBA (1998); USGPO (1991a, 1991b and 1996); U.S. Census Bureau (2000).

<sup>a/</sup>SBA Size Standards by NAICS code (13 CFR Part 121) correspond to classifications under SIC classification.

EPA believes that the definition of small business for the egg laying sector (revenues of \$9 million per year) might not truly characterize a small business in this sector. Therefore, EPA is proposing to use an alternative definition, as allowed by the RFA:

“...an agency, after consultation with the Office of Advocacy of the Small Business Administration and after the 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.” 5 U.S.C. §601(3).

EPA’s alternative definition identifies a small business for egg laying operations as any operation that generates up to \$1.5 million in annual revenue (see Table 9-1). Because this definition of a small business is not the definition established under the RFA, EPA is specifically seeking comment on the use of this alternative definition. EPA has also consulted with the SBA Chief Counsel for Advocacy on the use of this alternative definition (USEPA, 1999d). EPA believes this definition better reflects the agricultural community’s sense of what constitutes a small business and more closely aligns with the small business definitions codified by SBA for other animal operations.

There are four broad reasons why EPA believes that its alternative definition of small egg laying operations is more appropriate for the purpose of this rulemaking. These include: (1) EPA's definition is more consistent with size classes used by USDA and industry; (2) EPA's definition reflects the financial and institutional realities of the egg industry; (3) EPA's definition reflects similarities among the sectors of the poultry industry; and (4) EPA's definition captures the relevant segments of the industry (USEPA, 1999d). The four reasons for using the alternative definition of small egg laying operations are summarized below. Additional supporting data and analysis are provided in the rulemaking Record (USEPA, 1999d; USEPA, 2000f).

First, EPA's alternative definition is more consistent with size classes used by USDA (Madison, 1999) and more generally accepted by the regulated community (Gregory, 1999; Staples, 1998). USDA describes size classes reflective of farm level conditions at egg laying operations in terms of the number of houses, where a house has approximately 100,000 to 110,000 hens. Based on USDA's size classes, a small farm has a single house; a medium farm has two to five houses; and a large farm has more than five houses (i.e., more than 500,000 hens). Using USDA data, EPA estimates that a "small" egg operation by USDA standards generates approximately \$1.5 million in annual revenue (USEPA, 1999d and 2000f).<sup>4</sup>

In contrast, a definition of \$9 million in annual revenue fails to reflect farm level conditions based on USDA size classes and matching opinions from the farming community. Such an operation corresponds to an operation with more than six houses (with approximately 600,000 hens). EPA does not believe an operation with six chicken houses should be characterized as "small" for the proposed CAFO regulations. EPA visited one such facility. The facility resides on more than 200 acres and has an annual production of over 180 million eggs. The facility's extensive customer base includes three major supermarket chains and the U.S. military. Its distribution system spans four states. A facility with such a high production level and extensive customer base is not a small business.<sup>5</sup> EPA's alternative definition would decrease confusion and facilitate communication with the regulated community (both large and small businesses) and with other stakeholders.

Second, EPA's alternative definition better reflects the financial and institutional realities of the egg industry. EPA focuses its regulatory analyses for the proposed CAFO regulations at the animal production level since it is the operator who directly incurs all costs associated with the management and disposal of manure generated from animals that are raised or housed onsite. EPA believes, based on a preliminary review of the background information supporting the SBA definition (USGPO, 1991a and 1991b) that the \$9 million definition applies to entities at a different level in the marketing chain—e.g., to large cooperatives or integrators, rather than farms. The alternative definition would allow EPA to better focus on the needs and concerns of those

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<sup>4</sup>EPA estimates are derived using USDA-reported 1997 data: average yield of 255 eggs per layer per year (USDA/NASS, 1998b) and average annual producer price of 66.7 cents per dozen (USDA/NASS, 1998a).

<sup>5</sup>Information on EPA's farm site visits is in the rulemaking record.



businesses that are most likely to experience economic hardship associated with regulatory compliance.

Third, EPA's alternative definition better reflects similarities among the sectors of the poultry industry. EPA's analysis focuses on three sectors: egg laying, broiler, and turkey meat. The SBA definitions differ substantially between the egg laying sector and the other two sectors. As shown in Table 9-1, the small-business definition for layer operations is \$9 million in annual revenue; the small-business definition for both broiler and turkey operations is \$0.5 million. At the farm level, however, there are structural similarities among these three sectors, suggesting that small business definitions should not be so disparate for these operations. The sectors use similar technologies and similar manure management techniques. They have similar costs of production. They have similar industrial organization and marketing arrangements. Measured at the animal production level, the SBA definition of a small broiler or turkey operation is consistent with USDA's definition of a small- or medium-sized operation (based on the number of animals and housing structures, as discussed above).

In fact, prior to 1991, the SBA definition for layer operations was much closer to the definitions for the other two poultry sectors. The earlier SBA definition for layer operations was \$1.0 million. The definition was revised to \$7 million in 1991, and then escalated to \$9 million to account for inflationary changes (USGPO, 1991a and 1991b; Ray, 1999). One of the reasons cited for the 1991 increase was the "limited participation of small egg producers in government procurement" (USGPO, 1991a). For the regulatory flexibility assessment of the proposed CAFO regulations, EPA concludes that the alternative definition is more comparable to the definitions for other livestock sectors and is therefore more appropriate than the existing definition.

Finally, EPA's alternative definition is more appropriate in terms of capturing the relevant segments of the industry. Under EPA's alternative definition, small layer operations would account for roughly 60 percent of annual egg production (USEPA, 2000f). In contrast, under SBA's definition, small operations would account for approximately 90 percent of annual egg production. If EPA were to use SBA's definition, a very large share of total annual egg output would be generated from "small" operations. This would be inconsistent with the analysis of the broiler and turkey sector, where smaller operations represent roughly one-half of each sector's respective annual production. This would further contradict expectations by SBA in terms of the percent of sales attributable to small operations. According to SBA, about 99 percent of all farms in the economy are small and account for approximately 62 percent of sales (Perez, 2000; USEPA, 2000g). This agrees with the realities of the agricultural sector where the majority of farms are small, but account for a relatively small share of overall production. The trend in agriculture towards fewer, larger farms highlights that larger operations—while relatively few in number—represent a greater share of overall output.

EPA also considered another alternative definition for all six animal sectors based on the number of animals raised or housed at the CAFO site (USEPA, 2000e, 1999a, 1999i, and 1999n). Following discussions with representatives from both SBA and OMB during the SBAR Panel

process, EPA decided not to use this alternative definition for each of the animal sectors (USEPA, 2000g). A complete summary of EPA's correspondence with SBA on its proposal and use of an alternative definition is contained in the rulemaking record (see DCN 70509, DCN 70507, DCN 70473, DCN 70472, DCN 70511, DCN 70797, and DCN 93001).

### **9.2.2 Number of Small Businesses Affected by the Proposed CAFO Regulations**

There are three steps for determining the number of small CAFO businesses that may be affected by the proposed regulations. First, EPA identifies small businesses in the relevant livestock and poultry sectors by equating SBA's annual revenue definition with the number of animals at an operation. Second, EPA estimates the total number of small businesses in these sectors using farm size distribution data from USDA. Third, based on the regulatory thresholds being proposed, EPA estimates the number of small businesses that would be subject to the proposed requirements. These steps are described in the following sections.

#### ***9.2.2.1 Equating SBA Size Standards with Animal Inventory***

In the absence of entity level revenue data, EPA identifies small businesses in the livestock and poultry sectors by equating SBA's annual revenue definitions of "small business" to the number of animals at these operations (step 1). This step produces a threshold based on the number of animals that EPA uses to define small livestock and poultry operations and reflects the average farm inventory (number of animals) that would be expected at an operation with annual revenues that define a small business. This initial conversion is necessary because USDA data by farm size are not available by business revenue. With the exception of egg laying operations, EPA uses SBA's small business definition to equate the revenue threshold with the number of animals raised on site at an equivalent small business in each sector. For egg laying operations, EPA's alternative revenue definition of small business is used.

EPA estimates the number of animals at an operation to match SBA's definitions using SBA's annual revenue size standard (expressed as annual revenue per entity) and USDA-reported farm revenue data that are scaled on a per-animal basis (expressed as annual revenue per inventory animal for an average facility). (This calculation is shown below.) Per-animal financial data are calculated by multiplying the average value of the reported financial data per farm by the total number of farms and then dividing this by the total number of animals. (More information on this calculation is presented in Section 4.2.4.2 of this report.) The average per-animal revenues assumed for this analysis are shown in Table 9-2.

Financial data used by EPA are from the USDA's 1997 ARMS database. These data include farm financial data and corresponding summary information that match the reported average revenue to the total number of farms and the total number of animals in the sample set.

**Table 9-2. Number of Small CAFOs That May Be Affected by the Proposed Regulations**

Sector	Total Annual (Million) Revenue <sup>a/</sup> (x)	Revenue per Head <sup>b/</sup> (Avg. U.S.) (y)	Number of Animals at Small CAFO Businesses (z=x/y)	Estimated Number of Small AFOs	Two-Tier (500 AU) "Small" CAFO Businesses	Three-Tier "Small" CAFO Businesses
Cattle <sup>c/</sup>	\$1.5	\$1,060	1,400	106,450	2,280	2,600
Dairy	\$0.5	\$2,573	200	109,740	50	50
Hogs	\$0.5	\$363	1,400	107,880	300	300
Broilers	\$0.5	\$2	260,000	34,530	9,470	13,410
Egg Layers	\$9.0	\$25	365,000	ND	ND	ND
	\$1.5		61,000	73,710	200	590
Turkeys	\$0.5	\$20	25,000	12,320	0	500
<b>All AFOs <sup>d/</sup></b>	<b>NA</b>	<b>NA</b>	<b>NA</b>	<b>355,650</b>	<b>10,550</b>	<b>14,630</b>

NA=Not Applicable. ND = Not Determined. "AFOs" have confined animals on-site.

<sup>a/</sup>SBA Size Standards are at 13 CFR Part 121. EPA assumes an alternative definition of \$1.5 million in annual revenues for egg layers.

<sup>b/</sup> Average revenue per head across all operations for each sector derived from data obtained from USDA's 1997 ARMS data (USDA/ERS, 1999a). See Section 4.

<sup>c/</sup> Includes fed cattle, veal and heifers.

<sup>d/</sup> Total adjusts for operations with mixed animal types and includes designated CAFOs (expressed over a 10-year period). See Section 2 of this document for estimates of the total number of AFOs.

These data were obtained with the assistance of staff at USDA's ERS (as described in Section 4.2.3.2).<sup>6</sup> USDA's data report average national revenue for each sector, combining both livestock and nonlivestock farm revenue (income from crop sales and other farm-related income, including government payments). Use of total farm revenue corresponds to SBA's size standards that are expressed in terms of total annual business revenue (SBA, 1998; USGPO, 2000).

EPA uses the derived per-animal revenues shown in Table 9-2 to equate SBA's size standard (in revenues) with farm size based on the number of animals, as follows:

$$\frac{\text{Average \# Animals}}{\text{Farm}} = \frac{\text{SBA's Small Business Definition (\$ per year per farm)}}{\text{Average Total Revenue per head (\$/animal)}}$$

<sup>6</sup>As noted throughout this report, USDA periodically publishes aggregated data from the ARMS and Census databases and provides customized analyses of the data to members of the public and other government agencies. In providing such analyses, USDA maintains a sufficient level of aggregation to ensure the confidentiality of individual facility data.

The resultant number of animals represents the average animal inventory threshold for a small business. Estimated “small business” thresholds for each sector are shown in Table 9-2.

For the purpose of conducting its IRFA for this rulemaking, and based on the animal inventory thresholds discussed above, EPA is evaluating a “small business” for these sectors as an animal feeding operation that houses or confines less than: 1,400 fed beef cattle; 200 mature dairy cattle; 1,400 market hogs; 260,000 broilers; 61,000 layers; or 25,000 turkeys. Hereafter, all references to small CAFO businesses reflect the SBA definitions of “small” and the alternative definition proposed by EPA for small layer operations, applied on the basis of a calculated number of head.

#### ***9.2.2.2 Total Number of Operations that Match SBA Size Standards***

Using the threshold sizes identified for small businesses in the livestock and poultry sectors (Table 9-2), EPA matches these thresholds with the number of operations associated with those size thresholds, based on available USDA data, to estimate the total number of small animal confinement operations in these sectors (step 2).

The 1997 Census constitutes the primary data source that EPA uses to match the small business thresholds to the number of operations by size. Other supplemental data used includes other published USDA data and information from industry and the state agriculture extension agencies. In some cases, EPA extrapolated between two size groupings to obtain an estimate of the number of small livestock and poultry operations. Additional information is also used to subdivide sector level data into subsectors. For example, the number of hog operations that are farrow-finish versus grow-finish are distinguished according to market share information (USDA/APHIS, 1995b). Information that differentiates the number of egg laying operations according to manure management system (wet versus dry) are approximated based on conversations with State Extension personnel for selected states, as described in the *Development Document* (USEPA, 2000a). The number of breeder and nursery pig operations and veal and heifer operations are approximated based on information obtained from state extension personnel and EPA’s farm site visits (USEPA, 2000a).

For many of the animal sectors, it is not possible to estimate from available U.S. farm data what proportion of total livestock and poultry operations have feedlots and what proportion are grazing operations only. For the beef and hog sectors, the USDA has limited data on the number of operations that are feedlot operations only (USDA/APHIS, 1995b; USDA/NASS, 1999a and 1999b). For analytical purposes, EPA has assumed that all dairy and poultry operations potentially are confinement operations. More information on the farm size distribution data that EPA uses to match the size thresholds to the number of poultry and livestock operations is documented in the *Development Document* (USEPA, 2000a).

Table 9-2 shows EPA's estimates of the total number of small livestock and poultry operations using this approach. As shown, an estimated 355,650 animal confinement operations meet SBA's small business definition. This is 95 percent of the estimated total number of animal feeding operations (375,700 operations).

EPA recognizes that this approach may not accurately portray actual small businesses in all cases across all sectors. On the one hand, the resulting small business estimate would suggest that a 10-house broiler operation with 260,000 birds would be a small business. Information from industry sources, however, suggest that a two-house broiler operation with roughly 50,000 birds is small (Madison, 1999; USEPA, 2000e). Therefore, it is likely that some medium- and large-size broiler operations are being considered small businesses (USEPA, 2000g).

On the other hand, it is possible that the resulting small business estimate may have failed to identify some small businesses as "small" in the other sectors. For example, EPA's approach identifies as a "small business" hog operations with less than 1,400 pigs and turkey operations with less than 25,000 turkeys, which account for less than 94 percent of all operations and less than 30 percent of sales in these sectors. These proportions are below SBA's presumed coverage rates that define as small about 99 percent of all operations that account for approximately 62 percent of sales (Perez, 2000). Therefore, it is likely that there are additional small hog and turkey businesses that are not captured under the revised methodology (USEPA, 2000g).

### ***9.2.2.3 Total Number of Small CAFOs Subject to the Proposed Regulations***

Based on the regulatory thresholds for each co-proposed alternative, EPA estimates the number of small businesses that will be subject to the proposed requirements (step 3).<sup>7</sup> The 1997 Census constitutes the primary data source that EPA uses to match the small business thresholds (e.g., a small dairy operation has less than 200 milk cows) to the number of facilities that match that size group (e.g., the number of dairies with less than 200 cows, as reported by USDA). Other supplemental data used include other published USDA data and information from industry and the state extension agencies.

Table 9-2 shows the estimated total number of livestock and poultry operations that meet the SBA definition of a "small business" in each of the livestock and poultry sectors. Not all of small confinement operations would be subject to the proposed CAFO regulations, however. EPA's proposed regulations only apply to those operations that meet the regulatory definition of a CAFO or those that have been designated as a CAFO by the NPDES permitting authority due to risks posed to water quality and public health, as discussed in Section 3. The proposed changes *define* as a CAFO those operations that confine more than 300 or 500 AU (depending on co-

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<sup>7</sup>In this section, EPA discusses numbers of affected CAFOs and impacts under the two-tier structure at 500 AU threshold (Scenario 4a) and three-tier structure (Scenario 3) only. "Two-tier structure" in this section refers to the 500 AU threshold, except where otherwise noted.

proposed scenario). The proposed requirements may also apply to an operation that confines fewer than 300 or 500 AU if it is *designated* as a CAFO by the NPDES permitting authority on a case-by-case basis, based on an on-site inspection.

Of the estimated 355,650 animal confinement operations that meet SBA's small business definition, EPA estimates that 10,550 operations that will be subject to the proposed requirements that are small businesses under the two-tier structure. Under the three-tier structure, an estimated 14,630 affected operations are small businesses. These estimates include expected designated facilities. The difference in the number of affected small businesses is among poultry producers, particularly broiler operations. See Table 9-2.

Table 9-3 presents the estimated number of livestock and poultry operations that may be subject to the proposed requirements under each co-proposed scenario that are also small businesses ("small CAFO businesses") by facility size category. The number of small CAFO businesses are shown as follows: (1) operations defined as CAFOs with more than 1,000 AU, (2) operations defined as CAFOs with between 300 to 1,000 AU or 500 to 1,000 AU, depending on scenario, and (3) operations that may be designated as CAFOs with fewer than 300 or 500 AU that may be designated (varies by co-proposed alternative). The number of small CAFO businesses in each of the three size categories is developed using the same data approach used to identify the total number of small operations, discussed in Section 9.2.2.2.

Based on estimates shown in Table 9-3, EPA estimates that there are 10,220 operations with more than 500 AU that may be defined as CAFOs that also meet the "small business" definition, under the two-tier structure. Under the three-tier structure, there are 14,530 operations with more than 300 AU that may be defined as CAFOs that are small businesses that meet the proposed risk-based conditions (described briefly in Section 3; more detail is provided in Section VII of the preamble). By broad facility size group, EPA estimates that about 4,000 operations have more than 1,000 AU, adjusting for operations with more than a single animal type. EPA estimates that about 6,000 operations have between 500 and 1,000 AU (two-tier structure) and about 10,000 operations have between 300 and 1,000 AU (three-tier structure), accounting for mixed operations. EPA's analysis assumes that all small businesses with 300 to 1,000 AU under the three-tier structure obtain a NPDES permit and that none certify out of the program.

Among operations that are defined as CAFOs, depending on co-proposed scenario, most small CAFO businesses are in the broiler and cattle sectors. As defined for this analysis, EPA expects that there are no small CAFO businesses in the dairy sector with more than 300 AU (see Section 9.2.2.1) and that small dairies will be subject to the regulations only if they are designated as a CAFO by the Permitting Authority. Also, as defined for this analysis, there are no small

**Table 9-3. Total Number of Small CAFO Businesses Subject to Regulation**

Sector	All "Small" AFOs		Two-Tier Structure			Three-Tier Structure		
	All	>1,000 AU	500-1,000 AU	<500 AU	Total	300-1,000 AU	<300 AU	Total
Fed Cattle	104,350	350	1,000	40	1,390	1,140	0	1,490
Veal	850	10	80	0	90	130	0	140
Heifers	1,250	300	500	0	800	680	0	980
Dairy	109,740	0	0	50	50	0	50	50
Hogs	107,800	0	100	200	300	250	50	300
Broilers	34,530	3,610	5,840	20	9,470	9,800	0	13,410
Layers	73,710	0	180	20	200	600	0	590
Turkeys	12,320	0	0	0	0	500	0	500
Sum Total	444,560	4,270	7,700	330	12,300	13,080	100	17,300
<b>Total</b>	<b>355,565</b>	<b>4,060</b>	<b>6,160</b>	<b>330</b>	<b>10,550</b>	<b>10,470</b>	<b>100</b>	<b>14,630</b>

Sources: Values presented in the table are EPA estimates, derived from published USDA data, including 1997 Census of Agriculture (USDA/NASS, 1999a) supplemented with other data, as described in the *Development Document* (USEPA, 2000a). All numbers are rounded to the nearest ten.

"Total" eliminates double counting of operations with mixed animal types. Based on survey level Census data, operations with mixed animal types account for roughly 25 percent of operations less than 1,000 AU; few operations with more than 1,000 AU have more than a single animal type.

grow-finish hog operations that may be defined as CAFO under either co-proposed scenario; also, there are no small CAFO businesses in the turkey sector under the two-tier structure (Table 9-3).

The majority (about 90 percent) of small confinement operations have fewer than 300 AU (Table 9-3). EPA's total estimate of small affected CAFOs includes an additional 330 small operations with fewer than 500 AU that may be designated as CAFOs under the two-tier structure over a 10-year period (consistent with the 10-year time frame used for EPA's financial model). As these facilities are designated, EPA did not adjust this total to reflect possible mixed animal operations. All of these operations are small businesses. Under the two-tier structure, designated operations are expected to consist of beef, dairy, hog, egg layer and broiler confinement operations that are located in more traditional farming regions and are determined to be significant

contributors of pollution.<sup>8</sup> Under the three-tier structure, EPA expects that 100 dairy and hog operations will be designated as CAFO and, therefore, subject to the proposed regulations.

These estimates are based on farm data for 1997. Due to continued consolidation and facility closure since 1997, EPA's estimates may overstate the actual number of small businesses in these sectors. In addition, ongoing trends are causing some existing small- and medium-size operations to expand their inventories to achieve scale economies. Some of the CAFOs considered here as small businesses may no longer be counted as small businesses because they now have higher revenues.

### 9.2.3 Results of the Initial Assessment

Early on in the development of this rulemaking, EPA conducted a preliminary assessment of the potential impacts to small CAFO businesses based on the results of a costs-to-sales test for operations with more than 500 AU. This screening test indicated the need for additional analysis to characterize the nature and extent of impacts on small entities. This assessment is conducted for those CAFOs that are small businesses, as determined by EPA.

Table 9-4 presents the results of this screening test and indicates that about 80 percent (about 9,700) of the estimated number of small businesses with more than 500 AU that would be directly subject to the rule as CAFOs (two-tier) may incur costs in excess of three percent of sales. Compared to the total number of all small animal confinement facilities estimated by EPA (355,650 facilities), EPA estimates that operations that may incur costs in excess of three percent of sales comprise less than two percent of all small businesses in these sectors. (The cost and revenue data EPA uses for this assessment are presented in Section 9.4; more detailed information on these data is provided in Section 4 of this report.)

Based on the results of this initial assessment, EPA projected that the Agency would likely not certify that the proposal, if promulgated, would not impose a significant economic impact on a substantial number of entities. Therefore, EPA convened a Small Business Advocacy Review Panel and prepared an Initial Regulatory Flexibility Analysis (IRFA) pursuant to Sections 609(b) and 603 of the RFA, respectively, and prepared an economic analysis (see Sections 9.3 and 9.4).

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<sup>8</sup>EPA expects that USDA will continue to provide voluntary assistance to those additional operations that are now defined as CAFOs under the current permitting requirements (300 AU to 500 AU) that are not covered by proposed CAFO revisions under the two-tier structure.



**Table 9-4. EPA's Preliminary Assessment of Small Business Impacts using a Sales Test**

Sector	Small AFOs	Small CAFOs (>500 AU)	Costs Exceed 3% of Revenues		
			#Small CAFOs	%Small CAFOS	%Small AFOs
Fed Cattle	104,350	1,350	80	6%	1%
Veal	850	90	10	1%	1%
Heifers	1,250	800	20	3%	2%
Dairy	109,736	0	0	0%	0%
Hog-FF	57,800	100	20	20%	1%
Hog-GF	50,000	0	0	0%	0%
Broilers	34,530	9,450	9,450	100%	28%
Layers-Wet	9,010	20	0	0%	0%
Layers-Dry	64,700	160	0	0%	0%
Turkeys	12,320	0	0	0%	0%
<b>Sum Total</b>	<b>444,560</b>	<b>11,970</b>	<b>9,580</b>	<b>80%</b>	<b>2%</b>

Source: USEPA. Total does not adjust for operations with mixed animal types, for comparison purposes. Includes CAFOs with more than 500 AU. Excludes designated operations. Sales test results are shown for the proposed BAT Option and NPDES Scenario 4a (described in Section 3).

### 9.3 EPA COMPLIANCE WITH RFA REQUIREMENTS

#### 9.3.1 Outreach and Small Business Advocacy Review

As required by Section 609(b) of the RFA, as amended by SBREFA, EPA convened a Small Business Advocacy Review (SBAR) Panel for the proposed rule. The Panel was convened in December, 1999. Panel participants included representatives from EPA, the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Office of Advocacy of the Small Business Administration (SBA). "Small Entity Representatives" (SERs), who advised the Panel, included small livestock and poultry producers as well as representatives of the major commodity and agricultural trade associations. Throughout the development of these regulations, EPA conducted outreach to small businesses in the livestock and poultry sectors. EPA also consulted with SBA on the use of an alternative definition of small business for the egg laying sector.

Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small entity comments on issues related to the elements of the IRFA. The Panel's

activities and recommendations are summarized in the *Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule on National Pollutant Discharge Elimination System (NPDES) and Effluent Limitations Guideline (ELG) Regulations for Concentrated Animal Feeding Operations* (USEPA, 2000g), or "Panel Report." This document is included in the public record (DCN 93001). Section XII.G of the preamble provides a summary of the Panel's activities and recommendations and describes the subsequent action taken by the Agency. Section XII of the preamble also details various outreach activities conducted by EPA that include outreach to small businesses in these sectors.

### **9.3.2 EPA's Initial Regulatory Flexibility Analysis**

As required by Section 603 of the RFA, as amended by SBREFA, EPA has conducted a initial regulatory flexibility analysis. The IRFA must include a discussion of the reason the agency is considering the proposed rule, as well as the objectives and legal basis for the proposal. It must also include a description and estimate of the number of small businesses that will be affected. It must describe the reporting, recordkeeping, and other compliance requirements of the proposed rule and must identify any federal rules that may duplicate, overlap, or conflict with the proposed rule. Finally, the IRFA must describe any significant regulatory alternatives to the rule that would accomplish the stated objectives of the applicable statutes and which minimize impacts to small businesses. Sections 9.3.2.1 through 9.3.2.6 below address each of these requirements of the IRFA that EPA has prepared to support the proposed CAFO regulations.

Section 607 of the RFA further notes that to comply with the IRFA requirements, the Agency must "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." For this rulemaking, EPA has prepared an economic analysis of the impacts to small CAFO businesses. This analysis is provided in Section 9.4. Based on the results of this analysis, EPA has determined that the proposed regulations will result in financial stress to some affected small businesses, but not a substantial number of operations relative to the total number of affected small businesses in these sectors. Additional information and the detailed results of this analysis are presented in Section 9.4.2.

#### ***9.3.2.1 Reason EPA is Considering the Proposed Rule***

Despite more than twenty years of regulation, there are persistent reports of discharge and runoff of manure and manure nutrients from livestock and poultry operations. The proposed revisions to the existing ELG and NPDES regulations for CAFOs are expected to mitigate future water quality impairment and the associated human health and ecological risks by reducing pollutant discharges from the animal production industry.

EPA's proposed revisions also address the changes that have occurred in the animal production industries in the United States since the development of the existing regulations. The continued trend toward fewer but larger operations, coupled with greater emphasis on more intensive production methods and specialization, is concentrating more manure nutrients and other animal waste constituents within some geographic areas. This trend has coincided with increased reports of large-scale discharges from these facilities and continued runoff that is contributing to the significant increase in nutrients and resulting impairment of many U.S. waterways.

EPA's proposed revisions of the existing regulations will make the regulations more effective in protecting or restoring water quality. The revisions will also make the regulations easier to understand and better clarify the conditions under which an AFO is a CAFO and, therefore, subject to the regulatory requirements.

Additional information on why EPA is revising the existing regulations is provided in Section IV of the preamble.

#### ***9.3.2.2 Objectives and Legal Basis for the Proposed Rule***

A detailed discussion of the objectives and legal basis for the proposed CAFO regulations is presented in Sections I and III of the preamble.

#### ***9.3.2.3 Description and Estimate of Number of Small Entities Affected***

As presented in Section 2, EPA estimates that there are about 375,700 livestock and poultry operations nationwide of which 355,650 (95 percent) are small (Table 9-2). Of these, the proposed CAFO regulations are expected to affect—and impose compliance costs on—approximately 10,550 operations or 14,630 operations (Table 9-3), depending on co-proposed scenario. Most (about 80 percent) of the estimated number of small CAFO businesses are in the poultry sectors, with the majority in the broiler sector. The cattle sector accounts for another 15 to 18 percent of small CAFO businesses, depending on tier structure. The remaining number of affected small CAFO businesses are in the hog and dairy sectors.

Tables 9-5 and 9-6 show the numbers of affected small businesses by EPA's model CAFO designation, which characterizes each of the small businesses by sector, size, and key production region. (Values shown in the tables do not adjust for operations with more than a single animal type.) These estimated CAFO numbers by model type are used to evaluate small business impacts, presented in Section 9.4 of this report.

**Table 9-5. Numbers of Small CAFO Businesses by Sector, Size, and Region, Two-Tier Structure**

Sector	Region	CAFOs <300AU	CAFOs "Medium 1"	CAFOs "Medium 2"	CAFOs "Large 1"	CAFOs "Large 2"
Fed Cattle	CE			160	70	
	MW		40	840	280	
Veal	MW			80	10	
Heifers	MW			500	300	
Dairy	MW	50				
	PA					
Hog: FF	MA					
	MW	50	150	100		
Hog: GF	MA					
	MW					
Layer: Wet	SO			40		
Layer: Dry	MW			60		
	SO			100		
Broiler	MA		740	1,190	980	70
	SO		1,280	2,650	2,300	260
Turkey	MA					
	MW					
<b>Total</b>		<b>100</b>	<b>2,210</b>	<b>5,720</b>	<b>3,940</b>	<b>330</b>

Source: USEPA. Size and region breakouts are based on 1997 Census data provided in the *Development Document* (USEPA, 2000a). Facility size and region definitions for model CAFOs are provided in Section 4, Table 4-1. Rounded to nearest ten. Numbers do not adjust for mixed animal types and include expected designated CAFOs (<500 AU under two-tier and <300 under three-tier structure) are included in the counts and are shown over a 10-year period. Shaded cells indicate that there are no small CAFO businesses that will be affected by the regulations that meet the SBA definition of a small business.

**Table 9-6. Numbers of Small CAFO Businesses by Sector, Size, and Region, Three-Tier Structure**

Sector	Region	CAFOs <300AU	CAFOs "Medium 1"	CAFOs "Medium 2"	CAFOs "Large 1"	CAFOs "Large 2"
Fed Cattle	CE		20	160	70	
	MW		120	840	280	
Veal	MW		50	80	10	
Heifers	MW		180	500	300	
Dairy	MW	50				
	PA					
Hog: FF	MA					
	MW	50	150	100		
Hog: GF	MA					
	MW					
Layer: Wet	SO		50	20		
Layer: Dry	MW		130	60		
	SO		230	100		
Broiler	MA		3210	1190	980	70
	SO		2750	2650	2,300	260
Turkey	MA		320			
	MW		180			
<b>Total</b>		<b>100</b>	<b>7,390</b>	<b>5,700</b>	<b>3,940</b>	<b>330</b>

Source: USEPA. See Table 9-5.

#### ***9.3.2.4 Description of the Proposed Reporting, Recordkeeping, and Other Requirements***

The proposed CAFO regulations contain recordkeeping and reporting requirements. Costs associated with information collection include the recording of animal inventories, manure generation, findings from visual inspections of feedlot areas and fields, lagoon emptying, and other activities on a routine basis. Recordkeeping requirements also include collecting information on field application of manure and other nutrients (including amount, rate, method, incorporation, and dates), manure and soil analysis compilation, crop yield goals and harvested yields, crop rotations, tillage practices, rainfall and irrigation, and lime applications. Other

requirements include manure spreader calibration worksheets, manure application worksheets, maintenance logs, and soil and manure test results.

EPA has estimated the burden and costs associated with information collection imposed on CAFOs and states as a result of the proposed CAFO regulations. This analysis is provided in the Information Collection Request (ICR) document prepared by EPA (USEPA, 2000i). For the purpose of this analysis, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust existing procedures to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information request; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

EPA’s labor burden estimates for CAFO and state respondents are the hours of activity required to comply with changes to the NPDES CAFO program. For each activity, EPA estimates the burden in terms of the expected effort necessary to carry out these activities under normal conditions and reasonable labor efficiency. These activities and estimated burden and cost levels are described in more detail in the ICR (USEPA, 2000i). The ICR also contains a summary of wage rate information from USDA, state agricultural extension agencies, and the Bureau of Labor Statistics, compiled by EPA for the purpose of this analysis. Additional information on the ICR is provided in Section XIII.F of the preamble to this rulemaking. A summary of the analysis of impacts to CAFO operators is provided below. Additional information on the estimated burden and costs to states is provided in the ICR.

EPA identifies five burden activities to CAFO operators, including start-up activities, permit application, permit nutrient plan development, best available technology requirements, and ground water monitoring for new facilities. Start-up activities are steps that a CAFO owner or operator must take in preparation to comply with the information collection requirements of the proposed rule. Owners or operators that are potentially affected by the rule will need to familiarize themselves with the changes to the NPDES CAFO program to determine that they will need to apply for a permit (or certify out of the program, under three-tier structure only), develop a PNP, and implement the other BAT requirements. PNPs must be reviewed annually and rewritten every five years. Permit application activities involve completing and submitting either an NOI under a general permit or an application for an individual permit. These activities will be conducted once every five years.

PNP development and implementation will require owners or operators of CAFOs to apply for a permit and notify their permitting authority when the PNP has been developed or modified. This notice must include the number of animals covered by the plan, the number of acres receiving waste, the nutrient content of the manure, the application schedule and rate, and

the quantity that will be transferred off site. As part of their recordkeeping responsibilities, CAFO operators will be required to keep the plan on site for inspections and make it available to the permitting authority on request.

To meet the proposed BAT requirements, CAFO owners or operators will perform various activities which will need to be recorded, such as visual inspections of the feedlot facilities, testing or calibration of manure application equipment, collection of soil samples, recording of volume of manure and process wastewater produced as well as off-site transfer, and employee training. Existing beef and dairy sources as well as all NSPS have requirements will involve documentation of whether ground water is hydrologically linked to surface water at the CAFO site and, if it is, records of monitoring of ground water quality. Monitoring records must be maintained to demonstrate that no discharge has occurred.

In addition to recordkeeping costs, EPA estimates the capital and operation and maintenance (O&M) costs associated with these burden activities. A CAFO will incur capital costs when it purchases equipment or builds structures that are needed for compliance with the rule's reporting and recordkeeping requirements that the facility would not use otherwise. Consistent with the overall cost analysis for the proposed rule, capital costs are annualized assuming a 10-year amortization period and a 7 percent interest rate. Capital costs for the proposed rule include purchasing a soil auger to collect soil samples and a manure sampler. CAFOs applying manure on site (assumed to be 100 percent, although land application does not occur at 100 percent of CAFOs) will need to obtain a scale to calibrate the spreader. Some facilities will also need to install depth markers in their lagoons, and certain sources with ground water linked to surface water will need to install monitoring wells. EPA's estimates also include the one time cost for the nutrient management course in this cost category. A facility incurs O&M costs when it regularly uses services, materials, or supplies needed to comply with the rule's reporting and recordkeeping requirements that the facility will not use otherwise. Any cost for the operation and upkeep of capital equipment is considered an O&M cost. O&M costs may also be incurred on a non-annual basis, such as every three years. O&M costs include laboratory analysis of soil, manure, and ground water samples, training of person responsible for manure application, and maintenance of ground water monitoring wells.

EPA estimates that the public burden for this information collection request will require 1.2 to 1.6 million labor hours for all CAFO respondents to comply with the proposed regulations (USEPA, 2000i). Information collection at a CAFO is associated with permit application, PNP development, inspection and sampling, and ground water assessment. These estimates include the time required to review instructions, search existing data sources, gather and maintain all necessary data, and complete and review the information collection. EPA estimates total costs to regulated CAFOs associated with reporting and recordkeeping requirements under the proposed CAFO regulations at \$27 million annually (1999 dollars), under the two-tier structure. For the three-tier structure, EPA estimates costs to regulated CAFOs at \$35 million annually (USEPA, 2000i). This estimate excludes NPDES burden for CAFOs covered by other ICR estimates, as well as NPDES burden for co-permittees and off-site manure recipients.

Under the two-tier structure, EPA estimates that there will be approximately 7,300 CAFO respondents and an average of 80,700 CAFO responses per year. Under the three-tier structure, EPA estimates that there will be approximately 9,600 CAFO respondents and an average of 107,800 CAFO responses. Thus, the average burden per CAFO respondent is 163 to 166 hours and the average burden per CAFO response is 14 to 15 hours. For this analysis, EPA assumes that the administrative burden assumptions are generally the same regardless of CAFO size. Only soil sampling and PNP development burdens would differ by CAFO size. Costs are assessed using a weighted average acreage for all affected CAFOs and do not contain a breakdown for CAFOs with more than or less than 1,000 AU. This estimate likely overstates the time requirements at small CAFO businesses, since it is an average over all operations both large and small.

More detailed information on the burden and associated costs for each of the activities described above is provided in the ICR (USEPA, 2000i).

#### ***9.3.2.5 Identification of Relevant Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Regulations***

For this analysis, EPA assumes that all CAFOs are already in compliance with existing federal and state regulations affecting animal production facilities. The Small Business Advocacy Review Panel did not identify any federal rules that duplicate or interfere with the requirements of the proposed rule (USEPA, 2000g).

#### ***9.3.2.6 Significant Regulatory Alternatives***

EPA proposes to focus the regulatory revisions in this proposal on the largest operations, which present the greatest risk of causing environmental harm, and in so doing, has minimized the effects of the proposed regulations on small livestock and poultry operations. First, EPA is proposing to establish a two-tier structure with a 500 AU threshold. Unlike the current regulations, under which some operations with 300 to 500 AU are defined as CAFOs, operations of this size under the revised regulations would be CAFOs only by designation. Second, EPA is proposing to raise the size standard for defining egg laying operations as CAFOs. Third, EPA is proposing to eliminate the “mixed” animal calculation for operations with more than a single animal type for determining which AFOs are CAFOs.

Under the two-tier structure, EPA is proposing to revise the threshold for being defined as a CAFO down to 500 AU and eliminate the “middle category” for operations with between 300 and 1000 AU. This proposal would provide relief to small businesses by removing from the CAFO definition operations with between 300 AU to 500 AU that under the current rules are defined as CAFOs. EPA estimates that under the co-proposed alternatives, between 64 percent (two-tier) and 72 percent (three-tier) of all CAFO manure would be covered by the regulation.



(See Section 2 of this report.) Under the two-tier structure, the inclusion of all operations with more than 300 AU instead of operations with more than 500 AU, the CAFO definition would result in 13,800 additional operations being regulated, along with an additional 8 percent of all manure. An estimated 80 percent of these additional 13,800 CAFOs are small businesses (about 10,870 CAFOs). EPA estimates that by not extending the regulatory definition to operations with between 300 and 500 AU, these 10,870 small businesses will not be defined as CAFOs and will therefore not be subject to the proposed regulations. EPA estimates the additional costs of extending the regulations to these small CAFO businesses at almost \$150 million across all sectors. The difference in costs between the proposed BAT Option/Scenario and the proposed BAT Option and Scenario 4b combination may be approximated by comparing the estimated costs for these regulatory options, which are shown in Section 5.

Also, under the two-tier structure, EPA is proposing to raise the size standard for defining egg laying operations as CAFOs. This alternative would remove from the CAFO definition small egg laying operations with between 30,000 and 50,000 hens that under the current rules are defined as CAFOs, if they utilize a liquid manure management system. (The current regulations affects egg laying operations with more than 30,000 birds that use wet manure management systems only. Layer operations with dry manure systems are not covered by the regulations. EPA is proposing to regulate all layer operations of a certain size, regardless of the type of manure management systems used, as described in Section 3.) To provide relief to smaller operations, EPA is proposing to raise the size standard to apply to operations with more than 50,000 birds on-site. A higher size standard for egg laying operations is intended to avoid placing too much burden on small egg laying operations. These operations are virtually all small businesses (see Table 9-2). Most of these operations are concentrated in the Southern production regions. Data are not available to determine the number of egg laying operations with 30,000 to 50,000 layers. Therefore, EPA did not estimate the cost savings of raising the size standards for egg operations.

In addition, under both co-proposed alternatives, EPA is proposing to revise the threshold for being defined as a CAFO by eliminating the requirements for “mixed” operations (i.e., operations with more than a single animal type). Under the existing permit regulation, if a facility confines more than one animal type, each animal type is assigned a multiplication factor that is used to calculate the total number of animal units at the facility. Only poultry is excluded from this mixed animal type calculation under existing regulations. EPA is proposing to exclude mixed operations with more than a single animal type. The Agency determined that the inclusion of these operations would disproportionately burden small businesses while resulting in little additional environmental benefit. Since most mixed operations tend to be smaller in size, this exclusion represents important accommodations for small businesses. EPA expects that there are few large operations that confine more than a single animal type. If certain of these smaller operations are determined to be discharging to waters of the U.S., States can later designate them as CAFOs and subject them to the regulations. EPA’s decision not to include operations with more than a single animal type is also expected to simplify compliance and be more

administratively efficient, since the mixed operation multipliers were confusing to the regulated community and to enforcement personnel, and did not cover all animal types.

Overall, EPA's decision to mitigate the effects on small CAFO businesses through these scope considerations is intended to favor smaller—usually more traditional and often more sustainable—farm production systems where operators grow both livestock and crops and land apply manure nutrients. This is consistent with EPA's objectives under the USDA-EPA Unified National Strategy for Animal Feeding Operations, which targets only the largest operations since these pose the greatest *potential* risk to water quality and public health given the sheer volume of manure generated at these operations (USDA and USEPA, 1999). Larger operations that handle larger herds or flocks often do not have an adequate land base for manure disposal through land application. As a result, large facilities need to store significant volumes of manure and wastewater that have the potential, if not properly handled, to cause significant water quality impacts. In comparison, smaller operations manage fewer animals and tend to concentrate fewer manure nutrients at a single location. Smaller operations tend to be less specialized and are more diversified, engaging in both animal and crop production. These operations often have sufficient cropland and fertilizer needs to land apply manure nutrients generated at a livestock or poultry business.

#### 9.4 EPA'S ANALYSIS OF SMALL BUSINESS IMPACTS

This section discusses the data and methodology EPA uses to assess economic impacts on small CAFO businesses (Section 9.4.1) and presents the results of this analysis (Section 9.4.2). This economic analysis supports the IRFA (Section 9.3) by quantifying the effects of the proposed CAFO regulations.

##### 9.4.1 Data and Methodology

To examine the economic impacts of the proposed regulations on small CAFO businesses, EPA uses the same representative farm approach that is used to analyze impacts to all CAFOs (regardless of size), as described in Section 4 this EA. This approach evaluates impacts to select model CAFOs and extrapolates these results to the number of operations identified by each representative model, thus aggregating costs nationally across all sectors. Inputs for this analysis include the number of CAFOs represented by each model (see Section 9.3.3) and, for each model CAFO, the costs of the proposed regulations and selected financial characteristics (see Section 4).

EPA's analysis evaluates the economic achievability of the proposed regulatory options at small CAFO businesses based on changes in representative financial conditions across three criteria. These criteria are: a comparison of incremental costs to total revenue (sales test), projected post-compliance cash flow over a 10-year period, and an assessment of an operation's debt-to-asset ratio under a post-compliance scenario.

EPA determines economic impacts to small businesses by applying the proposed economic achievability criteria described in Section 4.2.5, which are used to divide the impacts of the proposed CAFO regulations into three categories (see Table 4-11). Accordingly, if an average model facility is determined to incur economic impacts under the proposed CAFO regulations that are regarded as “Affordable” or “Moderate,” then the results are considered to indicate economic achievability. “Moderate” impacts are not associated with operational change at the CAFO and are considered by EPA to indicate economic achievability. If an average operation is determined to incur “Stress,” this result is considered to potentially indicate that the proposed regulations might not be economically achievable, subject to other considerations. “Affordable” and “Moderate” impacts are associated with positive post-compliance cash flow over a 10-year period and a debt-to-asset ratio not exceeding 40 percent, in conjunction with a sales test result that shows that compliance costs are less than 5 percent of sales (“Affordable”) or between 5 and 10 percent of sales (“Moderate”). “Stress” impacts are associated with negative cash flow or a post-compliance debt-to-asset ratio exceeding 40 percent, or sales test results that show costs equal to or exceeding 10 percent of sales. More detail on this classification scheme, along with a discussion of the basis for EPA’s determination of these criteria for this analysis, is provided in Section 4.2.5.

Table 9-7 shows EPA’s estimated compliance costs for selected model CAFOs under the proposed BAT Option. Costs are not presented separately by facility model for each co-proposed scenario, since the only difference in costs between the two scenarios are associated with the difference in the numbers of regulated CAFOs. All costs shown are expressed on a per-animal basis and are differentiated by facility size, producing region, facility types, and other factors. Costs are reported in ranges across three types of land availability for manure application assumed for this analysis. These land availability types include: Category 1 farms, which have sufficient cropland for all on-farm nutrients generated; Category 2 farms, which have insufficient cropland; and Category 3 farms, which have no cropland. Ranges also reflect Option 3 and 3A costs.<sup>9</sup> Section 4.2.1 provides additional information on EPA’s cost models. Unit costs shown in Table 9-7 are aggregated by the average number of animals assumed for each model CAFO to derive total entity compliance costs used in this analysis. Information on EPA’s model CAFOs used for this analysis is provided in Section 4.2 of this report.

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<sup>9</sup>Option 3 assesses average costs to operations if there is no direct hydrologic connection to surface waters; Option 3A reflects costs to operations where there is a determined groundwater hydrologic connection (assumed at 24 percent of all affected operations).

**Table 9-7. Estimated Per-Head Facility Costs (BAT Option/Co-Proposed Scenarios) for Model CAFOs**

Sector	Region	Model CAFOs <300AU	Model CAFOs "Medium 1"	Model CAFOs "Medium 2"	Model CAFOs "Large 1"	Model CAFOs "Large 2"
			300 - 1,000 AU		>1,000 AU	
			(incremental compliance costs \$ per animal)			
Fed Cattle	CE		\$10.81-\$80.32	\$7.21-\$61.98	\$3.37-\$38.59	
	MW		\$15.87-\$67.24	\$11.31-\$50.56	\$7.12-\$34.65	
Veal	MW		\$2.65-\$7.78	\$2.54-\$4.75	\$2.50-\$4.75	
Heifers	MW		\$14.13-\$55.50	\$9.37-\$39.57	\$5.04-\$20.16	
	PA		\$10.63-\$60.86	\$6.86-\$43.96	\$3.51-\$27.14	
Dairy	MW	\$60.39-\$222.08				
	PA					
Hog: FF	MA					
	MW	\$5.80	\$6.03-\$7.45	\$4.35-\$5.65		
Hog: GF	MA					
	MW					
Layer: Wet	SO		\$0.83	\$0.39-\$0.60		
Layer: Dry	MW		\$0.02-\$0.27	\$0.02-\$0.23		
	SO		\$0.02-\$0.18	\$0.02-\$0.15		
Broiler	MA	\$0.07-\$0.13	\$0.07-\$0.13	\$0.07-\$0.12	\$0.07-\$0.12	\$0.05-\$0.10
	SO	\$0.07-\$0.15	\$0.07-\$0.15	\$0.07-\$0.13	\$0.06-\$0.13	\$0.05-\$0.11
Turkey	MA		\$0.07-\$0.71			
	MW		\$0.12-\$0.83			

Source: USEPA. Annualized costs are shown in Appendix A; actual costs are in the *Development Document* (USEPA, 2000a). Facility size and region definitions for model CAFOs are provided in Section 4, Table 4-1. Large operations roughly correspond to CAFOs with >1,000 AU and Medium operations correspond to CAFOs with 300-1,000 AU. Shaded cells indicate that there are no CAFOs that will be affected by the proposed regulations and that meet the SBA definition of a small business.

EPA also developed costs to confinement operations with less than 300 or 500 AU that may be designated as CAFOs by scaling the estimated compliance costs for the available “medium” and “large” CAFO models. (See Tables 9-5 and 9-6 for expected designated facilities under each co-proposed alternative.) The resulting costs—derived on a per-head basis—are adjusted by the average head counts at operations with fewer than 500 AU or 300 AU to derive the annualized per-facility compliance cost. EPA assumes that CAFOs with fewer than 500 AU or 300 AU have sufficient cropland for all on-farm nutrients generated (identified in the cost model as Category 1 costs). More detailed cost information is provided in the *Development Document* (USEPA, 2000a).

As explained in Section 4.2 of this report, EPA evaluates the effect of incurred compliance costs based on the total number of CAFOs in each sector, including mixed operations. This approach avoids understating costs at operations with more than one animal type that meets the size threshold for a CAFO or is designated as a CAFO by the Permitting Authority, and thus may incur costs to comply with the proposed requirements for each type of animal that is raised on site. Therefore, EPA’s compliance costs estimates likely represent the upper bound, since costs at facilities with more than a single animal type may, in some cases, be lower due to shared production technologies and practices across all animal types that are produced on site.

The financial data that EPA uses to analyze impacts on small CAFO businesses are from USDA’s ARMS database (see Section 4.2). These data are available for 1997 by commodity sector, facility size (animal inventory), and production region. Available 1997 financial data that are used to characterize average model CAFOs include gross farm revenue, net cash income (used to project cash flow), and baseline debt-to-asset ratios. Table 9-8 shows the gross revenue that EPA assumes for this analysis, expressed on a per-animal basis. Unit revenues shown in Table 9-8 are aggregated by the average number of animals assumed for each model CAFO to derive total entity revenue used in this analysis. Estimated cash flow and debt-to-asset ratios for CAFO models are provided in Section 4 of this report (Tables 4-5 and 4-7).

As Table 9-8 shows, USDA data indicate that operations with fewer than 300 AU, on average, have higher gross revenues when expressed on a per-animal basis than operations with more than 300 AU. This is explained by the fact that smaller farming operations tend to be more diversified and engage in both livestock and crop production. In general, larger businesses tend to be more specialized and concentrate on a single enterprise only. Consistent with SBA’s size standards that are expressed in terms of total annual business revenue (SBA, 1998), EPA assesses financial impacts at model CAFOs based on changes in *total* farm revenue. Total farm revenue, as reported in USDA’s ARMS database, includes gross cash income from both livestock and crop sales (including net Commodity Credit Corporation loans), government payments, and other farm-related income (income from machine-hire, custom work, livestock grazing, land rental, contract production fees, outdoor recreation, and other farm-related sources) (USDA/ERS, 1999a).

**Table 9-8. Estimated Per-Head Facility Revenues for Model CAFOs**

Sector	Region	Model CAFOs <300AU	Model CAFOs "Medium 1"	Model CAFOs "Medium 2"	Model CAFOs "Large 1"	Model CAFOs "Large 2"
			300 - 1,000 AU		>1,000 AU	
			(incremental compliance costs \$ per animal)			
Fed Cattle	CE		\$502		\$854	
	MW		\$535		\$862	
Veal	MW		\$535		\$862	
Heifers	MW		\$535		\$862	
	PA		\$502		\$854	
Dairy	MW	\$2,620				
	PA					
Hog: FF	MA					
	MW	\$606	\$304			
Hog: GF	MA					
	MW					
Layer: Wet	SO		\$25			
Layer: Dry	MW		\$25			
	SO		\$25			
Broiler	MA		\$1.5		\$1.1	
	SO		\$1.4		\$1.2	
Turkey	MA		\$11.2			
	MW		\$11.2			

Source: Derived from USDA/ERS, 1999a (see Section 4.2.4). Facility size and region definitions for model CAFOs are provided in Section 4, Table 4-1. Large operations roughly correspond to CAFOs with >1,000 AU and Medium operations correspond to CAFOs with 300-1,000 AU. Shaded cells indicate that there are no CAFOs that will be affected by the proposed regulations and that meet the SBA definition of a small business.

Higher total farm revenues per animal at smaller-sized farms (due to the inclusion of revenue from all farm-related sources) is demonstrated in the original USDA ARMS data that are presented in the individual subcategory sections of this report, including Section 6 (poultry), Section 7 (hogs), and Section 8 (cattle and dairy). Derived on a per animal basis, these data show that operations with less than 300 AU tend to generate a larger share of total revenue from other secondary sources, including other secondary livestock revenue as well as revenue from crop sales. Other sources of farm-related revenue that tend to be greater at operations with less than 300 AU, compared to operations with more than 300 AU, include other farm-related revenue, such as government payments and nonfarm income. Since EPA's small business analysis considers a business' total entity revenue, with SBA size standards, the derived per-unit revenues are relatively lower per-unit for model CAFOs with more than 300 AU compared to model CAFOs with fewer than 300 AU. EPA's analysis does not consider sources of non-farm revenue in its analysis, even though data from USDA indicate that nonfarm revenue often constitutes a significant share of total operating income (USDA/ERS, 2000d, 1996a and 1999a).

The same ARMS financial data, however, consistently indicate that per-unit cash expenses tend to be greater among smaller producers than among larger operations. This is consistent with expectations of economies of size in agricultural production. A review of the agricultural literature suggests that there may be a statistically positive relationship between farm size and per-unit production costs, such that as farm size (number of animals) increases, per-unit costs are lower (ERG, 2000d; Lazarus, et al., 1999). This may result in lower per-unit capital costs and create a competitive advantage among larger-sized operations relative to smaller ones. This literature review is provided in the rulemaking record (ERG, 2000d—see DCN 70641).

#### **9.4.2 Economic Analysis Results**

Using the proposed economic achievability criteria, discussed in Section 9.4.1, EPA's economic analysis indicates that the proposed regulations will not impose financial stress on a substantial number of operations, relative to the total number of affected confinement operations in these sectors. The results of this analysis are presented in Table 9-9 for each of the co-proposed tier structures. (Results for Scenario 5 (two-tier structure at 750 AU threshold) and Scenario 6 are not determined, but fall within the range of the results presented.)

Under both the two-tier and three-tier structures, EPA's analysis indicates that the proposed requirements will not impose stress impacts on any affected small businesses in the veal, dairy, hog, egg laying, and turkey sectors. Under the two-tier structure, the proposed requirements will not result in financial stress to affected small operations in the heifer sector. Operations in these sectors are expected to be able to absorb the costs associated with the

Table 9-9. Results of EPA's Small Business Analysis

Sector	Number of Small CAFOs	Affordable	Moderate	Stress	Affordable	Moderate	Stress
		Zero Cost Passthrough					
		(Number of Operations)			(% Affected Operations)		
<b>Two-Tier Structure (Proposed BAT Option/Scenario 4a)</b>							
Fed Cattle	1,390	1,130	250	10	81%	18%	1%
Veal	90	90	0	0	100%	0%	0%
Heifer	800	680	120	0	85%	15%	0%
Dairy	50	40	10	0	80%	20%	0%
Hogs	300	300	0	0	100%	0%	0%
Broilers	9,470	1,860	7,460	150	20%	79%	2%
Layers	200	200	0	0	100%	0%	0%
Turkeys	0	0	0	0	NA	NA	NA
<b>TOTAL</b>	<b>10,550</b>	<b>4,300</b>	<b>7,840</b>	<b>160</b>	<b>41%</b>	<b>74%</b>	<b>2%</b>
<b>Three-Tier Structure (Proposed BAT Option/Scenario 3)</b>							
Fed Cattle	1,490	1,100	380	10	74%	26%	1%
Veal	140	140	0	0	100%	0%	0%
Heifer	980	800	150	30	82%	15%	3%
Dairy	50	40	10	0	80%	20%	0%
Hogs	300	300	0	0	100%	0%	0%
Broilers	13,410	1,910	11,220	280	14%	84%	2%
Layers	590	590	0	0	100%	0%	0%
Turkeys	500	460	40	0	92%	8%	0%
<b>TOTAL</b>	<b>14,630</b>	<b>5,340</b>	<b>11,800</b>	<b>320</b>	<b>37%</b>	<b>81%</b>	<b>2%</b>

Source: USEPA. Impact estimates shown include impacts to designated operations. Option/Scenario definitions provided in Table 3-1. Category definitions ("Affordable," "Moderate" and "Stress") are provided in Table 4-13. Numbers may not add due to rounding. NA = Not Applicable.

Number of operations does not adjust for operations with mixed animal types, for comparison purposes, to avoid understating costs at operations with more than one animal type that may incur costs to comply with the proposed requirements for each type of animal that is raised on-site. The number of CAFOs includes designated facilities.



proposed CAFO regulations without having to rely on cost passthrough. EPA's analysis shows that operations across most sectors may experience moderate financial impacts (Table 9-9). Moderate impacts are not associated with operational change at the CAFO (i.e., will not result in facility or product line closure) and are considered by EPA to be economically achievable.

In the cattle and broiler sectors, however, EPA's analysis indicates that each of the co-proposed tier structures will result in financial stress on some small businesses in the fed cattle and broiler sectors, as will the three-tier structure on some small heifer operations. These small businesses may be vulnerable to closure. Overall, operations that may experience financial stress comprise about 2 percent of all affected small CAFO businesses. For the two-tier structure, EPA estimates that 10 small beef operations and 150 small broiler operations will experience financial stress. For the three-tier structure, EPA estimates that 40 small beef and heifer operations and 280 small broiler operations will experience financial stress. No designated operations under either co-proposed scenario are estimated to experience financial stress. Small broiler facilities with stress impacts are larger operations with more than 1,000 AU under both tier structures. Small cattle and heifer operations with stress impacts are those that have a ground water link to surface water. This analysis is conducted assuming that no costs are passed through between the CAFO and processor segments of these industries. Based on the results of this analysis, EPA is proposing that the proposed regulations are economically achievable to small businesses in these sectors.

EPA believes that the estimated financial impacts shown in Tables 9-9 are worst-case. These reasons are summarized below.

First, all results are estimated assuming no costs can be passed through between CAFOs and the processing sectors. As discussed in Section 5 of this report, if modest levels of cost passthrough are assumed in the broiler sectors, then the proposed regulations are affordable to all small broiler operations. EPA did not evaluate economic impacts to cattle operations under a cost passthrough scenario; however, it is expected that long-run market and structural adjustment by producers in this sector will diminish the estimated impacts. Even without assumptions of cost passthrough, EPA's analysis shows that adverse impacts will not be experienced by a substantial number of operations, as compared to the number of affected operations in these sectors. EPA has conducted an extensive literature review of issues concerning cost passthrough. Based on the results of the available empirical research on market power and price transmission in these industries, EPA believes that there is little evidence to support that increased production costs may not be passed through the market levels. A summary of this literature review is provided in the rulemaking record (ERG, 2000c — DCN 70640).

Second, as noted in the Panel Report, EPA believes that the number of small broiler operations is overestimated. In the absence of business level revenue data, EPA estimates the number of "small businesses" using the approach described in Section 9.2. Using this approach, virtually all (>99.9 percent) broiler operations are considered "small" businesses. This categorization may not accurately portray actual small operations in this sector since it classifies a

10-house broiler operation with 260,000 birds as a small business. Information from industry sources suggests that a two-house broiler operation with roughly 50,000 birds is more appropriately characterized as a small business in this sector (Madison, 1999; Staples, 1998). Therefore, it is likely that the number of small broiler operations may reflect a number of medium and large size broiler operations being considered as small entities. As discussed in Section 9.2.1, EPA consulted with SBA on the use of an alternative definition for small businesses in all affected sectors based on animal inventory at an operation during the development of the rulemaking.

Third, EPA believes that the use of a costs-to-sales comparison is a crude measure of impacts on small business in sectors where production contracting is commonly used, such as in the broiler sector (and also in the turkey, egg, and hog sectors, though to a lesser extent). As discussed in Section 4.2.4.5, lower reported operating revenues in the broiler sector reflect the predominance of contract growers in this sector. Contract growers receive a pre-negotiated contract price that is lower than the USDA-reported producer price, thus contributing to lower gross revenues at these operations (USDA, 1999). Lower producer prices among contract growers are often offset by lower overall production costs at these operations, since the affiliated processor firm pays for a substantial portion of the grower's annual variable cash expenses. Inputs supplied by the integrator may include feeder pigs or chicks, feed, veterinary services and medicines, technical support, and transportation of animals (USDA, 1996b). These variable cash costs comprise a large component of annual operating costs, averaging more than 70 percent of total variable and fixed costs at livestock and poultry operations (USDA, 1999). The contract grower also faces reduced risk because the integrator guarantees the grower a fixed output price (see Section 2.3.1 for more details on contracting in animal agriculture). Because production costs at a contract grower operation are lower than at an independently owned operation, a profit test (costs-to-profit comparison) is a more accurate measure of impacts at grower operations. However, financial data are not available that differentiate between contract grower and independent operations.

Fourth, EPA's initial regulatory flexibility analysis also does not consider a range of potential cost offsets available to most farms. One source of cost offset is manure sales, particularly of relatively higher value dry poultry litter. EPA estimates that sales of dry poultry litter could offset the costs of meeting the regulatory requirements on the order of more than 50 percent. This reduction alone exceeds the level of cost passthrough (42 percent) assumed for the cost impact analysis of the broiler sector. Details on how EPA calculated these manure sale offsets and how they would reduce the economic impacts at poultry operations are presented in Section 6.

Another source of potential cost offset is cost share and technical assistance available to farmers for on-farm improvements from various state and federal programs, such as the Environmental Quality Incentives Program (EQIP) administered by USDA. The EQIP program provides cost-share assistance to all livestock and poultry operations, regardless of size, for terraces, filter strips, and runoff trenches, as well as technical assistance in formulating conservation plans. More importantly, operations with 1,000 or fewer AU in confinement, which

make up the majority of small CAFO businesses, are also eligible to receive funding for construction of animal waste storage and treatment facilities (e.g., lagoons, holding tanks). Additionally, many poultry operations with more than 1,000 AU are considered small under SBA definitions, fall below the EQIP size threshold, and are eligible for waste storage and treatment funding (e.g., poultry operations with less than 455,000 broilers or less than 250,000 layers). Although funding may be limited, it is expected that the majority of funds are likely to go to operations eligible for waste storage and treatment funding (ERG, 2000a).

Many other state and federal cost share programs base eligibility not on size thresholds but on priority watersheds (e.g., USDA's Small Watershed Program; the New York City Watershed Program), priority contaminants (e.g., Kansas Non-Point Source Pollution Control Fund), or proposed waste management practices (e.g., Maryland, Minnesota, Missouri, Nebraska, and North Carolina state programs). However, technical assistance under most programs is available to all operations, regardless of watershed, contaminants, proposed practices, or size (ERG, 2000a). A review of cost-share and technical assistance programs available to animal feeding operations is provided in the rulemaking record (ERG, 2000a — DCN 70130).

Finally, this analysis does not take into account certain noneconomic factors that may influence an operation's decision to weather the boom and bust cycles that are commonplace in agricultural markets. Farm typology data from USDA indicate that a large share of farming operations (more than 90 percent) have annual sales of less than \$250,000 and are considered "small family farms" by USDA (USDA/ERS, 2000d and 2000e). Of these, the majority (about 60 percent) are "limited-resource," "retirement," or "residential" operations where farming is not the primary source of income (USDA/ERS, 2000e and 1999a). In many cases, these operations have negative annual income supplemented by sources of off-farm income that subsidize the farming operation (USDA/ERS, 2000d and 1996a).

USDA's ERS (1996a) reports that about 60 percent of farm operators reporting negative net income had nonfarm occupations. About 75 to 80 percent of farms rely on some nonfarm income, and even in the largest operations nonfarm income can be a significant portion of total household income (USDA/ERS, 1996a). More than 90 percent of farm operators with negative net income had nonfarm income averaging more than \$35,700 per year; even farms with positive net income rely somewhat on nonfarm income (Heimlich and Barnard, 1995; USDA/ERS, 1996a).

When farm income is negative over a period of time, sales tests can be very difficult to interpret (Heimlich and Barnard, 1995). One reason that incomes can remain negative over several years is that operators can supplement farm income with nonfarm income, and these losses can be used to reduce total income tax liabilities while the real estate value of the farm property appreciates. Additional noneconomic factors might also include the satisfaction of working for oneself, the ability to employ family members, a sense of tradition and the ability to pass on that tradition to future generations, and the fact that the operation is both a home and a livelihood. These and other noneconomic factors may influence the decision to close a livestock or poultry operation cannot be adequately addressed in an economic model. To the extent that these factors

play a role in that decision, EPA's economic model may overstate the possibility of closure among small businesses.

USDA's farm financial data include operations where farming is part-time and not the primary occupation, but excludes sources of nonfarm income at these operations. As noted in Section 4.2, the inclusion of these operations may result in lower average data values than would be the case if these operations were excluded from the analysis. EPA believes that the inclusion of these operations may tend to overstate impacts. Previous analyses by USDA and EPA have also noted the potential effect on average farm data of including these operations and have regarded these part-time business more as "hobbies or recreational activities" (Heimlich and Barnard, 1995; DPR, 1995). Heimlich and Barnard (1995) further indicate that considering non-farm income in addition to farm income may provide a more appropriate comparison to the costs of required measures where the motivation for staying in business is not necessarily purely economic.

Overall, EPA expects that the proposed CAFO regulations will benefit the smallest businesses in these sectors, since the regulations may create a comparative advantage for smaller operations (less than 300 or 500 AU), especially those operations that are not subject to the regulations. Except for the few AFOs that are designated as CAFOs, these smaller operations will not incur costs associated with the proposed requirements and may benefit from eventual higher producer prices as these markets adjust to higher production costs in the longer term.

# APPENDIX K EXAMPLE OF A SUCCESSFUL FRFA

## SECTION FOUR

### FINAL REGULATORY FLEXIBILITY ANALYSIS

This section considers the effects of the CAFO regulations on small businesses in the livestock and poultry industries. Section 4.1 discusses EPA's requirements under the Regulatory Flexibility Act. Section 4.2 outlines EPA's initial assessment of small businesses in the sectors affected by the regulations. Section 4.3 presents EPA's final regulatory flexibility analysis and summarizes other steps taken by the Agency to comply with the RFA. Section 4.4 presents the data, methodology, and results of EPA's analysis of impacts on small businesses for this rulemaking.

#### 4.1 THE REGULATORY FLEXIBILITY ACT AS AMENDED BY THE SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

The Regulatory Flexibility Act (RFA, 5 U.S.C *et seq.*, Public Law 96-354), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) generally requires an agency to prepare a regulatory flexibility analysis describing the impact of the regulatory action on small entities as part of the rulemaking. This analysis is required for any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a "significant impact on a substantial number of small entities." Small entities include small businesses, small organizations, and governmental jurisdictions. Because the CAFO regulations could have a significant economic impact on a substantial number of small entities, EPA has prepared this final regulatory flexibility analysis (FRFA).

In addition to the preparation of an analysis, the RFA, as amended by SBREFA, imposes certain responsibilities on EPA when the Agency proposes rules that might have a significant impact on a substantial number of small entities. These include requirements to consult with representatives of small entities about the proposed rule. The statute requires that, where EPA has prepared an initial regulatory flexibility analysis (IRFA), the Agency must convene a Small Business Advocacy Review (SBAR) Panel for the proposed rule to seek the advice and recommendations of small entities concerning the rule. The panel is composed of employees from EPA, the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Office of Advocacy of the Small Business Administration (SBA).

#### 4.2 INITIAL ASSESSMENT

Prior to the 2001 Proposal, EPA conducted an initial assessment according to Agency guidance on implementing RFA requirements (USEPA, 1999i). First, EPA must indicate whether the proposal is a rule subject to notice-and-comment rulemaking requirements. EPA determined that the proposed CAFO regulations were subject to notice-and-comment rulemaking requirements. Second, EPA should develop a profile of the affected small entities. EPA has developed such a profile of the livestock and poultry sectors, which includes all affected operations as well as small businesses. This information is provided in Section 2 and other sections of the Proposal EA (USEPA, 2001a). Third, EPA's assessment needs to

determine whether the rule would affect small entities and whether the rule would have an adverse economic impact on small entities.

For the proposed rulemaking, EPA could not conclude that costs are sufficiently low to justify “certification” that the regulations would not impose a significant economic impact on a substantial number of entities. Instead, EPA complied with all RFA provisions and conducted outreach to small businesses, convened an SBAR Panel, and prepared an IRFA. That analysis described EPA’s assessment of the impacts of the proposed CAFO regulations on small businesses in the livestock and poultry sectors. A summary of this analysis was published in the *Federal Register* at the time of publication of the 2001 Proposal (66 FR 3099-3103, see: USGPO, 2001a). More detailed information on EPA’s IRFA is provided in Section 9 of the Proposal EA. EPA’s Proposal EA also describes other requirements of EPA’s initial assessment of small businesses and summarizes the steps taken by EPA to comply with the RFA.

Since proposal, EPA has received new information and data related to small business in the livestock and poultry industries, including revisions to the SBA’s definition of “small business” in these sectors and updates to EPA’s estimate of the number of affected operations to reflect USDA estimates. This information was presented in the 2001 Notice (66 FR 58556; USGPO, 2001b). Section 4.2.1 of this report reviews SBA’s revised definitions of small entities in the livestock and poultry industry and discusses a rationale for using an alternative definition of small business in one sector. Section 4.2.2 then uses the definitions of small entities laid out in Section 4.2.1 to estimate the number of operations that meet this small business definition. Section 4.2.3 presents the results of the initial assessment EPA conducted for the 2001 Proposal, which provides a first level screen of potential impacts on small business CAFOs and serves as a signal for additional analysis.

#### 4.2.1 Definition of Small CAFO Businesses

The RFA defines a “small entity” as a small not-for-profit organization, small governmental jurisdiction, or small business. No small governmental operations operate CAFOs. A few not-for-profit organizations might operate CAFOs, but complete information is not available to warrant including not-for-profit organizations in this analysis. The analysis therefore focuses only on small businesses that are defined or designated as CAFOs. (Section 1 of this report describes the circumstances under which an AFO is defined or designated as a CAFO and is subject to the final regulations.)

The RFA requires, with some exceptions, that EPA define small businesses according to SBA’s size standards. SBA sets size standards for defining small businesses by number of employees or amount of revenues for specific industries. These size standards vary by North American Industry Classification System (NAICS) code. CAFOs are listed under NAICS 112, Animal Production.<sup>31</sup>

Table 4-1 shows SBA size standards by SIC code for each of the six livestock and poultry sectors, which are expressed in terms of average “annual receipts” (revenue). With one exception,

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<sup>31</sup> In September 2000, SBA updated the basis for its size standard from Standard Industrial Classification (SIC) codes to NAICS codes (USGPO, 2000; U.S. Census Bureau, 2000). By SIC code, these industries are listed under SIC 02, Livestock and Animal Specialties. The actual size standards for each sector, specified as an annual revenue threshold, did not change as a result of this update.

current SBA standards define a “small business” within each of the main livestock and poultry sectors as an operation that generates average revenues ranging from less than \$0.75 million per year (hog, dairy, broiler, and turkey sectors) to less than \$1.5 million per year (beef feedlot sector), averaged over the three most recent fiscal years (USGPO, 2000; SBA, 1998). The exception is the revenue threshold for a small chicken egg operation, which SBA has defined as a business that generates up to \$9 million annually. For reasons outlined in Section 9.2.1 of the Proposal EA, EPA believes that SBA’s definition of small business for the egg laying sector (revenues of \$9 million per year) does not truly characterize a small business in this sector. As discussed extensively in documentation supporting the 2001 Proposal, EPA is using an alternative definition of \$1.5 million annually for this analysis. Refer to the Proposal EA (USEPA, 2001a) and docket materials cited in that document, and the proposal itself (USGPO, 2001a).

SBA’s size standards differ from the revenue cutoff generally recognized by USDA, which has set \$250,000 in gross sales as its cutoff between small and large family farms (USDA, 1998).

As discussed in the 2001 Notice (66 FR 58570-58571; see USGPO, 2001b), recent revisions to SBA’s small business definitions for some sectors necessitate changes to EPA’s estimate of the number of AFOs that are potentially defined as CAFOs and subject to the final requirements. Prior to June 2001, SBA defined a “small business” for the dairy, hog, broiler, and turkey sectors as an operation with annual sales of less than \$0.5 million per year. On June 7, 2001, SBA raised the size standards for these four sectors to \$0.75 million per year. SBA’s notice of this change is at 66 FR 30646 (USGPO, 2001c). Although SBA did not revise its small business definition for the beef feedlot and egg laying sectors, updates to USDA estimates of the number of AFOs that are potentially defined as CAFOs also require changes to EPA’s overall estimates of the number of small businesses affected by the rulemaking. EPA’s revised estimates of the number of affected small businesses are presented in Section 4.2.2.

**Table 4-1. SBA Revenue Size Standards for Small Livestock and Poultry Operations**

NAICS Code (SIC Code)	NAICS Industry Description	SBA Size Standard <sup>a/</sup>	EPA-Assumed Revenue Cutoff
112112 (0211)	Beef Cattle Feedlots	\$1.5 million	same as SBA
112111 (0241/0212)	Beef Cattle Ranching and Farming	\$0.75 million	same as SBA
11221 (0213)	Hog and pig farming	\$0.75 million	same as SBA
11212 (0241)	Dairy cattle and milk production	\$0.75 million	same as SBA
11232 (0251)	Broilers and other meat-type chickens	\$0.75 million	same as SBA
11231 (0252)	Chicken egg production	\$9.0 million	\$1.5 million
11233 0253	Turkey production	\$0.75 million	same as SBA

Source: SBA, 1998; USGPO, 1991a, 1991b, 1996, 2000, 2001c; U.S. Census Bureau, 2000.

<sup>a/</sup>SBA Size Standards by NAICS code (13 CFR Part 121) correspond to classifications under SIC classification.

#### 4.2.2 Number of Affected Small Businesses

EPA uses three steps to determine the number of small businesses that might be affected by the CAFO regulations. First, EPA identifies small businesses in the relevant livestock and poultry sectors by equating SBA's annual revenue definition with the number of animals at an operation. Second, EPA estimates the total number of small businesses in these sectors using farm size distribution data from USDA. Third, based on the regulatory thresholds being promulgated, EPA estimates the number of small businesses that would be subject to the final requirements. These steps are summarized below. More detailed information on this approach is presented in Section 9.2.2 of the Proposal EA.

In the absence of entity level revenue data, EPA identifies small businesses in the livestock and poultry sectors by equating SBA's annual revenue definitions of "small business" to the number of animals at these operations (step 1). This step produces a threshold based on the number of animals that EPA uses to define small livestock and poultry operations and reflects the average farm inventory (number of animals) that would be expected at an operation with annual revenues that define a small business. This initial conversion is necessary because USDA data by farm size are not available by business revenue. With the exception of egg laying operations, EPA uses SBA's small business definition to equate the revenue threshold with the number of animals raised onsite at an equivalent small business in each sector (shown in Table 4-1). For egg laying operations, EPA uses an alternative revenue definition of small business, discussed in Section 4.2.1.

EPA estimates the number of animals at an operation to match SBA's small business definitions based on annual revenue size standard (expressed as annual revenue per entity) and USDA-reported farm revenue data that are scaled on a per-animal basis (expressed as annual revenue per inventory animal for an average facility). Financial data used for this calculation are from USDA's 1997 ARMS database (USDA/ERS, 1999a). USDA's data report average national revenue for each sector, combining both livestock and nonlivestock farm revenue (income from crop sales and other farm-related income, including government payments). EPA uses the derived per-animal revenues shown in Table 4-2 to equate SBA's size standard (in revenues) with farm size based on the number of animals, as follows:

$$\frac{\text{Average Number of Animals}}{\text{Farm}} = \frac{\text{SBA's small business definition (\$ per year per farm)}}{\text{average total revenue per head (\$/animal)}}$$

The resultant number of animals represents the average animal inventory threshold for a small business. Estimated "small business" thresholds for each sector are shown in Table 4-2. Additional information on this approach and the data used for this calculation are outlined in Section 4.2.2 of the Proposal EA. The resultant size threshold represents an average animal inventory for a small business.

For the purpose of conducting its FRFA for this rulemaking, EPA is defining "small business" for these sectors as an operation that houses or confines less than the following: 1,400 fed beef cattle (includes fed beef, veal, and heifers); 300 mature dairy cattle; 2,100 market hogs; 37,500 turkeys; 61,000 layers; or 375,000 broilers (Table 4-2). As shown in Table 4-2, with the exception of dairy and some poultry operations, SBA's small business definition for these sectors more or less corresponds to operations with fewer than 1,000 AU being considered small businesses.

EPA then estimates the total number of small businesses in these sectors using facility size distribution data from USDA (step 2). Using the threshold sizes identified for small businesses in the



livestock and poultry sectors (Table 4-2), EPA matches these thresholds with the number of operations associated with the size thresholds, based on available USDA data, to estimate the total number of small animal confinement operations in these sectors. EPA's estimates of the number of potential CAFOs, derived from these USDA data (Kellogg, 2002), are presented in Section 3.1 of this report. This constitutes the primary data source that EPA uses to match the small business thresholds corresponding to SBA's definitions.

Because the USDA data are organized by broad AU groupings—operations with more than 1,000 AU, 750 AU, 500 AU and 300 AU—EPA has matched the animal thresholds above to the closest available AU grouping as follows. For hogs, EPA assumes that data reported for the 1,000 AU threshold (about 2,500 hogs) provide a close approximation of the 2,100 hog threshold to determine the number of small businesses in this sector. For dairies, EPA assumes that the 500 AU threshold (about 350 dairy cows) approximates the 300 dairy cow threshold. For turkey and egg laying operations with dry manure systems, EPA assumes that the 750 AU threshold (about 61,500 layers and 38,500 turkeys) approximates the 61,000 layers and 37,500 turkeys threshold. Because egg-laying operations with wet manure systems are regulated based on a different AU threshold (1,000 AU is equivalent to 30,000 birds), EPA assumes that all estimated operations for this category are small businesses. The resultant estimates of the number of small businesses in these sectors derived under these assumptions, in conjunction with available USDA data (Kellogg, 2002), are presented in Table 4-2.

For both cattle and broilers, EPA also relies on data on operations with more than 1,000 AU (corresponding to operations with 1,000 beef, veal, and heifers, and about 125,000 broilers), but uses these data as a starting point to assess the total number of small businesses in these sectors. To further determine the number of small businesses with more than 1,000 AU (corresponding to operations with less than 1,400 cattle and 375,000 broilers, as shown in Table 4-1), EPA assumes that, for cattle, about 40 percent of operations with more than 1,000 AU are potentially small businesses. This assumption is based on available USDA data on the share of feedlots with between 1,000 and 2,000 head, calculated as a share of all operations with more than 1,000 AU (Krause, 1991). For broilers, EPA assumes that nearly all operations are small businesses, with the exception of the largest 330 operations, which EPA assumes have more than 375,000 birds. This assumption is consistent with that assumed for the 2001 Proposal and is consistent with USDA broiler sales data and information (USDA/NASS, 2000a). The resultant estimates of the number of small businesses in these sectors using this approach, in conjunction with USDA data (Kellogg, 2002) are presented in Table 4-2.

USDA estimates that there were approximately 238,000 animal confinement facilities in 1997 (see Section 3). Table 4-2 presents EPA's estimates of the total number of small livestock and poultry operations that are potentially small businesses. Using the approach outlined in this section, EPA estimates that about 227,000 operations (95 percent of all operations) are small businesses. However, not all of these operations would be affected by the CAFO regulations.

EPA recognizes that this approach might not accurately portray actual small businesses in all cases across all sectors. On the one hand, the resulting small business estimate would suggest that a 15- to 20-house broiler operation with 375,000 birds would be a small business. Information from industry sources, however, suggests that a two-house broiler operation with roughly 50,000 birds is small (Madison, 1999; USEPA, 2000d). Therefore, it is likely that some medium- and large-size broiler operations are being considered small businesses (USEPA, 2000e).

On the other hand, it is possible that the resulting small business estimate might have failed to identify some small businesses in the other sectors as "small." For example, EPA's approach identifies

as a “small business” hog operations with fewer than 2,500 pigs and turkey operations with fewer than 41,250 turkeys, which account for less than 93 percent and 80 percent of all operations, respectively, and less than 40 percent of sales in these sectors (Kellogg, 2002). These proportions are below SBA’s presumed coverage rates, which define as small about 99 percent of all operations and account for approximately 62 percent of sales (Perez, 2000). Therefore, it is likely that there are additional small hog and turkey businesses that are not captured under the revised methodology (USEPA, 2000e).

**Table 4-2. Number of Small CAFOs That Might Be Affected by the CAFO Regulations**

Sector	Total Annual (\$million) Revenue <sup>a/</sup> (x)	Revenue per Head <sup>b/</sup> (Avg. U.S.) (y)	Number of Animals at Small CAFO Businesses (z = x/y)	Estimated Number of AFOs	Total “Small” AFOs	Small Business CAFOs
Cattle <sup>d/</sup>	\$1.5	\$1,060	1,400	21,800	20,430	<b>1,200</b>
Dairy	\$0.75	\$2,573	300	94,800	91,360	<b>1,294</b>
Hogs	\$0.75	\$363	2,100	51,800	47,850	<b>1,485</b>
Broilers	\$0.75	\$2	375,000	17,800	17,450	<b>1,822</b>
Egg Layers	\$9.0	\$25	365,000	ND	ND	ND
	\$1.5		61,000	6,400	5,460	<b>486</b>
Turkeys	\$0.75	\$20	37,500	3,300	2,660	<b>27</b>
All AFOs	NA	NA	NA	<b>237,800<sup>e/</sup></b>	<b>227,120<sup>e/</sup></b>	<b>6,314</b>

NA=Not Applicable. ND = Not Determined. “AFOs” have confined animals on-site.

<sup>a/</sup> SBA size standards are at 13 CFR Part 121. EPA assumes an alternative definition of \$1.5 million in annual revenues for egg laying operations.

<sup>b/</sup> Average revenue per head across all operations for each sector derived from data obtained from USDA’s 1997 ARMS data (USDA/ERS, 1999a). For more information, see Section 4 of EPA’s Proposal EA (USEPA, 2001a).

<sup>c/</sup> Total small business CAFOs do not include estimates of designated CAFOs.

<sup>d/</sup> Includes fed cattle, veal and heifers.

<sup>e/</sup> USDA total include estimates of the number of operations with “cattle other than fattened cattle or milk cows” and also adjusts for double counting, accounting for roughly 42,000 operations (Kellogg, 2002). See Section 3. EPA’s total for broilers and egg layers also differs because of differing 1,000 AU definitions (see Section 3).

The final step (step 3) in EPA’s approach is to estimate the number of small businesses subject to the CAFO regulations based on the regulatory thresholds being promulgated, as discussed in Section 3 of this report. Not all small confinement operations would be subject to the CAFO regulations. The final regulations apply only to those operations that meet the regulatory definition of a CAFO or those that have been designated as CAFOs by the NPDES permitting authority because of risks posed to water quality and public health, as discussed in Section 1. The regulations *define* as a CAFO those operations that confine more than 1,000 AU, as well as a subset of operations with between 300 and 1,000 AU. The final regulations may also apply to an operation that is *designated* as a CAFO by the NPDES permitting authority on a case-by-case basis, based on an on-site inspection. As described in this section, EPA’s estimates of the number of operations is based on USDA information for 1997 (Kellogg, 2002), which

constitutes the primary data source that EPA uses to determine the number of potential small businesses that might be subject to the regulations.

Table 4-3 presents the estimated number of livestock and poultry operations that might be subject to the CAFO regulations and are also small businesses (“small business CAFOs”) by facility size category. EPA estimates that of the approximately 238,000 animal confinement facilities in 1997 roughly 95 percent are small businesses. Not all of these operations would be affected by the final rule. Table 4-3 shows EPA’s estimates of the number of small business CAFOs that are expected to be affected by this rule. For this analysis, EPA estimates that about 6,200 affected CAFOs across all size categories are small businesses, accounting for more than 40 percent of the estimated 14,515 affected facilities. EPA estimates that among CAFOs with more than 1,000 AU about 2,330 operations are small businesses (accounting for about one-fourth of all CAFOs in this size category). Most affected small businesses are in the broiler sector. Among CAFOs with between 300 and 1,000 AU, EPA estimates about 3,830 operations are small businesses, with most of the affected small businesses are in the hog, dairy, and broiler sectors.

These estimates are based on USDA data for 1997. Because of continued consolidation and facility closure since 1997, EPA’s estimates might overstate the actual number of small businesses in these sectors. Ongoing trends are causing some existing small and medium operations to expand their inventories to achieve economies of scale. Some of the CAFOs considered here as small businesses might no longer be counted as small businesses because they now have higher revenues. Furthermore, some CAFOs might now be owned by a larger, vertically integrated firm and might no longer be small businesses. EPA expects that there are few such operations, but it does not have data or information to reliably estimate the number of CAFOs that meet this description. In addition, for reasons noted in the record, EPA believes that the number of small broiler operations is overestimated and might actually include a number of medium and large broiler operations that should not be considered small businesses.

Table 4-3 also shows the expected number of small businesses that may be designated as CAFOs and subject to the rule. EPA estimates that about 172 operations will be designated as CAFOs. This estimate is expressed over the 5-year permit period (that is, assumes that roughly 35 operations will be designated annually). Among these, an estimated 160 operations are in the 300 to 1,000 AU size category; about 12 operations have fewer than 300 AU. (See Table 3-1.) EPA assumes that all of these operations are small businesses.<sup>32</sup> For analysis purposes, EPA also assumes that these operations are located in more traditional production regions and are characterized by operations with available land for land application of manure but also high technology needs (see discussion in Section 4.4).

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<sup>32</sup>EPA expects that USDA will continue to provide voluntary assistance to those additional operations that are now defined as CAFOs under the current permitting requirements and are not covered by the final regulations.

**Table 4-3. Total Number of Small Business CAFOs Subject to Regulation**

Sector	All AFOs	Total Small Business AFOs	Small Business CAFOs >1,000 AU (Defined)	Small Business CAFOs 300-1000 AU (Defined)	Small Business CAFOs (Designated)
	(Number of operations)				
Fed Cattle	17,800	16,570	538	174	15
Veal	3,840	160	5	7	0
Heifers	170	3,700	97	230	3
Dairy	94,790	91,360	0	1,330	30
Hogs	51,770	47,850	0	1,485	52
Broilers	17,780	17,450	1,303	520	52
Layers	6,450	5,460	383	48	10
Turkeys	3,310	2,660	0	31	10
<b>Total</b>	<b>237,820<sup>a/</sup></b>	<b>227,120<sup>b/</sup></b>	<b>2,326</b>	<b>3,825</b>	<b>172<sup>b/</sup></b>

Sources: Values presented in the table are EPA estimates, derived from published USDA data (Kellogg, 2002). All numbers are rounded to the nearest ten.

<sup>a/</sup>USDA total include estimates of the number of operations with “cattle other than fattened cattle or milk cows” and also adjusts for double counting, accounting for roughly 42,000 operations (Kellogg, 2002). See Section 3. EPA’s total for broilers and egg layers also differs because of differing 1,000 AU definitions (see Section 3).

<sup>b/</sup>Number of designated facilities shown over 5-year permit period. EPA assumes all estimated designated facilities are small businesses.

#### 4.2.3 Results of the Initial Assessment for the 2001 Proposal

For past regulations, EPA has often analyzed the potential impacts to small businesses by evaluating the results of a costs-to-sales test, measuring the number of operations that will incur compliance costs at varying threshold levels (including ratios where costs are less than 1 percent, between 1 and 3 percent, and greater than 3 percent of gross income).<sup>33</sup> EPA conducted such an analysis at the time of the 2001 proposal, indicating that about 80 percent of the estimated number of small businesses directly subject to the rule as CAFOs might incur costs in excess of three percent of sales. These results were based on an assessment of the potential impacts on small CAFO businesses based on the results of a sales test for all operations with more than 500 AU. This screening test indicated the

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<sup>33</sup> EPA believes that its more refined analysis used for its general analysis (presented in Section 3 of this EA) better reflects the potential impacts to regulated small businesses.

need for additional analysis to characterize the nature and extent of impacts on small entities. This assessment is conducted for those CAFOs that are small businesses, as determined by EPA.

The results of this screening test for the 2001 Proposal indicate that, measured against all confinement operations with more than 500 AU, about 80 percent of the estimated number of small businesses could incur costs in excess of 3 percent of sales. Compared to the total number of all small animal confinement facilities estimated by EPA, operations that are estimated to incur costs in excess of three percent of sales constitute less than two percent of all small businesses in these sectors. The results of this analysis are presented in Section 9.2.3 of the Proposal EA.

Based on the results of this initial assessment, EPA projected that it would likely not certify that the regulations would not impose a significant impact on a substantial number of entities. This is because EPA's initial assessment indicates that the regulations could impose a significant economic impact on a substantial number of entities. Therefore, prior to the 2001 Proposal, EPA convened a SBAR Panel and prepared an initial regulatory flexibility analysis (IRFA) pursuant to Sections 609(b) and 603 of the RFA, respectively, and prepared an economic analysis. Sections 4.3 and 4.4 of this report present the results of EPA's final regulatory flexibility analysis (FRFA).

### 4.3 EPA COMPLIANCE WITH RFA REQUIREMENTS

#### 4.3.1 Outreach and Small Business Advocacy Review

As required by Section 609(b) of the RFA, as amended by SBREFA, EPA convened a SBAR Panel for the proposed rule. See 66 FR 3121-3124; 3126-3128 (January 12, 2001). The Panel was convened in December 1999. Panel participants included representatives from EPA, the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Office of Advocacy of the Small Business Administration (SBA). "Small Entity Representatives" (SERs), who advised the Panel, included small livestock and poultry producers as well as representatives of the major commodity and agricultural trade associations. Throughout the development of these regulations, EPA conducted outreach to small businesses in the livestock and poultry sectors. EPA also consulted with SBA on the use of an alternative definition of small business for the egg laying sector.

Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small entity comments on issues related to the elements of the IRFA. The Panel's activities and recommendations are summarized in the *Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule on National Pollutant Discharge Elimination System (NPDES) and Effluent Limitations Guideline (ELG) Regulations for Concentrated Animal Feeding Operations* (April 7, 2000), or "Panel Report" (USEPA, 2000e). This document is included in the public record (DCN 93001). Section 12 of the preamble to the 2001 Proposal provides a summary of the Panel's activities and recommendations and describes the subsequent action taken by the Agency (see 66 FR 3121-3124). Section 12 of the preamble to the 2001 Proposal also details various outreach activities conducted by EPA, which include outreach to small businesses in these sectors.

For the 2001 Proposal, EPA prepared an economic analysis of the impacts on small businesses, which is provided in Section 9.4 of the Proposal EA. EPA's economic analysis supporting the final regulations is provided in Section 4.4 of this report.

For all final regulations for which an FRFA is prepared, Section 212 of the RFA requires that the Agency also issue a small entity compliance guide providing a plain language explanation of how to comply with the final regulations. EPA's small entity compliance guide for the CAFO regulations will be issued following promulgation.

#### **4.3.2 EPA's Final Regulatory Flexibility Analysis**

For the proposed regulations, EPA has conducted an IRFA, as required by Section 603 of the RFA, as amended by SBREFA. The IRFA must contain the following: (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 that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and (5) identification, to the extent practicable, of all relevant Federal rules that might duplicate, overlap or conflict with the proposed rule. The IRFA shall also contain a description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities. Sections 9.3.2.1 through 9.3.2.6 of the Proposal EA show how EPA addressed each of these requirements in the IRFA it prepared to support the 2001 Proposal. EPA also prepared an economic analysis of the impacts on small CAFO businesses, which is provided in Section 9.4 of the Proposal EA (USEPA, 2001a).

For the final regulations, EPA has conducted an FRFA, as required by Section 604 of the RFA, as amended by SBREFA. The FRFA addresses the issues raised by public comments on the IRFA, which was part of the proposal of this rule. The FRFA must 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 that 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 that affect the impact on small entities was rejected. Sections 4.3.2.1 through 4.3.2.5 of this report address each of these FRFA requirements.

##### ***4.3.2.1 Need for and Objectives of the CAFO Regulations***

A detailed discussion of the need for the regulation is presented in Section 4 of the 2001 Proposal (66 FR 2293-2972-2976). A summary is also provided in Sections 1 and 10 of the Proposal EA. In summary, EPA's rationale for revising the existing regulations include the following: address reports of continued discharge and runoff from livestock and poultry operations in spite of the existing

requirements; update the existing regulations to reflect structural changes in these industries over the past few decades; and improve the effectiveness of the existing regulations.

Despite nearly 30 years of regulation, there are persistent reports of discharge and runoff of manure and manure nutrients from livestock and poultry operations. Revisions to the existing ELG and NPDES regulations for CAFOs are expected to mitigate future water quality impairment and the associated human health and ecological risks by reducing pollutant discharges from the animal production industries.

EPA's revisions also address the changes that have occurred in the animal production industries in the United States since the development of the existing regulations. The continued trend toward fewer but larger operations, coupled with greater emphasis on more intensive production methods and specialization, is concentrating more manure nutrients and other animal waste constituents within some geographic areas. This trend has coincided with increased reports of large-scale discharges from these facilities and continued runoff that is contributing to the significant increase in nutrients and resulting impairment of many U.S. waterways.

EPA's revisions to the existing regulations will make the regulations more effective in protecting or restoring water quality. The revisions will also make the regulations easier to understand and will clarify the conditions under which an AFO is a CAFO and, therefore, subject to the regulatory requirements.

A detailed discussion of the objectives and legal basis for these regulations is presented in Sections 1 and 3 of the preamble to the final rule and also the 2001 Proposal (see: 66 FR 2959 or USGPO, 2001a).

#### *4.3.2.2 Significant Comments in Response to the IRFA*

The significant issues raised by public comments on the IRFA address exemptions for small businesses, disagreement with SBA definitions and guidance on how to define small businesses for these sectors, and general concerns about EPA's financial analysis and whether the analysis adequately captures potential financial effects on small businesses.

Commenters generally recommend that EPA exempt all small businesses from regulation, arguing in some cases that regulating small businesses could affect competition in the marketplace, discourage innovation, restrict improvements in productivity, create entry barriers, and discourage potential entrepreneurs from introducing beneficial products and processes. Several commenters claimed that EPA had misrepresented the number of small businesses. In particular, several commenters objected to SBA's small business definition for dairy operations, claiming it understates the number of small businesses in this sector (see, for example, NMPF, 2001). One commenter claimed that EPA's estimate of the total number of operations is understated and therefore must understate the number of small businesses (Department of Agriculture, 2001). Some commenters objected to the consideration of total farm-level revenue to determine the number of small businesses because this approach understates the number of small businesses, despite SBA guidance that bases its definitions on total entity revenue for purposes of defining a small business (NCBA, 2001). Other commenters, however, claimed that EPA's approach does not truly capture operations that are, in fact, small businesses but reflect larger corporate operations (see, for example, Citizens Against Poultry Pollution, 2001). Another commenter

recommended that EPA simply consider any operation with fewer than 1,000 AU as small businesses (Wyoming Office of Federal Land Policy, 2001). EPA also received comments requesting that EPA consider use of regional-specific definitions of small business because of concerns that the revenue-based SBA definition might not be applicable to operations in Hawaii since producers in that State generally face higher cost of production and also higher producer prices relative to revenue and cost conditions at farms in the contiguous 48 States. Comments from SBA recommended that EPA adopt the Panel's recommendation not to consider changing the designation criteria for operations with fewer than 300 animal units as a means to provide relief to small businesses (SBA, 2001). SBA also recommends that EPA adopt the SBAR Panel's approach and allow permitting authorities to focus resources where there is greatest need (SBA, 2001). Finally, some commenters generally questioned the results of EPA's financial analysis, giving similarly stated concerns about EPA's financial data and models used for its main analysis (see, for example, NCBA, 2001).

In response, EPA notes that the projected impacts of today's final regulations on small businesses are lower than the projected impacts of the proposed rule. For example, the final rule does not extend the effluent guideline regulations to CAFOs with between 300 and 1,000 AU, as was proposed in the 2001 proposal. Instead, EPA is retaining the existing regulatory threshold, applying the effluent guideline to CAFOs with more than 1,000 AU only. Requirements for CAFOs with between 300 and 1,000 AU will continue to be subject to the BPI requirements as determined by the permitting authority, thus requiring that fewer small businesses adopt the effluent guideline standards. More information on this topic is available in section IV of this preamble. Section 4 of the final rule preamble discusses other regulatory changes since the 2001 proposal, indicating greater alignment with SBAR Panel recommendations. Refer to Section 4 of the preamble for more information on the comments and EPA's responses to those comments, as well as EPA's justification for final decisions on these options.

EPA received two comments from one commenter requesting that EPA not use the alternative definition for egg-laying operations but instead consider regional-specific conditions for determining the number of small businesses. The commenter expressed concern that SBA's revenue-based definition might not be applicable to operations in Hawaii since producers in that State generally face higher cost of production and also higher producer prices relative to revenue and cost conditions at farms in the contiguous 48 States. There are a number of reasons why EPA did not use a regional-specific definition of small business for egg operations. First, as instructed under the Regulatory Flexibility Act (RFA), EPA uses small business definitions as defined by the Small Business Administration (SBA) for all sectors (except for the egg-laying sector). Since size standards set by the Small Business Administration (SBA) do not vary by region, EPA follows SBA's lead. Second, the regulations set requirements by the number of animal units at a farm, not the revenues associated with those animal units. A 1,000 AU egg-laying operation in the Midwest will be subject to the same effluent limitations guidelines as a 1,000 AU egg-laying operation in Hawaii and the territories. Third, the economic analysis, uses a representative farm approach. Only the broadest regional information could be obtained through USDA and other sources. Although some small subregions or localities might face unique issues, without performing a Section 308 survey of all regulated entities EPA must rely on the representative farm approach. (See also response to comment DCN CAFO201246C-6 regarding EPA's use of a representative farm approach, which is consistent with longstanding practices at USDA and the land grant universities.) Fourth, very few impacts are seen in the egg-laying sector, regardless of size. Even if EPA had classified the majority of egg-laying operations with less than 1,000 AU as small businesses, this would not have changed the outcome of the Agency's small business analysis in any material way. Finally, even if EPA were to classify all operations as small businesses in areas outside the contiguous 48 States (including Hawaii and Alaska), this would only raise the total number of small business by less than 10 operations. See



response to comment DCN CAFO NODA600053-5 regarding EPA's consideration of regional-specific definition of small business for the regulated sectors.

Regarding EPA's estimate of the number of small businesses, the Agency continues to follow SBA guidance and SBA definitions on how to define small businesses for these sectors. However, EPA has made substantial changes to the financial data and models used for its main analysis, which is also used to evaluate financial effects on small businesses. Both the 2001 Notice (66 FR 58556) and the 2002 Notice (67 FR 48099) describe the public comments received by EPA on the baseline financial data and the methodological approach developed by the Agency to evaluate financial effects. These comments and how EPA has addressed them are discussed more fully throughout this report. EPA's detailed responses to comments, and the comments themselves, are contained in the Agency's comment response document (see, for example, DCN CAFO200179D-3).

#### *4.3.2.3 Description and Estimate of Number of Small Entities Affected*

The small entities subject to this rule are small businesses. No nonprofit organizations or small governmental operations operate CAFOs. As discussed in section 7 of the preamble to the final rule, to estimate the number of small businesses affected by this final rule, EPA relied on the SBA size standards for these sectors, with the exception of size definitions for the egg sector. SBA defines a "small business" in these sectors as an operation with average annual revenues of less than \$0.75 million for dairy, hog, broiler, and turkey operations; \$1.5 million in revenue for beef feedlots; and \$9.0 million for egg operations. The definitions of small business for the livestock and poultry industries are in SBA's regulations at 13 CFR 121.201. For this rule, EPA proposed and solicited public comment on and is using an alternative definition for small business for the egg-laying operations. EPA defines a "small" egg laying operation for purposes of its regulatory flexibility assessments as an operation that generates less than \$1.5 million in annual revenue. EPA consulted with SBA on the use of this alternative definition, as documented in the rulemaking record for the 2001 proposal. Given these considerations, EPA evaluates "small business" for this rule as an operation that houses or confines fewer than 1,400 fed beef cattle (includes fed beef, veal, and heifers); 300 mature dairy cattle; 2,100 market hogs; 37,500 turkeys; 61,000 layers; or 375,000 broilers. The approach used to derive these estimates is described in Section 4.2.

Using these definitions and available data from USDA and industry, EPA estimates that about 6,200 affected CAFOs across all size categories are small businesses. Among CAFOs with more than 1,000 AU, EPA estimates that about 2,330 operations are small businesses. Among CAFOs with between 300 and 1,000 AU, EPA estimates that about 3,870 operations are small businesses. Table 4.3 shows EPA's estimates of the number of regulated small businesses across all industry sectors. Table 4.4 provides this information by sector and by representative CAFO model.

**Table 4-4. Numbers of Small CAFO Businesses by Sector, Size Grouping, and Region**

Sector	Region	Total	CAFOs "Large 1"	CAFOs "Large 2"	CAFOs "Medium 3"	CAFOs "Medium 2"	CAFOs "Medium 1"
Fed Cattle	All	858	538		49	95	176
	CE	605	342		39	79	145
	MW	209	170		8	11	20
	PA	28	23		1	1	3
	SO	1	0		0	0	1
	MA	15	3		1	4	7
Veal	MW	12	5		1	2	4
Heifers	All	329	97		29	70	133
	MW	127	0		6	14	107
	CE	120	58		14	35	13
	PA	82	39		9	21	13
Dairy	All	1,294					1,294
	CE	276					276
	MW	361					361
	PA	227					227
	SO	97					97
	MA	333					333
Hog: FF	All	916			123	252	541
	MA	811			105	216	490
	MW	105			18	36	51
Hog: GF	All	568			103	174	291
	MA	500			88	148	264
	MW	68			15	26	27
Broiler	All	1,822	1,034	269	184	197	138
	MA	1,223	698	182	120	133	90
	SO	599	336	87	64	64	48
Layer: Dry	All	59				21	38
	MW	29				10	19
	SO	30				11	19
Layer: Wet	SO	431	383		48		
Turkey	All	26				9	17
	MA	14				5	9
	MW	12				4	8

Source: USEPA. Preliminary based on estimates associated with the August 4, 2002, cost estimates. Size and region breakouts are based on an analysis of the 1997 Census data by USDA (Kellogg, 2002). Facility size and region definitions for model CAFOs are provided in Section 2, Table 2-1. Shaded cells indicate that there are no small CAFO businesses that will be affected by the regulations and that meet the SBA definition of a small business. Estimates do not include number of designated CAFOs.

#### *4.3.2.4 Description of the Reporting, Recordkeeping, and Other Requirements*

The final regulations would require all AFOs that meet the CAFO definition to apply for a permit, develop and implement a nutrient management plan, collect and maintain records required by applicable technology-based effluent discharge standards, and submit an annual report to the responsible NPDES permitting authority. (No nonprofit organizations or small governmental operations operate CAFOs.) All CAFOs would also be required to maintain records of off-site transfers of manure. Record-keeping and reporting burdens include the time to record and report animal inventories, manure generation, field application of manure (amount, method, date, weather conditions), manure and soil analysis results, crop yield goals, findings from visual inspections of feedlot areas, and corrective measures. Records may include manure spreader calibration worksheets, manure application worksheets, maintenance logs, and soil and manure test results. EPA believes the owner/operator has the skills necessary to keep these records and make reports to the permitting authority.

State permitting authorities will incur reporting burdens when they update their NPDES programs to incorporate the regulatory changes in the final rule. They will incur record keeping burdens as they implement the final rule. Data collection and record keeping activities include reviewing CAFO permit applications and periodic reports, and tracking compliance through on-site inspections.

EPA has estimated the burden and costs associated with information collection imposed on CAFOs, including small businesses, and also States as a result of the CAFO regulations. This analysis is provided in the Information Collection Request for the Final NPDES and ELG Regulatory Revisions for Concentrated Animal Feeding Operations (EPA ICR NO. 1989.02) prepared by EPA (USEPA, 2002j), which updates an analysis conducted for the 2001 Proposal (USEPA, 2000f).

For the purpose of this analysis, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust existing procedures to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information request; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

EPA's labor burden estimates for CAFO and State respondents are the hours of activity required to comply with changes to the NPDES CAFO program. For each activity, EPA estimates the burden in terms of the expected effort necessary to carry out these activities under normal conditions and reasonable labor efficiency. These activities and estimated burden and cost levels are described in more detail in the Supporting Statement for the ICR (USEPA, 2002j). The ICR also contains a summary of wage rate information from USDA and the Bureau of Labor Statistics, compiled by EPA for the purpose of this analysis. Additional information on the ICR is provided in the preamble supporting the final regulations. A summary of the analysis of impacts to CAFO operators is provided below. Additional information on the estimated burden and costs is provided in the ICR (USEPA, 2002j).

EPA identifies four burden categories to CAFO operators, including start-up activities, permit application, best available technology requirements, and NPDES record keeping and reporting requirements.

Start-up activities are steps that a CAFO owner or operator must take in preparation to comply with the information collection requirements of the final rule. Owners or operators that are potentially affected by the rule will need to familiarize themselves with the changes to the NPDES CAFO program to determine that they will need to apply for a permit.

Permit application activities include completing and submitting either an NOI to obtain coverage under a general permit or an application for an individual permit. These activities will be conducted once every five years. The final rule requires that the following information be provided on the application forms: the name of the owner or operator; facility address and mailing address; latitude and longitude of the production area; a topographic map; the type and number of animals in open confinement and housed under a roof; the type of containment and total capacity for manure, litter, and wastewater storage; the number of acres for land application; the estimated amount of manure generated per year; and estimated amount of manure transferred off site each year. As part of their record keeping responsibilities, CAFO operators will be required to keep the plan on site for inspections and make it available to the permitting authority on request. Nutrient management plans must be reviewed and rewritten at least every five years.

CAFO owners or operators will perform and record various activities to meet the BAT requirements such as visual inspections of the feedlot facilities, inspections of manure application equipment, collection of soil samples, and recording of volume of manure and process wastewater produced. CAFOs with more than 1,000 AU will also be required to record information for transfers of manure, litter, and process wastewater to other people.

In addition to the labor costs associated with these activities, EPA estimates the capital and operation and maintenance (O&M) costs incurred to collect data and keep records. A CAFO will incur capital costs when it purchases equipment or builds structures that are needed for compliance with the rule's reporting and record keeping requirements that the facility would not use otherwise. Consistent with the overall cost analysis for the final rule, capital costs are annualized assuming a 10-year amortization period and a 7 percent interest rate. Capital costs for the final rule include such items as purchasing a soil auger to collect soil samples and a manure sampler. Some facilities will also need to install depth markers in their lagoons. A facility incurs O&M costs when it regularly uses services, materials, or supplies needed to comply with the rule's reporting and record keeping requirements that the facility will not use otherwise. Any cost for the operation and upkeep of capital equipment is considered an O&M cost. O&M costs may also be incurred on a non-annual basis, such as every five years for a soil analysis. O&M costs include laboratory analysis of soil and manure.

EPA estimates that the public burden for this information collection request will require 1.6 million labor hours for all CAFO respondents to comply with the final regulations and 0.3 million labor hours for State permitting authority respondents (USEPA, 2002j). Information collection and reporting at a CAFO is associated with applying for permits, developing nutrient management plans, conducting site inspections, tracking land application and off-site manure transfers. These estimates include the time required to review instructions, search existing data sources, gather and maintain all necessary data, and complete and review the information collection. EPA estimates costs to regulated CAFOs at \$29 million annually, which includes \$25 million in labor costs and \$4 million capital and O&M expenditures; annual State costs of \$10 million include \$8.6 million in labor costs and \$1.6 million in O&M expenditures (USEPA, 2002j). This estimate excludes NPDES burden for CAFOs covered by other ICR estimates.

Under the final rule, EPA estimates that there will be an annual average of 11,712 CAFO respondents and an annual average of 82,705 CAFO responses, which includes multiple responses per CAFO. Thus, the annual average burden per CAFO respondent is 138 hours and the average burden per CAFO response is 19 hours. For this analysis, EPA assumes that the administrative burden assumptions are generally the same regardless of CAFO size. The annual average burden per State respondent is 10,152 and the average burden per response is 16 hours (USEPA, 2002j).

More detailed information on the burden and associated costs for each of the activities described above is provided in the ICR (USEPA, 2002j). Section 10 of the final rule preamble further summarizes the expected reporting and record-keeping requirements under the final regulations based on information compiled as part of the *Information Collection Request for the Final NPDES and ELG Regulatory Revisions for Concentrated Animal Feeding Operations* (OMB ICR NO. 2040-0250) prepared by EPA.

#### ***4.3.2.5 Steps Taken to Minimize Significant Economic Impacts on Small Entities***

For the final regulations, EPA has adopted an approach for a regulatory program that mitigates impacts on small business, recognizes and promotes effective non-NPDES State programs, and works in partnership with USDA to promote environmental stewardship through voluntary programs, and financial and technical assistance. EPA's proposal included many options that were not finally adopted in deference to these principles.

Because of the estimated impacts on small entities EPA is not certifying that this rule will not impose a significant impact on a substantial number of small entities. EPA has complied with all RFA provisions and conducted outreach to small businesses, convened a SBAR panel, prepared an Initial Regulatory Flexibility Analysis (IRFA) and a Final Regulatory Flexibility Analysis (FRFA), and also prepared an economic analysis. The Agency's actions include the following efforts to minimize impacts on small businesses:

- Retained structure of existing regulations, which allows EPA and states to focus on the largest producers;
- Retained existing designation criteria and process;
- Retained existing definition of an AFO;
- Retained conditions for being defined as a Medium CAFO;
- Eliminated the "mixed" animal calculation for operations with more than a single animal type for determining which AFOs are CAFOs;
- Raised the duck threshold for dry manure handling duck operations; and
- Adopted a dry-litter chicken threshold higher than proposed.

EPA went to some length to explore and analyze a variety of ELG regulatory alternatives to minimize impacts on small businesses. The record for today's rule includes extensive discussions of the alternatives, EPA's analysis of those alternatives, and the rationale for the Agency's decisions. In large part, the Agency incorporated most of the alternative considerations to reduce the burden to small businesses. By way of example, today's regulations will affect fewer small businesses at significantly reduced costs, as compared to the estimates of the number of operations and expected costs to those affected entities based on the requirements set forth in the 2001 proposal. For more information on EPA's option selection rationale, see Section 4 of the preamble to the final rule.

#### 4.4 EPA'S ANALYSIS OF SMALL BUSINESS IMPACTS

This section discusses the data and methodology EPA uses to assess economic impacts on small CAFO businesses (Section 4.4.1) and presents the results of this analysis (Section 4.4.2). This economic analysis supports the FRFA (Section 4.3) by quantifying the effects of the CAFO regulations. Based on the results of this analysis, EPA has determined that the CAFO regulations would result in financial stress to some affected small businesses, but not a substantial number of operations relative to the total number of affected small businesses in these sectors.

##### 4.4.1 Data and Methodology

To examine the economic impacts of the final regulations on small CAFO businesses, EPA uses the same representative farm approach that is used to analyze impacts on all CAFOs (regardless of size), as described in Section 2 of this EA.<sup>34</sup> This approach evaluates impacts on select model CAFOs and extrapolates these results to the number of operations identified by each representative model, thus aggregating costs nationally across all sectors. Inputs for this analysis include the number of CAFOs represented by each model (see Section 4.3.3) and, for each model CAFO, the costs of the final regulations and selected financial characteristics (see Section 2).

EPA's analysis evaluates the economic achievability of the final regulatory options at small CAFO businesses based on financial criteria established for this analysis. These criteria reflect a combination of both farm level and enterprise level criteria. Three farm level criteria are assessed: (1) a comparison of incremental costs to total revenue (sales test), (2) projected post-compliance cash flow over a 10-year period, and (3) an assessment of an operation's debt-asset ratio under a post-compliance scenario. Projected post-compliance cash flow over a 10-year period is also assessed at the enterprise level in order to evaluate the potential effects at a facility's livestock or poultry enterprise, apart from the effects assessed for the entire facility.

EPA used the results from these analyses to divide affected CAFOs into three financial impact categories: Affordable, Moderate, and Stress. CAFOs experiencing affordable or moderate impacts are considered to experience some financial impact on operations, but EPA does not expect the costs of complying with this rule to make such operations vulnerable to closure. EPA considers that for CAFOs in both the "Affordable" and "Moderate" impact categories the final requirements are economically achievable. Operations experiencing financial stress, however, are considered to be vulnerable to closure because of the costs of this rule. EPA considers that for CAFOs in the "Stress" impact category, the final requirements might not be economically achievable, subject to other considerations. For more information on this decision framework, see Table 2-8 and Figure 2-1.

EPA conducted its analysis first at the farm level based on data reflecting financial conditions for the entire farm operation (e.g., reflecting income and cost information spanning the entire operation, thus

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<sup>34</sup> For past regulations, EPA has often analyzed the potential impacts to small businesses by evaluating the results of a costs-to-sales test, measuring the number of operations that will incur compliance costs at varying threshold levels. EPA conducted such an analysis at the time of the 2001 proposal, but believes that its more refined analysis used for its general analysis better reflects the potential impacts to regulated small businesses.

considering the operation's primary livestock production, along with other income sources such as secondary livestock and crop production, government payments, and other farm-related income). Based on the farm level results, EPA also assessed the financial effects on CAFOs at the enterprise level (e.g., limiting the scope of the assessment to the operation's livestock or poultry enterprise, and excluding other non CAFO-related sources of income from the analysis).

Starting with the farm level analysis, EPA considers the regulations to be economically achievable for a representative model CAFO if the average operation has a post-compliance sales test estimate within an acceptable range, a positive post-compliance cash flow over a 10-year period, and a post-compliance debt-to-asset ratio not exceeding a benchmark value. Specifically, if the sales test shows that compliance costs are less than 3 percent of sales, or if post-compliance cash flow is positive and the post-compliance debt-to-asset ratio does not exceed a benchmark (depending on the baseline data) and compliance costs are less than 5 percent of sales, EPA considers the options to be "Affordable" for the representative CAFO group. (Although a sales test result of less than 3 percent does indicate "Affordable" in the farm level analysis, further analysis is conducted to determine the effects at the operation's livestock or poultry enterprise.) The benchmark values assumed for the debt-asset test are sector-specific. EPA assumes a 70 percent benchmark value for the debt-asset test to indicate financial stress in the hog and dairy sectors, and an 80 percent benchmark for the debt-asset test to indicate financial stress in the beef cattle sector. These benchmark values address public comment received and alternative debt and asset data submitted for the livestock sectors. For the poultry sectors, however, EPA did not obtain alternative debt and asset data and continues to evaluate data used for proposal against a 40 percent benchmark value.

A sales test of greater than 5 percent but less than 10 percent of sales with positive cash flow and a debt-to-asset ratio of less than these sector-specific debt-asset benchmark values is considered indicative of some impact at the CAFO level, but at a level not as severe as those indicative of financial distress or vulnerability to closure. These impacts are labeled "Moderate" for the representative CAFO group. EPA considers both the "Affordable" and "Moderate" impact categories to be economically achievable by the CAFO, subject to the enterprise analysis (see below). If, with a sales test of greater than 3 percent, post-compliance cash flow is negative or the post-compliance debt-to-asset ratio exceeds these sector-specific debt-asset benchmarks, or if the sales test shows costs equal to or exceeding 10 percent of sales, EPA considers the final regulations to be associated with potential financial stress for the entire representative CAFO group. In such cases, each of the operations represented by that group might be vulnerable to closure. For operations that are determined to experience financial "Stress" at the farm level, the final requirements are likely not economically achievable.

The enterprise level analysis builds on the farm level analysis, evaluating effects at a farm's livestock or poultry enterprise. If the farm level analysis shows that the regulations impose "Affordable" or "Moderate" effects on the operation, the enterprise level analysis is conducted to determine whether the enterprise's cash flow is able to cover the cost of regulations. This analysis uses a discounted cash flow approach similar to that used to assess the farm level effects, in which the net present value of cash flow is compared to the net present value of the total cost of the regulatory options over the 10-year time frame of the analysis. Over the analysis period, if an operation's livestock or poultry enterprise maintains a cash flow stream that both exceeds the cash costs of the rule (operating and maintenance costs plus interest) and covers the net present value of the principal payments on the capital, EPA concludes that the enterprise will likely not close because of the CAFO rule. This analysis is conducted on a pass/fail basis. If the net present value of cash flow minus the net present value of the rule's costs is greater than zero, the enterprise passes the test and the enterprise is assumed to continue to operate. EPA

considers these results to indicate that the final requirements are economically achievable. If the net present value of cash flow is not sufficient to cover the net present value of the cost of the rule, EPA assumes that the CAFO operator would consider shutting down the livestock or poultry enterprise. That is, if an operation fails the enterprise level analysis, these operations are determined to experience financial “Stress” and the final requirements are likely not economically achievable.

More detail on the classification scheme established for this analysis, along with a discussion of the basis for EPA’s use of these criteria, is provided in Section 2. Section 2.3. presents the baseline (farm and enterprise level) financial data that EPA uses to analyze impacts on small CAFO businesses.

Appendix B shows EPA’s estimated compliance costs for selected model CAFOs under the final BAT Option. These costs reflect the range of facility level costs for model CAFOs based on estimated per-unit costs aggregated by the average number of animals assumed for each model. All costs shown are expressed on a per-animal basis and are differentiated by facility size, producing region, facility types, and other factors. Costs are reported in ranges across three types of land availability for manure application and also across three types of technology needs assumed for model CAFOs for the purpose of this analysis. The land availability types include: Category 1 farms, which have sufficient cropland for all on-farm nutrients generated; Category 2 farms, which have insufficient cropland; and Category 3 farms, which have no cropland. USDA data/information grouping facilities into the categories of technology adoption and use are: “least needs” and “most needs” operations (assumed to account for 25 percent each of all facilities) and also “average needs” (assumed to account for 50 percent of all operations). These groupings are based on available USDA data; detailed information is available in the *Development Document* supporting the proposed regulations (USEPA, 2002). Section 2 provides a summary on EPA’s engineering cost models.

To estimate financial effects on operations with between 300 and 1,000 AU that may be defined as CAFOs under the NPDES permit regulations, EPA assumes that the estimated costs for CAFOs with between 300 and 1,000 AU to comply with the effluent guideline regulations are similar to the costs that will be incurred by sized operations of that size to comply with BPJ requirements under the revised NPDES regulations. Because the costs to comply with the effluent guideline represent the likely high end of the possible cost range, estimated impacts on operations in this size range might be overstated.

To estimate financial effects on expected designated facilities, EPA uses the same general approach described in Section 2 of this report to assess impacts on an estimated 344 designated facilities over a 10-year period.<sup>35</sup> For this analysis EPA uses estimated costs for the smallest size model CAFO among operations with between 300 and 1,000 AU (“Medium” operations)<sup>36</sup> for model CAFOs developed for operations located in the more traditional production regions (Midwest for the livestock and turkey operations and South for the broiler and egg-laying operations; Table 2-1 shows these definitions). For example, EPA assumes that operations characterized as having available land for land application of manure (Category 1 model facilities) and high technology needs (“most needs” or Category H) may be characterized as Category 1H models for purposes of costing across the range of

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<sup>35</sup> As shown in Table 3-3, EPA estimates 172 designated facilities over a 5-year permit period. For the purpose of this analysis, EPA assumes that half are expected to be designated during the first 5 years, and the other half, in the second 5 years.

<sup>36</sup>Medium 3 for wet layer operations.



land base and technology needs cost models. These cost estimates are shown in Appendix B. More detailed cost information is provided in the *Development Document* (USEPA, 2002).

For CAFOs with between 300 to 1,000 AU, operations are distributed in the key regions (Midwest or South) in the key category group (Category 1H) across the Medium 1, 2, and 3 model sizes. For all sectors excluding hog, the farm counts are distributed evenly across these three size groups. The hog models are more complex, because the engineering costs are divided by size, region, operation type (farrow finish and grow finish) and manure process (liquid and pit for Medium models), and the financial models are divided by size, region, and contract versus independent, and so forth, leading to a much larger matrix of models than those for other sectors. The designated counts were distributed in a ratio of NPDES farm counts over the Medium 1, 2, and 3 models for liquid and pit manure processes, by contract vs. independent and by farrow finish and grow finish in the Midwest 1H categories. For designated CAFOs with fewer than 300 AU, operations are placed in one model for each sector, with the exception of hog facilities. Hog operations are distributed evenly among the model types (manure process by grow finish or farrow finish and by contract versus independent). Costs for these “Small” models are developed using the Medium 1, Category 1H costs for each sector (or in the case of hog, each process and operation type). The cost per head for the Medium 1, 1H operation was applied to an assumed 300 AU number of head to estimate an annualized compliance cost per “small” facility. Because there was no Medium 1 size for wet layer, the Medium 3 size group per head cost was applied to the number of head associated with 300 AU.

#### 4.4.2 Economic Analysis Results

Using the economic achievability criteria established for this analysis, discussed in Section 4.4.1, EPA’s economic analysis indicates that the CAFO regulations will not impose financial stress on a substantial number of operations, relative to the total number of affected confinement operations in these sectors. The results of this analysis are presented in Table 4-5.

EPA estimates that about 6,200 small business CAFOs would be affected by this rule. For this analysis, EPA estimates that about 6,200 affected CAFOs are small businesses, consisting of about 2,330 operations with more than 1,000 AU and about 3,830 operations with between 300 and 1,000 AU. Most of these affected small businesses are in the hog, dairy, and broiler sectors.<sup>37</sup>

In examining the effects on small businesses for the final rule, EPA followed the same approach used to evaluate the impacts on existing CAFOs, as described in Section ES.2. For the purposes of this analysis, EPA assumes that small business CAFOs with between 300 and 1,000 AU would incur costs similar to those estimated for CAFOs with more than 1,000 AU (although these smaller-sized operations will be subject to BPJ and not the ELG requirements under the revised NPDES requirements). These upper end cost estimates could, therefore, overstate the financial effects for small businesses in this size category. For past regulations, EPA has often analyzed the potential impacts to small businesses by evaluating the results of a costs-to-sales test, measuring the number of operations that will incur compliance costs at varying threshold levels (including ratios where costs are less than 1 percent,

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<sup>37</sup> For reasons noted in the record, EPA believes that the number of small broiler operations is overestimated and might actually include a number of medium and large broiler operations that should not be considered small businesses.

between 1 and 3 percent, and greater than 3 percent of gross income). EPA conducted such an analysis at the time of the 2001 proposal, indicating that about 80 percent of the estimated number of small businesses directly subject to the rule as CAFOs might incur costs in excess of three percent of sales. EPA believes that its more refined analysis used for its general analysis (presented here) better reflects the potential impacts to regulated small businesses.

Using this approach, EPA's analysis indicates that the final rule could cause financial stress to some small businesses, making these businesses vulnerable to closure. These results are presented in Table 4-5a (Option 1) and Table 4-5b (Option 2).

For Option 1, the analysis indicates that, among all small business CAFOs in the veal, dairy, hog, turkey, and egg-laying sectors, the impacts due to this rule can be characterized as "Affordable" or "Moderate." EPA estimates that a total of 172 small businesses (3 percent of all small business CAFOs with more than 300 AU) would experience financial stress and might be vulnerable to closure. By sector, these closures are comprised of about 131 small businesses in the beef sector, 38 businesses in the heifer sector, and 3 businesses in the broiler sector. Most of these (nearly 90 percent) are operations with fewer than 1,000 AU. For Option 2, the analysis indicates that, among all small business CAFOs in the veal, dairy, hog, turkey, and egg-laying sectors, the impacts due to this rule can be characterized as "Affordable" or "Moderate." EPA estimates that a total of 262 small businesses (4 percent of all small business CAFOs with more than 300 AU) would experience financial stress and might be vulnerable to closure. By sector, these closures are comprised of about 183 small businesses in the beef sector, 50 businesses in the heifer sector, and 19 businesses in the broiler sector. Nearly 90 percent of these potential closures are operations with fewer than 1,000 AU.

These estimates of the number of potential CAFO closures are cumulative and reflect the results of both the farm level analysis and the enterprise level analysis. These results are based on an analysis that does not consider the longer term effects on market adjustment and also available cost-share assistance from Federal and State farm conservation programs. EPA believes that such adjustments could lessen the economic impacts of the final regulations over time.

Table 4-5 shows the results of this analysis aggregated across all estimated designated operations with less than 1,000 AU, indicating that nearly one-half of all designated operations may go out of business. Closures among designated operations are all in the broiler, beef, and heifer sectors.

**Table 4-5a. Results of EPA's Small Business Analysis (Option 1)**

Sector	Number of Small CAFOs	Affordable	Moderate	Stress	Affordable	Moderate	Stress
		(Number)			(Percent of Total Operations)		
<b>CAFOs &gt;1000 AU (excl. designated operations)</b>							
Fed Cattle	712	581	0	131	82%	0%	18%
Veal	12	12	0	0	100%	0%	0%
Heifer	327	289	0	38	88%	0%	12%
Dairy	1,330	1,330	0	0	100%	0%	0%
Hogs	1,485	1,485	0	0	100%	0%	0%
Broilers	1,823	1,395	424	3	77%	23%	0%
Layers: Dry	24	24	0	0	100%	0%	0%
Layers: Wet	407	407	0	0	100%	0%	0%
Turkeys	31	31	0	0	100%	0%	0%
<b>Total</b>	<b>6,151</b>	<b>5,554</b>	<b>424</b>	<b>172</b>	<b>90%</b>	<b>7%</b>	<b>3%</b>
<b>CAFOs &gt;1,000 AU</b>							
Fed Cattle	538	533	0	5	99%	0%	1%
Veal	5	5	0	0	100%	0%	0%
Heifer	97	97	0	0	100%	0%	0%
Dairy	0	--	--	--	--	--	--
Hogs	0	--	--	--	--	--	--
Broilers	1,303	1,065	234	3	82%	18%	0%
Layers: Dry	0	--	--	--	--	--	--
Layers: Wet	383	383	0	0	100%	0%	0%
Turkeys	0	--	--	--	--	--	--
<b>Total</b>	<b>2,326</b>	<b>2,083</b>	<b>234</b>	<b>8</b>	<b>90%</b>	<b>10%</b>	<b>0%</b>

**Table 4-5a. Results of EPA’s Small Business Analysis (Option 1)**

Sector	Number of Small CAFOs	Affordable	Moderate	Stress	Affordable	Moderate	Stress
		(Number)			(Percent of Total Operations)		
<b>Operations 300 - 1,000 AU (Defined as CAFOs)</b>							
Fed Cattle	174	48	0	126	27%	0%	73%*
Veal	7	7	0	0	100%	0%	0%
Heifer	230	192	0	38	83%	0%	17%
Dairy	1,330	1,330	0	0	100%	0%	0%
Hogs	1,485	1,485	0	0	100%	0%	0%
Broilers	520	330	190	0	63%	37%	0%
Layers: Dry	24	24	0	0	100%	0%	0%
Layers: Wet	24	24	0	0	100%	0%	0%
Turkeys	31	31	0	0	100%	0%	0%
<b>Total</b>	<b>3,825</b>	<b>3,471</b>	<b>190</b>	<b>164</b>	<b>91%</b>	<b>5%</b>	<b>4%</b>
<b>Operations &lt;1,000 AU (Designated as CAFOs)</b>							
Fed Cattle	30	4	0	26	13%	0%	87%
Veal	0	0	0	0	NA	NA	NA
Heifer	6	0	0	6	0%	0%	100%
Dairy	60	60	0	0	100%	0%	0%
Hogs	104	104	0	0	100%	0%	0%
Broilers	104	0	0	104	0%	0%	100%
Layers: Dry	4	4	0	0	100%	0%	0%
Layers: Wet	16	16	0	0	100%	0%	0%
Turkeys	20	20	0	0	100%	0%	0%
<b>Total</b>	<b>344</b>	<b>208</b>	<b>0</b>	<b>136</b>	<b>61%</b>	<b>0%</b>	<b>40%</b>

Source: USEPA. May not add due to rounding. Does not include the number of CAFOs includes designated facilities. Assumes that the costs that will be incurred by those sized operations to comply with BPJ-based limitations under the revised NPDES regulations are similar to the estimated costs that would be incurred if Medium CAFOs had to comply with the ELG.

“Layers: dry” are operations with dry manure systems. “Layers: wet” are operations with liquid manure systems.

**Table 4-5b. Results of EPA's Small Business Analysis (Option 2)**

Sector	Number of Small CAFOs	Affordable	Moderate	Stress	Affordable	Moderate	Stress
		(Number)			(Percent of Total Operations)		
<b>CAFOs &gt;1000 AU (excl. designated operations)</b>							
Fed Cattle	712	529	0	183	74%	0%	26%
Veal	12	12	0	0	100%	0%	0%
Heifer	327	277	0	50	85%	0%	15%
Dairy	1,330	1,306	24	0	98%	2%	0%
Hogs	1,485	1,483	2	0	100%	0%	0%
Broilers	1,823	1,026	780	19	56%	43%	1%
Layers: Dry	24	24	0	0	100%	0%	0%
Layers: Wet	407	407	0	0	100%	0%	0%
Turkeys	31	31	0	0	100%	0%	0%
<b>Total</b>	<b>6,151</b>	<b>5,129</b>	<b>806</b>	<b>262</b>	<b>83%</b>	<b>13%</b>	<b>4%</b>
<b>CAFOs &gt;1,000 AU</b>							
Fed Cattle	538	522	0	16	97%	0%	3%
Veal	5	5	0	0	100%	0%	0%
Heifer	97	88	0	9	91%	0%	9%
Dairy	0	--	--	--	--	--	--
Hogs	0	--	--	--	--	--	--
Broilers	1,303	763	532	9	58%	41%	1%
Layers: Dry	0	--	--	--	--	--	--
Layers: Wet	383	383	0	0	100%	0%	0%
Turkeys	0	--	--	--	--	--	--
<b>Total</b>	<b>2,326</b>	<b>1,795</b>	<b>532</b>	<b>34</b>	<b>76%</b>	<b>23%</b>	<b>1%</b>

**Table 4-5b. Results of EPA’s Small Business Analysis (Option 2)**

Sector	Number of Small CAFOs	Affordable	Moderate	Stress	Affordable	Moderate	Stress
		(Number)			(Percent of Total Operations)		
<b>Operations 300 - 1,000 AU (Defined as CAFOs)</b>							
Fed Cattle	174	7	0	167	4%	0%	96%
Veal	7	7	0	0	100%	0%	0%
Heifer	230	189	0	41	82%	0%	18%
Dairy	1,330	1,306	24	0	98%	2%	0%
Hogs	1,485	1,483	2	0	100%	0%	0%
Broilers	520	263	248	10	51%	48%	1%
Layers: Dry	24	24	0	0	100%	0%	0%
Layers: Wet	24	24	0	0	100%	0%	0%
Turkeys	31	31	0	0	100%	0%	0%
<b>Total</b>	<b>3,825</b>	<b>3,334</b>	<b>274</b>	<b>228</b>	<b>87%</b>	<b>7%</b>	<b>6%</b>
<b>Operations &lt;1,000 AU (Designated as CAFOs)</b>							
Fed Cattle	30	4	0	26	13%	0%	87%
Veal	0	0	0	0	NA	NA	NA
Heifer	6	0	0	6	0%	0%	100%
Dairy	60	60	0	0	100%	0%	0%
Hogs	104	104	0	0	100%	0%	0%
Broilers	104	0	0	104	0%	0%	100%
Layers: Dry	4	4	0	0	100%	0%	0%
Layers: Wet	16	16	0	0	100%	0%	0%
Turkeys	20	20	0	0	100%	0%	0%
<b>Total</b>	<b>344</b>	<b>208</b>	<b>0</b>	<b>136</b>	<b>61%</b>	<b>0%</b>	<b>40%</b>

Source: USEPA. May not add due to rounding. Does not include the number of CAFOs includes designated facilities. Assumes that the costs that will be incurred by those sized operations to comply with BPJ-based limitations under the revised NPDES regulations are similar to the estimated costs that would be incurred if Medium CAFOs had to comply with the ELG.

“Layers: dry” are operations with dry manure systems. “Layers: wet” are operations with liquid manure systems.

EPA believes that the estimated financial impacts shown in Tables 4-5(a) and 4.5(b) represent the worst case. The reasons are summarized below.

First, all results are estimated assuming no costs can be passed through between CAFOs and the processing sectors. As discussed in Section 3 of this report, if modest levels of cost passthrough are assumed in the broiler sectors, the BAT requirements are affordable to all small broiler operations. EPA did not evaluate economic impacts on cattle operations under a cost passthrough scenario; however, it is expected that long-run market and structural adjustment by producers in this sector will diminish the estimated impacts. Even without an assumption of cost passthrough, EPA's analysis shows that adverse impacts will not be experienced by a substantial number of operations, as compared to the number of affected operations in these sectors. EPA has conducted an extensive literature review of issues concerning cost passthrough. Based on the results of the available empirical research on market power and price transmission in these industries, EPA believes that there is little evidence to support the position that increased production costs may not be passed through the market levels. A summary of this literature review is provided in the rulemaking record (ERG, 2000c — DCN 70640).

Second, as noted in the SBAR Panel Report, EPA believes that the number of small broiler operations is overestimated. In the absence of business level revenue data, EPA estimates the number of "small businesses" using the approach described in Section 4.2. Using this approach, virtually all (>99.9 percent) broiler operations are considered "small" businesses. This categorization may not accurately portray actual small operations in this sector because it classifies a 15- to 20-house broiler operation with 375,000 birds as a small business. Information from industry sources suggests that a two-house broiler operation with roughly 50,000 birds is more appropriately characterized as a small business in this sector (Madison, 1999; Staples, 1998). Therefore, it is likely that the number of small broiler operations might include a number of medium and large size broiler operations being considered small entities. As discussed in Section 9.2.1 of the Proposal EA, EPA consulted with SBA on the use of an alternative definition for small businesses in all affected sectors based on animal inventory at an operation during the development of the rulemaking.

Third, EPA believes that a costs-to-sales comparison is a crude measure of impacts on small business in sectors where production contracting is commonly used, such as in the broiler sector (and also in the turkey, egg, and hog sectors, though to a lesser extent). As discussed in Section 4.2.4.5 of the Proposal EA, lower reported operating revenues in the broiler sector reflect the predominance of contract growers in this sector. Contract growers receive a prenegotiated contract price that is lower than the USDA-reported producer price, thus resulting in lower gross revenues at these operations (USDA/ERS, 1996b; Perry et al., 1999; Farm Journal, 1998). Lower producer prices among contract growers are often offset by lower overall production costs at these operations, because the affiliated processor firm pays for a substantial portion of the grower's annual variable cash expenses. Inputs supplied by the integrator may include feeder pigs or chicks, feed, veterinary services and medicines, technical support, and transportation of animals (USDA, 1996a). These variable cash costs compose a large component of annual operating costs, averaging more than 70 percent of total variable and fixed costs at livestock and poultry operations (USDA/ERS, 1999a). The contract grower also faces reduced risk because the integrator guarantees the grower a fixed output price (see Section 2 of the Proposal EA for more information on contracting in animal agriculture). Because production costs at a contract grower operation are lower than that at an independently owned operation, a profit test (costs-to-profit comparison) is a more accurate measure of impacts at grower operations. However, financial data are not available that differentiate between contract grower and independent operations.

Fourth, EPA's initial regulatory flexibility analysis also does not consider a range of potential cost offsets available to most farms. As discussed in Section 2.4 of this report, one source of potential cost offset is cost share and technical assistance available to farmers for on-farm improvements from various State and Federal programs, such as the Environmental Quality Incentives Program (EQIP) administered by USDA. Cost sharing for eligible producers under EQIP may cover up to 75 percent of the costs of certain conservation practices, such as grassed waterways, filter strips, manure management facilities, capping of abandoned wells, and other practices important to improving and maintaining the health of natural resources in the area. Technical assistance is also available for formulating conservation plans. In the Spring of 2002, new Farm Bill legislation passed by Congress might significantly raise government expenditures for this program. Total EQIP authorization for FY 2002 to FY 2007 is \$5.8 billion, ranging from \$400 million to \$1.3 billion per year over the period. This compares to current authorized levels of about \$200 million per year. The new legislation targets 60 percent of available EQIP funds to livestock and poultry producers, including confinement and grass-based systems. The new legislation also removed the previous EQIP eligibility requirements that restricted funding for certain structural practices to operations with fewer than 1,000 AU (as measured by USDA), replacing this restriction with an overall payment limitation of \$450,000 per producer over the authorized life of the 2002 Farm Bill. Many other State and Federal cost share programs base eligibility not on size thresholds but on priority watersheds (e.g., USDA's Small Watershed Program; the New York City Watershed Program), priority contaminants (e.g., Kansas Non-Point Source Pollution Control Fund), or proposed waste management practices (e.g., Maryland, Minnesota, Missouri, Nebraska, and North Carolina state programs). However, technical assistance under most programs is available to all operations, regardless of watershed, contaminants, proposed practices, or size (ERG, 2000a). A review of cost-share and technical assistance programs available to AFOs is provided in the rulemaking record (ERG, 2000a—DCN 70130).

Section 2.4 also describes another source of potential cost offset, which is manure sales, particularly of relatively higher value dry poultry litter. EPA estimates that sales of dry poultry litter could offset the costs of meeting the regulatory requirements on the order of more than 50 percent. As illustrated in the Proposal EA, this reduction alone exceeds the level of cost passthrough (42 percent) assumed at proposal for the cost impact analysis of the broiler sector. Details on how EPA calculated these manure sale offsets and how they would reduce the economic impacts at poultry operations are presented in Section 6 of the Proposal EA.

Finally, this analysis does not take into account certain noneconomic factors that might influence an operation's decision to weather the boom and bust cycles that are commonplace in agricultural markets. Farm typology data from USDA indicate that a large share of farming operations (more than 90 percent) have annual sales of less than \$250,000 and are considered "small family farms" by USDA (USDA/ERS, 2000d, 2000e). Of these, about 60 percent are "limited-resource," "retirement," or "residential" operations where farming is not the primary source of income (USDA/ERS, 2000e, 1999a). In many cases, these operations have negative annual income supplemented by sources of off-farm income that subsidize the farming operation (USDA/ERS, 2000d and 1996a).

USDA's ERS (1996a) reports that about 60 percent of farm operators reporting negative net income had nonfarm occupations. About 75 to 80 percent of farms rely on some nonfarm income, and even in the largest operations nonfarm income can be a significant portion of total household income (USDA/ERS, 1996a). More than 90 percent of farm operators with negative net income had nonfarm income averaging more than \$35,700 per year; even farms with positive net income rely somewhat on nonfarm income (Heimlich and Barnard, 1995; USDA/ERS, 1996a).



When farm income is negative over a period of time, sales tests can be very difficult to interpret (Heimlich and Barnard, 1995). One reason that incomes can remain negative over several years is that operators can supplement farm income with nonfarm income, and these losses can be used to reduce total income tax liabilities while the real estate value of the farm property appreciates. Additional noneconomic factors might also include the satisfaction of working for oneself, the ability to employ family members, a sense of tradition and the ability to pass on that tradition to future generations, and the fact that the operation is both a home and a livelihood. These and other noneconomic factors might influence the decision to close a livestock or poultry operation cannot be adequately addressed in an economic model. To the extent that these factors play a role in that decision, EPA's economic model might overstate the possibility of closure among small businesses.

USDA's farm financial data include operations where farming is part-time and not the primary occupation, but exclude sources of nonfarm income at these operations. As noted in Section 4.2 of the Proposal EA, the inclusion of these operations may result in lower average data values than would be the case if these operations were excluded from the analysis. EPA believes that including of these operations might tend to overstate impacts. Previous analyses by USDA and EPA have also noted the potential effect on average farm data of including these operations and have regarded these part-time business more as "hobbies or recreational activities" (Heimlich and Barnard, 1995; DPRA, 1995). Heimlich and Barnard (1995) further indicate that considering non-farm income in addition to farm income may provide a more appropriate comparison to the costs of required measures where the motivation for staying in business is not necessarily purely economic.

Overall, EPA expects that the CAFO regulations will benefit the smallest businesses in these sectors, because the regulations might create a comparative advantage for small operations that are not subject to the regulations. Except for the few AFOs that are designated as CAFOs, these small operations will not incur costs associated with the final requirements and may benefit from eventual higher producer prices as these markets adjust to higher production costs in the long term.

## APPENDIX L ABBREVIATIONS USED IN THIS GUIDE

Advocacy	Office of Advocacy, U.S. Small Business Administration
AFO	animal feeding operation
ANPRM	advance notice of proposed rulemaking
APHIS	Animal and Plant Health Inspection Service
APA	Administrative Procedure Act
ATA	American Trucking Association
AU	animal unit
BLM	Bureau of Land Management
CAFO	concentrated animal feeding operation
CFPB	Consumer Financial Protection Bureau
C.F.R.	Code of Federal Regulations
CMS	Centers for Medicare and Medicaid Services
DOC	Department of Commerce
DOD	Department of Defense
DOT	Department of Transportation
DHS	Department of Homeland Security
E.O.	Executive Order
EPA	Environmental Protection Agency
EQIP	Environmental Quality Assessment Program
ERS	Economic Research Service (USDA)
FAA	Federal Aviation Administration
FAR	Federal Acquisition Regulation
FCC	Federal Communications Commission
FERC	Federal Energy Regulatory Commission
FR	Federal Register
FRA	Federal Railroad Administration
FRFA	final regulatory flexibility analysis
GAO	General Accounting Office, now Government Accountability Office
HHS	U.S. Department of Health and Human Services
ICR	information collection request
IPS	Interim Payment System
IRFA	initial regulatory flexibility analysis
IRS	Internal Revenue Service
MMS	Minerals Management Service
NAAQS	national ambient air quality standard
NAICS	North American Industry Classification System
NAIHP	National Association of Independent Housing Professionals
NAMB	National Association of Mortgage Brokers
NEPA	National Environmental Policy Act
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NPDES	National Pollutant Discharge Elimination System
NPRM	notice of proposed rulemaking
NWMA	Northwest Mining Association

OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
P.L.	Public Law
RCRA	Resource Conservation and Recovery Act
RFA	Regulatory Flexibility Act
RIA	regulatory impact analysis
RSPA	Research and Special Programs Administration
RUS	Rural Utilities Service
SBA	Small Business Administration
SBIC	small business investment company
SBJA	Small Business Jobs Act
SBREFA	Small Business Regulatory Enforcement Fairness Act
SERS	small entity representatives
SIC	Standard Industrial Classification system
SMR	specialized mobile radio
USDA	U.S. Department of Agriculture
U.S.C.	United States Code
UPL	upper payment limit
VOCs	volatile organic compounds

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