DEPARTMENT OF JUSTICE
Procedures to Ensure Proper Consideration of Potential Impact of Agency Regulations on Small Entities Pursuant to Executive Order 13272

As part of its compliance with Executive Order 13272, *Proper Consideration of Small Entities in Agency Rulemaking*, the Department of Justice follows established procedures, and will implement enhancements and new procedures as appropriate, to ensure that the potential impacts of the Department's draft rules on small businesses, small governmental jurisdictions, and small organizations are properly considered during the rulemaking process.

1. The Office of Legal Policy ("OLP") serves as the Department's Regulatory Policy Office under Executive Order 12866 and acts as the principal liaison between the rulemaking components of the Department, the Office of Management and Budget ("OMB"), and SBA. OLP reviews virtually all rulemaking actions to be published by components of the Department.[1] As part of its responsibilities, OLP ensures that each rulemaking component has considered whether its regulatory initiatives may have an impact on small entities, and that it has properly analyzed those potential impacts under the applicable legal and policy standards.

- OLP's principal responsibilities are to plan, develop and coordinate the implementation of major policy initiatives of high priority to the Department and the Administration. 28 C.F.R. § 0.23 (2002). Accordingly, OLP reviews regulatory policy initiatives proposed by components of the Department to ensure that they conform with the Attorney General's and the President's priorities and policy direction.

- OLP's Regulatory Review Team, under the direction of a Deputy Assistant Attorney General, takes a comprehensive approach to rule review to ensure that all legal requirements are satisfied; that the rule reflects sound legal and policy principles and is clearly written; and that the rule has been properly cleared both with the Department's senior management offices and with OMB, as well as with other interested agencies. As appropriate, rules may also be reviewed by other OLP staff to bring in additional specialized expertise.

- OLP is administratively located in the Senior Management Offices within the headquarters structure of the Justice Department. This is relevant to the effective implementation of issues relating to the pending rules, including compliance with Executive Order 13272, because OLP has direct access to senior decision makers in the event that any concerns it may have about the adequacy component assessment of a rule's impact on small entities cannot be resolved at a staff level.

2. OLP provides timely information and advice to all rulemaking components about their legal requirements under laws or Executive Orders (especially new laws or orders) affecting the rulemaking process, including the requirements to consider the impacts on small business.

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[1] The few rules that OLP does <u>not</u> review pertain to formal, on-the-record scheduling actions of the Drug Enforcement Administration conducted pursuant to 5 U.S.C. § 554; Privacy Act rules; and some minor internal agency administrative regulations.

• Shortly after passage of the Small Business Regulatory Enforcement Fairness Act of 1996 ("SBREFA"), OLP informed all of the Department's rulemaking components of that Act's requirements, in particular with regard to the need for components to assess the impact of their rules on small entities. Subsequently, OLP circulated to the Department's components SBA's *Guide to the Regulatory Flexibility Act.*

• As part of its March 23, 1998 memo circulating SBA's *The Regulatory Flexibility Act: An Implementation Guide for Federal Agencies*, OLP stated:

> agencies that rely on unfounded waivers of regulatory flexibility requirements or inadequate RFA analyses are now at risk of adverse action in the federal courts. . . . All rulemaking components of the Department are well advised to be cognizant of the importance of fully complying with the RFA, as amended by SBREFA, in preparing both proposed and final rules.

• On August 15, 2002 (just two days after President Bush signed Executive Order 13272), OLP circulated copies of the Order to the rulemaking components of the Department. In an accompanying note, OLP asked that when components submit rules to OLP, that they also submit an evaluation of the impact of the rule's impact on small entities. OLP advised the components that, continuing current practice, OLP will review each component's evaluation of a rule's impact on the private sector and on small entities and will coordinate with SBA's Chief Counsel for Advocacy, as appropriate. This staff-level advisory was subsequently formalized and expanded by a memorandum from Viet D. Dinh, Assistant Attorney General, to the heads of the Department's rulemaking components.

• When SBA finishes updating *The Regulatory Flexibility Act: An Implementation Guide for Federal Agencies*, OLP will circulate the revised guide to the Department's rulemaking components.

3. Each rulemaking component is responsible for reviewing its rules, while they are still under development, to consider whether the draft rule is in compliance with applicable legal and policy standards. This review includes, *inter alia,* the rule's potential impact on small entities and the means of ameliorating adverse impacts where possible.

• Most Department regulations are developed by the relevant program office in the issuing component. The Department's principal rulemaking components have established procedures whereby, after drafting by the program office, rules are reviewed within the component, at a minimum, by a senior official before being submitted to OLP. In addition, rules developed by components having their own Office of General Counsel are also reviewed by that office before being submitted to OLP.

• For example, Immigration and Naturalization Service ("INS") rules typically are also reviewed by INS's Office of Policy and Planning; the Immigration Services Division; Congressional and Public Affairs; Field Operations; and the INS Office of Management.

• OLP provides additional regulatory-development assistance – including assistance regarding small business matters – to those components of the Department that do not frequently issue regulations. *See* Appendix "A".

4. With respect to the potential impacts on small entities, OLP conducts a review of each rule to determine:

- whether a sufficient factual basis exists to support any assertion of an exemption or waiver of the requirements of the Regulatory Flexibility Act exists pursuant to 5 U.S.C. 601(2) or 5 U.S.C. 608;[2]
- whether a sufficient factual basis exists to support a decision to prepare a certification in lieu of a initial regulatory flexibility analysis ("IRFA") or final regulatory flexibility analysis ("FRFA");
- the adequacy and completeness of any IRFA or FRFA prepared by the issuing component; and
- whether impacts that the issuing component believes to be on “individuals” are, in reality, on “small entities” because they are being regulated in their capacity as business people (*e.g.*, individual doctors, lawyers, accountants, pharmacists, or international business travelers).

OLP requires that each certification in lieu of preparing an IRFA or a FRFA contain a clear and specific statement of who the rule affects as well as the factual reasons why the particular rule does not have a substantial impact on a significant number of small entities.

Details of the procedures components should follow to evaluate the potential impact of a rule on small entities are set forth in Appendix "B".

5. OLP also reviews regulations to ensure they fully comply with other applicable laws, policies, and procedures, including:

- the Administrative Procedure Act;
- the Unfunded Mandates Reform Act;
- the Paperwork Reduction Act;[3]
- the Congressional Review Act;
- Executive Order 12866 "Regulatory Planning and Review"; and
- Executive Order 13132 "Federalism".

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[2] Section 601(2) of the RFA states that the term "rule" means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of the Administrative Procedure Act (APA), or any other law. Section 553(b) does not apply to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice. Section 608 of the RFA allows an agency to waive or delay the requirements of an Initial Regulatory Flexibility Analysis ("IRFA") if a final rule is being promulgated in response to an emergency which makes preparing an IRFA impracticable. However, the agency must prepare a Final Regulatory Flexibility Analysis ("FRFA") within 180 days from the date of publication of the final rule or the rule will shall lapse and have no effect.

[3] The Department’s Justice Management Division (JMD) is responsible for the clearance of all forms and information collections under the Paperwork Reduction Act. In addition, OLP conducts a review of information collection issues as part of its regulatory review process, including matters relating to the clarity of the guidance being provided and the means to reduce the burden of information collections.

While these reviews do not, strictly speaking, pertain to Executive Order 13272, the nature of OLP's review involves all aspects of the regulatory process, thus helping to identify issues that may be of concern to small entities, regardless of how they are characterized by the issuing component.

6. In addition to its own review of rules, OLP circulates draft rules to other components of the Department that may be interested and/or affected, and will coordinate with them their review of the issuing component's rules.

• For example, OLP typically coordinates the review of INS rules with the Executive Office for Immigration Review ("EOIR") (a component independent of INS that houses the Board of Immigration Appeals and the immigration judges), with the Civil Division's Office of Immigration Litigation, and, as appropriate, with the Civil Rights Division's Office of Special Counsel for Unfair Immigration Related Employment Practices ("OSC"). While the primary focus of these reviewing offices is not small business matters, their review of INS rules nonetheless provides additional opportunities to identify any unanticipated negative impacts that INS rules may have on individuals or small entities.

7. Once all relevant components have completed their review, OLP transmits the rule along with a briefing memorandum to either the Deputy Attorney General's Office or the Associate Attorney General's Office, depending upon which office has supervisory authority over the rule-issuing component. Among other issues, OLP identifies in its briefing memorandum any consequences the rule may have on small entities and the steps that the issuing component has taken to consider or mitigate any burdens on small entities.

• The review of rules in the Deputy Attorney General's Office or the Associate Attorney General's Office is completed before a rule is submitted to OMB. This stage of the review process ensures that rules are in conformity with all Administration priorities and policies.

8. When the issuing component (or OLP) has identified a rule that may have a significant economic impact upon a substantial number of small entities, OLP will forward the rule to SBA for review at the same time the rule is forwarded to OMB, and will coordinate SBA's comments with the component.

• To ensure that the Department fully complies with the Regulatory Flexibility Act and with Executive Order 13272, OLP also will send informational copies of appropriate rules to SBA even where the issuing component has certified that the rule will not have a significant economic impact upon a substantial number of small entities. In general, OLP anticipates sending SBA informational copies of rules that are designated "significant" pursuant to Executive Order 12866 and also anticipates sending SBA any "non-significant" rules that might be of particular interest to small entities. OLP is happy to engage in a dialogue regarding what rules SBA would like to receive.

9. OLP serves as the Department's rulemaking liaison with OMB and is actively involved in all aspects of the regulatory clearance process with OMB under Executive Order 12866 as well as Executive Order 13272. In particular, OLP works to ensure that each component has fully

responded to concerns raised by OMB’s Office of Information and Regulatory Affairs ("OIRA") regarding the burdens that rules would impose, in order to minimize those burdens where possible, consistent with meeting the necessary objectives.

10. For appropriate rules, OLP also coordinates with the Department's Office of Public Affairs and with the issuing component's public affairs office concerning any press or other outreach materials that may be helpful to small entities.

APPENDIX "A"- OLP Rulemaking Information Package

OLP prepares and makes available to rulemaking components – particularly to those components that do not frequently engage in rulemaking – a comprehensive memorandum outlining the rule development and clearance process and the issuing component's responsibilities under relevant laws and Executive Orders. In addition to its memorandum, OLP also circulates to the developing component a set of the laws and Executive Orders most relevant to the regulatory process. These documents include, *inter alia*, copies of material relating to the impact of regulations on small entities:

N Executive Order 12620 *"Governmental Actions and Interference with Constitutionally Protected Property Rights";*
N Executive Order 12866 *"Regulatory Planning and Review";*
N Executive Order 12988 *"Civil Justice Reform"*;
N Executive Order 13132 *"Federalism";*
N Executive Order 13272 *"Proper Consideration of Small Entities in Agency Rulemaking";*
N SBREFA;
N 13 CFR Part 121 (SBA's Small Business Size Regulations);
N 15 U.S.C. § 632 (provisions relating to the definition of a small business concern, and to SBA's size standards);
N The Unfunded Mandates Reform Act of 1995;
N SBA's *The Regulatory Flexibility Act: An Implementation Guide for Federal Agencies*;
N Flowchart of the RFA analysis process prepared by SBA's Office of Advocacy;
N SBA guidance concerning the Interagency Process for Avoiding Judicial Review under the RFA; and
N SBA summary of court cases illustrating judicial assessments of the adequacy of agency compliance with the RFA.

APPENDIX "B" - Procedures Department Components Should Follow to Evaluate the Potential Impact of a Rule on Small Entities.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires federal agencies to consider the impact of regulations on small entities in developing the proposed and final regulations. If a proposed rule is expected to have a significant economic impact on a substantial number of small entities, the rulemaking component must prepare an IRFA. The IRFA or a summary of it must be published in the *Federal Register* with the proposed rule.

An initial regulatory flexibility analysis is prepared in order to ensure that the issuing component has considered all reasonable regulatory alternatives that would minimize the rule's economic burdens or increase its benefits for the affected small entities, while achieving the objectives of the rule or statute. The component's analysis should describe the objectives of the proposed rule, addresses its direct and indirect effects and explains why the component chose the regulatory approach described in the proposal over the alternatives.

Section 603(a) requires an agency to prepare an analysis that describes the impact of the proposed rule on small entities. Pursuant to Section 607, the agency may provide either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or a more general descriptive statement if quantification is not practicable or reliable, when complying with 603 (requirements for an IRFA) or 604 (requirements of a FRFA) of the RFA.

Under Section 603(b) of the RFA, each initial regulatory flexibility analysis is required to address: (1) reasons why the agency is considering the action, (2) the objectives and legal basis for the proposed rule, (3) the kind and number of small entities to which the proposed rule will apply; (4) the projected reporting, recordkeeping and other compliance requirements of the proposed rule, and (5) all federal rules that may duplicate, overlap or conflict with the proposed rule.

While these five factors are necessary elements to an adequate IRFA, they are not the sole factors necessary to perform an adequate analysis. Most important, section 603(c) requires that each initial regulatory flexibility analysis contain a description of any significant alternatives to the proposal that accomplish the statutory objectives and minimize the significant economic impact of the proposal on small entities. These alternatives could include the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; the clarification, consolidation or simplification of compliance and reporting requirements under the rule for small entities; the use of performance rather than design standards; or an exemption from coverage of the rule or any part of the rule for small entities.

Components should consider regulatory alternatives that may include less stringent requirements for all regulated entities or for different classes of regulated entities. The section 603(c) analysis, a key part of the regulatory flexibility analysis, informs both the component level

decisionmaker and the reviewing officials in OLP and in the Department's Senior Management Offices of the pros and cons of each alternative, so they can make informed regulatory decisions.

The steps necessary under 603(b) include:

1) A description of the reasons why action by the agency is being considered. This is currently included in the preamble to all proposed regulations.

2 A succinct statement of the objectives and legal basis for the proposed rule. This is currently included with proposed rules.

3) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply. The issuing component should describe the industry or economic sector in total and its small and large entity segments, including a description of the industry or sector at the time of proposal, along with an explanation of any existing dynamics, such as trends in employment or birth of entities.

The definition of a small entity is an important element of this analysis. Issuing components may either use the statutory definition of small entity or may propose an alternate definition in consultation with the SBA Office of Advocacy. The statutory small business definitions vary by 4-digit SIC code and are found at 13 CFR Part 121, last repromulgated in the January 31, 1996, Federal Register.

In the component's analysis, small entities may be further divided into multiple classes of small businesses, for example, 0-9, 10-49 and 50-500 employees. This segmentation allows the agency to differentiate different types of effects on different-sized small entities, which might lead to a different approach being applied to the very smallest entities.

The component must include a description of the industries and economic sectors as identified by, for example, their four-digit Standard Industrial Classification Codes that directly or indirectly would be affected by the proposed regulation.

4) A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule. The description should include 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. This cost analysis should describe each item and estimate the costs, comparing large and small entities. It should distinguish the initial costs from recurring or operating costs. This information normally should be available in large part from the paperwork burden analysis prepared under the requirements of the Paperwork Reduction Act.

5) An identification, to the extent practicable, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule. This should include information for regulated entities on other rules governing the same activities.

Certification: When a Full Analysis is Not Required

If a proposed rule is not expected to have a significant economic impact on a substantial number of small entities, either adversely or beneficially, the component is not required to perform an initial regulatory flexibility analysis. In these instances, the RFA authorizes an agency head to certify a rulemaking. To perform an adequate certification, the issuing component must undertake a threshold analysis to determine the economic impact of a proposed rule on small entities. Once this preliminary analysis is undertaken, an agency then can determine whether to certify or undertake a complete initial regulatory flexibility analysis.

The certification of a finding of no significant impact on a substantial number of entities must be published with the proposed rule in the *Federal Register*. The notice must be accompanied by an explanation of the factual basis for the certification. Under the 1996 amendments, the certification is subject to judicial review if the final rule is challenged.

There is currently no case law that identifies the trigger levels of significant economic impact, or substantial number of small entities. However, because the purpose of the analysis is to aid the decisionmaker in resolving regulatory issues affecting small entities, it is the opinion of the Office of Advocacy that any rulemaking that generates the interest of a significant number of small entities warrants the application of the RFA's analysis tools.

Final Regulatory Flexibility Analysis

When an agency issues any final rule, the issuing component must prepare a final regulatory flexibility analysis ("FRFA") or certify that the rule will not have a significant economic impact on a substantial number of small entities. The FRFA must discuss the comments received, the alternatives considered and the rationale for the final rule. Either the summary or the final regulatory flexibility analysis itself must be published in the Federal Register with the final rule. Under the 1996 amendments, the final regulatory flexibility analysis is subject to judicial review if the final rule is challenged.

The new law amends the requirements of the final regulatory flexibility analysis contained in the original 1980 legislation. Each final regulatory flexibility analysis must contain the following:

1) A succinct statement of the need for and objectives of the rule;

2) A summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the component's assessment of such issues and a statement of any changes made in the proposed rule as a result of such comments;

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

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

5) A description of the steps the issuing component has taken to minimize the significant economic impacts 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 the reasons for rejecting each of the other significant alternatives.

Again, the most important section is the analysis of the relative merits and demerits of the alternatives and the rationale for the final agency action. An issuing component may not simply rely on its preamble to the final rule to comply with the requirements for a final regulatory flexibility analysis. The RFA requires specific discussion of small entity alternatives designed to reduce adverse impacts or enhance the beneficial impacts of a rulemaking.

The RFA amendments modify the Administrative Procedure Act requirements by turning the consideration of small entity issues into a major aspect of rulemakings. Failure to fully comply with these requirements could result in arbitrary and capricious rulemaking.

Although components may not be legally required to perform an initial or final regulatory flexibility analysis on every rulemaking, they should aspire to perform these analyses for every rule that would have an economic impact on small entities. The act generally provides that agencies must prepare both an initial and final regulatory flexibility analysis for rules that may have a significant economic impact on a substantial number of small entities. In practice, this requires components to prepare an analysis whenever a rule's impact on small entities cannot be described as *de minimis*. This practice will move away from speculative analysis towards more fact-based decisionmaking within the spirit of the law. SBA believes that an agency's resources should be shifted from the effort to determine whether regulatory flexibility analysis is required to the more productive consideration of regulatory options for small entities subject to the rule.