

The Office of Advocacy can assist program office staff who have questions regarding the definitions of small entities and the process for using alternative definitions. Program staff with such questions should contact the Office of Advocacy, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416; telephone (202) 205-6533. In addition, these definitions are discussed in Chapter 1 of the Office of Advocacy's guide for complying with the Act, entitled *The Regulatory Flexibility Act: An Implementation Guide for Federal Agencies* ("Office of Advocacy Guide"), which is available on the Office of Advocacy's Internet site at: <http://www.sba.gov/advo/>.

c. What Is the Preliminary Assessment of a Proposed Rule's Economic Impact Based on the Size and Type of Entities Affected and the Likely Overall Cost?

After defining the small entities that would be affected by a proposed rule, the program office staff must gather and consider sufficient information for determining whether the rule, if promulgated, will have a significant economic impact on a substantial number of small entities. There are no "hard" boundaries for the terms "significant economic impact" and "substantial number" of small entities. Significance should be considered relative to the size of the small businesses, the size of competitors' businesses, and any disparity in impact the rule might have on small businesses. It may be appropriate to group small businesses and other small entities into more than one category for purposes of the analysis. The Office of Advocacy Guide, Chapter 1, suggests criteria that may be used to determine significance, including the percentage of revenue or profits affected and effect on the ability of firms to make capital investments. The interpretation of "substantial number" should be made on an industry-specific basis. As explained in the Office of Advocacy Guide, Chapter 1, the absolute number of small entities required to meet the "substantial number" test may vary greatly depending on the size of the universe of small entities within a particular economic or other activity.

The level, scope and complexity of the preliminary analysis under the Act also will vary depending on the characteristics and composition of the industry to be regulated and the nature of proposed regulatory requirements. For example, the level of data collection and analysis in the preliminary assessment will be different for: (1) A proposed rule to establish new energy efficiency standards for a type of home

appliance (e.g., refrigerators or furnaces), and (2) a procurement regulation that applies principally to DOE's management and operating contractors but has requirements that flow down to subcontractors, some of whom may be small entities. In the former example of appliance standards, a fairly rigorous analysis of the economic impact on small manufacturers may be warranted because new energy efficiency standards often impose costs on all manufacturers of the affected products, and competition within the industry may be affected. In the latter procurement contract example, it may be difficult to estimate the number of small subcontractors who would be affected by new contract requirements. However, if DOE is contractually obligated to reimburse contractors for the cost of complying with regulatory requirements, the proposed rule would not have a significant economic impact on small entities. Because it is clear that such a proposed rule would not have an adverse economic impact, there is no need to determine the exact number of small contractors that might be affected by the proposed new requirements.

d. Is There Sufficient Factual Basis for Concluding That the Proposed Rule Would Not Have a Significant Economic Impact on a Substantial Number of Small Entities?

The Act permits the head of the agency to forego the preparation of an IRFA upon a written certification that the rule will not have a significant economic impact on a substantial number of small entities. The Act requires certifications to be supported by a "statement of factual basis" (5 U.S.C. 605(b)). At a minimum, the statement of factual basis must contain a description of the small entities that would be directly affected by the proposed rule and the potential economic impacts, as well as the program office's reasoning and assumptions underlying the certification. This statement will be subject to public comment, which will assure either that the certification was not erroneous, or that erroneous certifications are corrected. If the program office is uncertain of the impact on small entities, it should consider: (1) Performing an IRFA with the available data and information, and (2) soliciting public comment on the issue of impacts on small entities. Based on information obtained during the comment process, the program office may determine that a sufficient factual basis exists to certify, in the notice of final rulemaking, that the rule will not

have a significant economic impact on a substantial number of small entities.

The Office of Advocacy Guide, Chapter 1, gives examples of adequate and inadequate certifications. One example given of an inadequate certification is an agency statement that the rule would not have a significant economic impact on small entities because they would not be subject to any requirements not applicable to large entities. The Office of Advocacy filed comments with the agency, objecting to the certification because a principal purpose of the Act was to address disproportionate impacts of "one-size-fits-all" regulations on small entities. Therefore, the justification that the same requirements applied to both small and large businesses was inadequate. Other examples of inadequate certifications referenced in the Office of Advocacy Guide involve unsupported generalizations that were inconsistent with readily available factual information about the small entities that would be regulated by a proposed rule.

2. The Initial Regulatory Flexibility Analysis and Notification to Advocacy. If an IRFA is required, the DOE program office must inform the Office of General Counsel point of contact for the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA) — currently the Assistant General Counsel for Regulatory Law—that an IRFA is being prepared. This notice may be given when a draft notice of proposed rulemaking is submitted to the Office of General Counsel for review. To comply with the notification requirement in section 3(b) of E.O. 13272, the Office of General Counsel point of contact for OIRA will provide a copy of the draft notice of proposed rulemaking and the draft IRFA to the Office of Advocacy either when: (i) The submission is made to OIRA under E.O. 12866, or (ii) if review under E.O. 12866 is not required, no later than 10 business days before the notice of proposed rulemaking is published in the **Federal Register**.

The IRFA, or a summary, must be included in the Supplementary Information portion of the notice of proposed rulemaking. The IRFA must describe the economic impact of the proposed rule on small entities that would be directly affected by the proposed rule. Sections 603(b) and (c) of the Act set forth the elements of an IRFA. Each of the elements is discussed in more detail in Chapter 2 of the Office of Advocacy Guide. Section 603(b) requires that the IRFA contain:

- Reasons why action by the agency is being considered;