EPA Task Force Report on

IMPROVING EPA REGULATIONS

June 15, 2001

EPA's regulations define the technical, operational, and legal details of many of the Nation's environmental programs. The credibility of our decisions depends on the science and analysis underlying these regulations. Their quality determines how well environmental programs actually work and the extent to which they achieve health and environmental goals.

EPA publishes hundreds of rules each year – some routine and non-controversial, others dealing with complex, cutting-edge scientific issues, or imposing major economic impacts. Our procedures for developing these rules are driven by legal requirements and Executive Orders and our desire to improve process efficiency and the quality of our rules.

A well-run regulatory process helps achieve better environmental protection by ensuring that we fully analyze the options for dealing with an environmental problem from scientific, economic, policy, and practical perspectives. We can then choose an approach that balances all relevant factors and achieves the best overall environmental result. Our process for analyzing regulatory options is particularly important when the answer to an environmental problem is complex and must address competing concerns.

Careful identification and analysis of options can enable EPA to achieve an optimal degree of environmental protection at less cost and with less paperwork burden, and with more flexibility and easier implementation. Ensuring that our regulations have a sound analytical foundation reduces both controversy and, to some extent, court challenges. It also increases the likelihood of compliance by the regulated community, which is key to achieving real environmental improvement.

On April 10, 2001, Administrator Whitman directed EPA's Acting Assistant Administrators to reexamine the Agency's regulatory development process and identify ways to strengthen it and improve the quality of supporting scientific, economic, and policy analysis. She also emphasized the need to add more flexibility, use voluntary and non-regulatory approaches where effective, and create strong partnerships with States and businesses to meet environmental goals.

Under the guidance of the Acting Assistant Administrators, four workgroups of EPA rulemaking staff and managers worked together to identify actions to optimize the production of Agency regulations. This report describes the actions we recommend to meet the Administrator's expectations. Some of these actions reflect recommendations made before, but never fully implemented; others suggest new approaches to the regulatory development process.

How EPA Develops Regulations

EPA develops regulations in response to legal requirements, court orders, Presidential initiatives, or priorities set by the Administrator. The intent of our Action Development Process is to ensure that the appropriate offices and stakeholders are involved, and that we conduct the scientific, economic, and policy analyses necessary to develop and select regulatory options. These steps include:

- **Tiering** – The EPA office responsible for the rule (the lead office) assigns the rule to one of three tiers. Tier 1 includes the rules that are the most visible and controversial, and of most interest to the Administrator. Tier 2 includes rules with extensive cross-media issues or which require extensive cross-Agency involvement. (Tier 1 and 2 regulations require a cross-Agency workgroup and early senior management direction.) Tier 3 includes all rules not considered Tier 1 or 2. The tier designation is reviewed by the Regulatory Steering Committee (comprised of representatives of EPA's Assistant Administrators), and approved by the Administrator's Office.

- **Analytic Blueprint** – The cross-Agency workgroup coordinates the development of the regulation and, as a first step, prepares an analytic blueprint – the plan for the analyses, consultation, and other activities that support the regulation. The blueprint details how we will obtain the economic, scientific, technical, and intergovernmental information needed to make sound decisions, as well as the analyses required by law or Executive Order (e.g., Federalism). It also addresses significant policy issues, including implementation issues (such as the need for real-time compliance assistance tools), as well as international factors like treaties, transboundary or global pollution, and other countries' relevant experiences. Development of the blueprint is guided by senior management in the program offices and, in some cases, the Administrator's Office. It is then circulated for approval by workgroup program managers and, in the case of Tier 1 and 2 rules, senior management. A blueprint is required for Tier 1 and 2 regulations, and strongly recommended for Tier 3.

- **Options Development** – To develop regulatory options, the lead program office consults with a broad range of stakeholders, which may include state, local, and tribal governments, industry, small businesses, public interest groups, and others. The workgroup conducts the analyses in the analytic blueprint and considers other issues such as disproportionate impacts on minority groups, children's health issues, and innovative alternatives to the regulation.

- **Options Selection** – Once the options are developed, management considers the scientific findings, the relative benefits and costs, and the policy issues identified through the various analyses and consultations. If management selects a rulemaking option, the workgroup drafts the preamble to the rule, the proposed regulatory text, and supporting documents.

- **Final Agency Review** – The lead office prepares a final draft and circulates it to the workgroup for final review and approval. If the rule is in Tier 1 or 2, the Office of Policy, Economics and Innovation (OPEI) chairs a final Agency review meeting to assure that all issues are resolved, that all requirements have been met, and that the rule is ready for OMB review (where required) or *Federal Register* publication.

General Findings

In general, the Task Force finds that the existing system for developing our regulations is well designed, but that certain areas need improvement. We can do more to enhance the quality of information supporting our decisions and to ensure that science and economic issues are adequately addressed at the right stages in regulatory development. We must ensure that our analyses are sufficiently broad and completed in time for decision-makers to use in considering options. EPA science and economics experts should participate in planning and conducting essential analyses and research, and we need to pay more attention to developing and selecting options. A broader array of policy options, including innovative alternatives and market-based approaches, should be developed for consideration by Agency decision-makers.

More accountability is needed to ensure proper senior management direction. Key Agency leaders may not be involved until the rulemaking is well underway or near completion. As a result, some regulations may not fully reflect Administration priorities, or significant issues may arise too late to be resolved efficiently. EPA regulations would be enhanced by earlier direction from senior managers and more active management involvement in selecting options and resolving issues. This is especially important for cross-cutting Agency issues, such as the assumptions supporting scientific or economic analyses, or approaches to regulating a particular industry or addressing a specific chemical.

Although the process itself is basically sound, its application varies greatly across the Agency. Consistency and accountability are needed to ensure effective implementation. For example, the criteria for placing rules in the correct tier are not as clear as they could be. On some Tier 1 and 2 regulations, other program offices and Regions don't always have the opportunity to weigh in on key decision points, such as identifying needed analyses or selecting options. Analytic blueprints aren't always being used as the planning tool they were designed to be, and consultation with stakeholders isn't always carried out appropriately or at the right time. Finally, we have to do a better job of ensuring that managers and staff receive the training they need to implement the process effectively.

Recommendations for Improvement

The Task Force believes that EPA's regulatory process could be significantly improved through:

< ***better science and economic analysis,***
< ***broader consideration of policy options,*** and
< ***greater accountability.***

The Task Force also believes that we need to improve our process for making significant non-regulatory decisions that are embodied in policies, guidance documents, and strategies.

Better Science and Economic Analysis

The Task Force recommends several actions to strengthen the quality, consistency, and comprehensiveness of the scientific and economic analyses that support our regulations. It is absolutely essential that EPA leaders have the best possible scientific and economic information to consider when making decisions. But it's important to note that science and economics are only two of the many factors that must be considered. Other factors might include implementation by states or local governments, disproportionate impacts on low income communities, the limitations of available technology, or whether a certain approach can actually be enforced. The role of science and economics is, therefore, to *inform* the decisionmaking, not to dictate the final decision.

Sound Science

During EPA's first 30 years, we addressed most of the nation's easier environmental problems. Today we are working on far more complex environmental problems, often involving multi-media impacts from multiple sources of pollution. In this context, the definition of the environmental problem is far less certain, possible solutions are more difficult to identify, and the costs of dealing with them are likely to be much greater. To make decisions based on sound science, policymakers need information that reflects the latest findings in relevant, high quality research and analyses, usually spanning a variety of scientific disciplines, such as chemistry, toxicology, and engineering. This information must be presented in a form that non-scientists can understand and use correctly. To meet this need, strong scientific support must be provided throughout the rulemaking process.

Action 1: *Ensure that science has a more prominent role in EPA decision-making.*

< Designate an EPA Science Advisor to consult with program offices, review analyses, and advise the Administrator on the quality of the science that supports EPA decisions.
< Clarify that providing support to EPA rulemaking is a key ORD function.
< Ensure that EPA scientists are appropriately involved in determining needed analyses and research, identifying alternatives, and selecting options.

- < Clarify the roles of the Science Advisory Board, the Science Policy Council, and other groups that deal with cross-Agency science issues; consolidate where appropriate.
- < Require that all regulatory decision packages include a plain language discussion of the uncertainties in the scientific analyses and how they affect the decision.

Sound Economics

Environmental economics is a rapidly evolving field, and there has been a dramatic expansion in the universe of economic and social issues that must be considered as we make decisions. EPA is legally required to conduct certain types of economic analyses as we develop regulations, but these analyses are also important for considering voluntary, non-regulatory approaches. The Task Force found that most of EPA's economic analyses are of high quality, but problems arise when economic issues are not addressed early in the process. There is also a need for more consistency in dealing with economic issues, and greater coordination between EPA scientists and economists as we deal with science, costs, and benefits analysis.

Action 2: *Ensure appropriate use of high quality economic analysis in EPA decision-making*.

- < Designate an EPA Economics Advisor to consult with program offices, review analyses, and advise the Administrator on the quality of the economic analyses that support EPA decisions.
- < Ensure that EPA economists are appropriately involved in determining needed analyses and research, identifying alternatives, and selecting options.
- < Require that all regulatory decision packages include a plain language discussion of the uncertainties in the economic analyses and how they affect the decision.

Action 3: *Strengthen EPA's ability to address cross-cutting economic issues*.

- < Create a formal cross-agency mechanism to evaluate key recurring and cross-cutting economic issues and develop standard EPA positions on these issues.
- < Strengthen the integration of scientific and economic analyses.

Broader Consideration of Policy Options

To develop a variety of viable options for solving complex environmental problems, EPA must examine many different types of policy issues – legal, scientific, economic, social, public health, and environmental – including their interactions and effects under different scenarios. These issues should be considered throughout the decisionmaking process, and our analyses must be based on high quality information. The analytic blueprint is a good tool for planning how to analyze these issues, but its use is inconsistent across the Agency.

Existing requirements for developing regulations include a number of different types of analyses, ranging from paperwork reduction to potential impacts on various groups such as children, minority communities, small businesses, states, tribes, and local governments. In addition to addressing these requirements, workgroups and managers must also consider the policy issues mentioned above and the Administration's priorities. This can impose an overwhelming workload that may result in tradeoffs between meeting deadlines and thoroughly analyzing all relevant issues.

The options selection process, in particular, needs more serious attention. For some rules, it may be necessary to establish a two-stage process for selecting options. We must also improve our efforts to consult with policy advisors, co-regulators and external stakeholders.

Action 4: *Strengthen analysis of policy issues.*

- Clarify the policy questions to be addressed in the analytic blueprint, including implementation and compliance issues, information issues, innovative alternatives, burden on states and local governments, international considerations, and priorities of the Administration.
- Ensure that blueprint addresses these issues, as well as all analyses required by statute or Executive Order.
- Assist managers and workgroups in understanding analytical requirements, conducting high quality analyses, and addressing Agency priorities.

Action 5: *Expand management involvement in selecting options.*

- Conduct formal options selection on all Tier 1 and key Tier 2 rules. Obtain early direction from the Administrator or Deputy Administrator on Tier 1 rules, and full involvement by all affected Assistant Administrators and the Lead Region on Tier 1 and 2 rules.
- Where appropriate, establish a two-stage process for selecting options: early on, to set the general approach (e.g, regulatory or voluntary) and later, after analyses are substantially complete (e.g., to select specific options to propose).

Action 6: *Consult more effectively with policy advisors, co-regulators, and stakeholders.*

- Integrate the work of EPA's policy advisory councils (e.g., Regulatory Policy Council, Science Policy Council); consolidate where appropriate; add responsibility for economic policy considerations.
- Strengthen the involvement of states, tribes, and local governments earlier and throughout the process to ensure that their views are taken into account, particularly in developing, analyzing, and selecting options.
- Strengthen stakeholder involvement early in the process to ensure that their views are taken into account in developing, analyzing, and selecting options;
- Integrate EPA guidance on how we consult with external groups.

Action 7: *Improve consideration of implementation issues*

- Throughout the regulatory development process, consider the full range of implementation issues, including real-time compliance guides, state authorization issues and approaches, permitting and variances.

Greater Accountability

The Task Force concludes that we need to be more disciplined in properly implementing the Action Development Process. The primary responsibility, accountability, and authority for ensuring that the rulemaking process is appropriately carried out -- including the scientific analyses, the economic analyses, and the compilation of the rulemaking record -- lies with Assistant Administrator and the managers in the office initiating the rule. Senior managers in the lead program office must be actively involved not only in addressing issues, but also in providing strategic direction and managing the process. All players must adhere to process requirements, including tiering and the preparation and implementation of analytic blueprints.

Through the Regulatory Steering Committee, regulatory coordinators in each program office play a valuable role, both for their individual offices and for the Agency as a whole. But we're not fully utilizing other resources, such as OPEI, to support the regulatory process and ensure that it works effectively. Although it's a difficult task, we also need to do a better job of assessing whether our regulations are achieving their desired objectives. Finally, we need to periodically evaluate the effectiveness of our regulatory process.

Action 8: *Establish clear roles and responsibilities for Agency managers in rulemaking.*

- Get early direction on the Administrator's priorities and issues.
- Set regularly scheduled meetings with the Deputy Administrator and affected AAs and Regions to select options and resolve issues on high priority decisions.
- Ensure that managers take an active role in setting strategic direction, assuring high quality analyses, selecting options and resolving issues.
- Direct Lead Regions to assist lead offices in getting Regional input, especially on implementation issues.

Action 9: *Create a management system to ensure timely and thorough analysis, elevate issues, and move the process forward.*

- Use the tiering process more effectively to ensure broader Agency involvement and executive input on cross-cutting scientific, economic or policy issues.
- Assign to OPEI responsibility for:
  - ensuring proper adherence to the overall regulatory process,
  - identifying and helping resolve cross-Agency issues,
  - assisting program offices in conducting thorough analysis, complying with relevant laws and Executive Orders, and addressing Administration priorities,
  - tracking significant rules, non-regulatory actions, and issues; and

- S ensuring timely options selection.
- < Provide managers with the necessary tools (e.g., guidance) and specialized training to carry out their regulatory development responsibilities.

Action 10: *Evaluate the effectiveness of regulations and the regulatory development process*.

- < Develop mechanisms to monitor and determine if rules are achieving their desired environmental outcomes.
- < Develop and implement a strategy to further improve the effectiveness of the regulatory development process.

Better Management of Significant Non-Regulatory Activities

EPA performs many important functions that don't involve rulemaking, such as producing policies, guidance, and strategies. The development process for these activities also needs to be improved. Offices should, but rarely do, use the Action Development Process to identify "significant" non-regulatory activities and ensure appropriate cross-Agency attention and involvement. Because the process was developed primarily for rules, it is not always clear how to apply it to non-regulatory activities. The Task Force recommends a clearer, more comprehensive approach to managing these important policy decisions.

Action 11: *Improve the Action Development Process to identify significant, non-regulatory activities and ensure appropriate cross-Agency resolution of issues raised by these activities.*

- < Modify the existing process to better manage significant non-regulatory activities or create a separate process if necessary.

Next Steps

Our goal is to make EPA's decision process more efficient, effective, and environmentally protective. Success in meeting this goal will depend on effective implementation of the recommendations that the Administrator accepts. Improving our decisionmaking process will require conscious choices and tradeoffs, and other important work will necessarily shift to a lower priority. This will undoubtedly require realignment of resources, which should be reflected in Agency budget documents and strategic plans. Schedules may also need to be changed.

To implement the recommendations in this report, the Task Force proposes a set of key actions (Attachment 1). These are the first steps needed to put the recommendations in place. Pending the Administrator's decisions, a more detailed implementation plan will be prepared. The Task Force also compiled a set of more detailed recommendations and ideas (Attachment 2) that could significantly improve the quality of our policy decisions. These are valuable ideas that should be seriously considered during implementation.