

THE U.S. REGULATORY PROCESS IN ENVIRONMENTAL PROTECTION

A Half Century of Progress Supplemental Report

Victor J. Kimm and Michael H. Levin

EPA Alumni Association

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The EPA Alumni Association (EPAA AA) has initiated a Half Century of Progress project consisting of a series of web-based documents. An integrated summary essay, [Protecting the Environment: A Half Century of Progress](#), is available on the Association website, as are seven supporting program essays and this supplemental report on the U.S. environmental regulatory process. The Association has developed these materials to inform high school and college students and other members of the public about the major environmental problems and issues encountered in the United States in the latter half of the 20th century, as well as the actions taken and progress made in mitigating these problems.

A number of former EPA program managers and subject matter experts worked together to produce each of the essays. This document was reviewed by the EPA AA Board of Directors and members of the association. We welcome comments on this document, which you may submit to [the EPA Alumni Association](#).

Protecting the Environment: A Half Century of Progress

Supplemental Report

THE U.S. REGULATORY PROCESS IN ENVIRONMENTAL PROTECTION

- As a result of post-Earth Day (1970) pollution control legislation:
 - air we breathe and drinking water we consume are cleaner,
 - the quality of our waterways is significantly improved,
 - the solid waste we generate is better managed,
 - dangerous abandoned or active waste sites continue to be cleaned up,
 - the threat of toxic chemicals to our people, wildlife and resources is reduced.
- Substantial improvements in public health and the environment generally have been attained without the major economic dislocations predicted by some.
- While this progress has involved controversy over the costs of compliance and whether required pollution reduction is too much or not enough, regulations have been one of the major forces for ongoing gains in environmental quality.
- As noted in the [Half Century of Progress essay](#), significant progress in improving environmental quality also has been obtained through voluntary non-regulatory programs such as [Energy Star](#) and [Waste Wise](#).

This paper provides a basic understanding of the evolving process that has been used over the last half century to develop environmental regulations.

Rationale

- Pollution control regulations flow from laws based on three principles:
 - ⊖ Intervention by states or the Federal government is needed to protect peoples' health, well-being and the general environment. Without it, many industrial and other entities would not take into

account the costs to the public from contaminated air, water or land and would have little reason to control their emissions or discharges;

- ⊖ polluters generally should be responsible for ameliorating the adverse impacts of their pollution (sometimes called the ‘polluter pays’ principle);
- ⊖ Nation-wide “baseline” standards often are needed to protect public health *and* protect complying states or pollution sources from unfair competition by those who otherwise might not comply.
- The U.S. has substantially improved environmental quality over the past 50 years, largely through successful implementation of a wide range of pollution-reduction regulations by both public and private sectors.
- While these regulations have increased regulated entities’ expenditures for pollution-control, they have produced direct benefits to the public, including fewer deaths and illnesses, that by most estimates far exceed such costs.⁸ They also have benefited regulated entities by encouraging them to find more efficient ways to eliminate or reduce pollution, and by allowing them to avoid much higher costs of addressing extensive contamination later on.
- Regulations have fostered public and private-sector research and development in pollution prevention, process changes that reduce waste generation, and new technologies that can reduce harmful pollution at lower cost.
- *Targeted* financial and technical assistance from the U.S. Environmental Protection Agency (EPA) has helped states and tribal governments enhance their ability to manage environmental-protection programs and shoulder major implementation responsibilities. This has substantially reduced federal program costs over time.
- *General* financial assistance from federal and state governments (for example, the ability to claim tax credits or deductions for steps that reduce pollution) has helped regulated entities comply more rapidly and inexpensively.

Goals and Framework

Since 1970 the U.S. Congress has directed wide use of the regulatory process to reduce pollution and enhance environmental quality to protect Americans' health and safety and preserve our diverse natural environment.

- Regulations are legal requirements that (when finally issued) have the force of law and require regulated parties to comply over specified times, with violations subject to formal compliance orders, civil fines and/or criminal penalties.
- Each regulation is subject to checks and balances on the power of regulatory agencies. These checks require “due process” (i.e., basic fairness) for all affected parties, including the right to seek relief from the courts where they believe an agency acted beyond its authority, did not sufficiently fulfill its pollution-control responsibilities, or failed to give interested persons a meaningful chance to make their views known when the regulation was developed. The courts vigorously police these requirements. For example, they have ruled that even informal agency policies can be “regulations” subject to these “notice and comment” guarantees. They also have ordered many rules to be issued by fixed deadlines – results that can speed certain protections but may delay efforts to implement others.
- Since at least 1984 every President also has issued Executive Orders requiring agencies to consider less-costly alternatives when proposing regulations. These executive actions also mandate government-wide review of the costs and benefits of ‘major’ proposed rules. Resulting reviews can be contentious: regulated parties often dispute an agency’s compliance-cost estimates, and it can be difficult to assign dollar values to some environmental benefits like improved water quality or preservation of ecosystems. However, the review process itself is well-established.

Required Procedures

- The regulatory process is not new. It dates to the First Congress, which directed President Washington to develop rules governing trading by citizens with Native Americans. It has been used by Congress to create and direct a wide range of regulatory activities that deal with railroads, energy, highways, stock exchanges, telecommunication, social security, pensions, health care and worker protection, among many other subjects.
- Before a federal agency can regulate, Congress must first enact a law giving that agency authority to develop regulations. The law may provide either very general or more specific guidance about the purposes and shape of regulation. It may or may not contain a list of factors such as cost or available pollution-control technology to be considered in developing concrete rules.
- Since the 1930s Congress broadly has delegated to federal agencies like EPA the authority to develop specific regulatory requirements, particularly where Congress thought it lacked the technical expertise to do so.
- In the 1940s Congress enacted the Administrative Procedures Act to further ensure due process for those affected by regulatory requirements, including broad authority for interested parties to comment on proposed regulations and to seek judicial review. Because many details are not spelled out in the environmental laws, the federal courts have played a major role in defining the form and stringency of environmental regulations and how they are made.
- Taken together, these procedures are meant to guarantee that all stakeholders, including the general public, can participate in developing specific regulations, and that the costs, economic and social impacts, benefits and alternatives respecting proposed rules are thoroughly vetted.
- As a practical matter these “procedural fairness” requirements also mean that traditional environmental rulemaking now may take 3 to 5 years (with extensive analysis and documentation) to produce a new ‘major’ regulation. Such rules often are challenged in court, taking several more years before their requirements may become enforceable. In general, the

same procedural requirements also apply should an agency seek to revoke an established rule. In fact, these requirements then may apply more forcefully, since the agency typically must justify why it changed its mind and eliminated a rule on which many affected parties may have relied.

- Accordingly, EPA and other regulatory agencies have developed innovations that seek to streamline and accelerate required rulemaking, while providing better assurance that the results may be acceptable to affected parties. These time saving innovations have included: 1) holding negotiations among stakeholders before a rule is proposed, 2) making federal and state reviews simultaneous rather than sequential; 3) providing states authority to make program or permit changes under pre-approved criteria without federal approval; and 4) giving regulated parties the flexibility to choose where to make pollution reductions, as long as equivalent or better overall reductions are secured.
- An example of effective regulatory negotiations has been development of far-reaching improvements in vehicular fuel efficiencies and reduced greenhouse gas emissions negotiated between several federal government units and major auto makers, phased in over time, and referenced in the Half Century of Progress [air pollution essay](#).

Making a Rule

While details may vary with the particular environmental program or type of rule, a regulation typically is developed through the following basic steps.

- EPA issues statutory ‘information requests’ seeking data on the scope of a problem, who contributes to it, what processes or pollution controls they use, and what further pollution-reduction measures may be feasible for them to take. For major health-based rules like national ambient air quality standards or national standards for drinking water, this step also may involve major science reviews, such as a review and critique of the available scientific literature.

- EPA may issue an Advance Notice of Proposed Rulemaking (ANPR) indicating its preliminary approach, alternative approaches, and supporting evidence. Like the steps below the ANPR is published in the Federal Register,² giving potentially affected parties legal notice of agency plans.
- EPA then must issue a Notice of Proposed Rulemaking (NPR) in the Federal Register² detailing its proposed regulation, who may be affected, potential alternatives, underlying reasoning, and supporting or adverse scientific, engineering and economic data. The NPR often is accompanied by substantial further information such as feasibility analyses and a draft Regulatory Impact Analysis (RIA), especially for 'major' proposed rules whose expected economic impacts will exceed \$100 million per year.
- A public comment period follows during which interested parties may react to the proposed rule, submit supporting or countering information, and propose their own alternatives. They also may testify at public hearings convened in one or more locations around the country. Depending on a regulation's scope, complexity and possible impacts, public comment periods generally are 30 to 90 days after the proposal's publication.
- The agency must review and consider all comments it receives and usually prepares a detailed Response to Comments (RTC), a summary of which may be included in the preamble to a published final rule. During this post-comment review period EPA may request additional information or conduct further studies. For some rules, special review requirements may apply, such as mandates that EPA convene a small business panel to identify additional less-costly options if a "substantial number of small entities" likely will be affected. Additional information received by such means also must be publicly noticed for comment.
- Both the draft proposed rule and draft final rule are reviewed for impacts, alternatives and cross-agency consistency by the Office of Management and Budget (OMB) in the Office of the President. As appropriate, OMB coordinates review and comment from other relevant Federal agencies and departments and subsequently may return draft rules to EPA for further

analysis or revision. Significant rules also are reviewed by other EPA offices for legal, economic, scientific and programmatic sufficiency. A proposed or final rule cannot be signed and published until all pertinent reviews are completed. In addition, the Congress may review and disapprove a rule under the 1996 Congressional Review Act, subject to the President's signature.

- All information underlying the rule – generally including scientific or engineering studies, comments, testimony, communications with interested parties, and a final Response to Comments document and Regulatory Impact Analysis -- become part of the public record when a final rule is published.
- After publication of a final rule any affected party may seek judicial review, usually in the federal Court of Appeals for the District of Columbia Circuit. The Court may suspend the rule pending its decision if it believes opponents likely will prevail 'on the merits' and that suspension will not harm the public interest. It may affirm the rule, return it to the agency but leave it in effect, or require the agency to redo it before it can have legal effect. Aggrieved participants may ask the U.S. Supreme Court to review final Appeals Court decisions. The Supreme Court has decided numerous significant cases regarding EPA rules since 1971.

Lessons Learned

Experience over the last 50 years has yielded some general conclusions about how environmental rulemaking should be conducted, the evidence required to support it, and how much positive or negative impact a rule can be expected to have.

- Effective regulation development should employ processes that are as transparent as possible, allowing all stakeholders fair advance notice of the agency's intentions and ample opportunities to participate as regulations develop.
- To facilitate transparency and understanding it can be helpful to address:

- risk assessment, regarding the potential harm of targeted substances or circumstances before any new pollution controls.
- risk management -- selecting permissible approaches that will produce the 'biggest bang for the buck' in overall risk reduction.
- risk communication – assuring that risk conclusions above are clearly and simply conveyed to stakeholders and the general public.
- Regulatory decision-making often involves significant uncertainty – there typically will be unknowns about the scope and degree of pertinent risks and the full costs or benefits of contemplated remedial actions. The best an agency often can do is seek to narrow those uncertainties, creating feedback loops that allow mid-course corrections if better information is developed later. However, because compliance is “dynamic” and triggers ongoing adjustments by affected parties, actual compliance costs often turn out to be far less than a rule’s opponents initially suggest.
- Many EPA programs now seek to track these adjustments along with a rule’s real-world effects through (for example) ongoing monitoring and reporting of key pollutant concentrations in ambient air or water bodies. Tracking helps assure regulatory accountability by identifying when a rule is producing intended effects, or if not how it might be modified to do so.
- EPA makes wide use of outside-expert science advisory committees, including panels established by the agency’s Science Advisory Board and the National Academy of Sciences, for peer review and other types of expert advice to help ensure that its research, analyses and subsequent regulatory decision-making are consistent with mainstream scientific, engineering and economic information. Maintaining EPA’s professional competence is important to successful solicitation and use of the advice provided by such committees, since by law the responsibility for making final decisions rests with the Agency.
- Stakeholders – especially industry and environmental-group stakeholders – often have sharply divergent views that they pursue aggressively. The Agency should expect to be sued where costs or post-rule risks of a regulation are perceived to be high. Some have suggested that if a major

EPA rule is not challenged by everyone involved, EPA may not have “done its job.”

- EPA may mitigate such conflicts (and the scope of resulting litigation) by integrating in rulemaking some of the ‘streamlining’ steps noted above. For example, use of incentives to provide flexibility in rule compliance by affected dischargers will not make opposition disappear, especially if opposition is based on hostility to any reduction requirements. But it often can reduce compliance costs, enlist potential opponents who see financial opportunities, and help the rule be sustained in court.
- No regulation or collection of regulations can assure perfect protection, costless progress, or a pristine environment. That seems especially true because many remaining environmental problems involve smaller, more dispersed and/or difficult-to-regulate pollution sources – for example, runoff from farms, contamination from urban storm-water flows, collective emissions from consumer products, or carbon-dioxide emissions whose direct reduction by end-of-pipe “control technology” often may not be feasible.

These problems may have to be addressed by approaches that enlist emitters or dischargers by deploying common interests to move whole regulatory systems forward over time – for example, by using ‘emissions trading’ or discharge fees that can encourage both more-than-required reductions, and their disclosure to support better environmental planning. (See HCP [air pollution essay, Appendix \(“Market based or incentives programs”\)](#)). The 1990 Clean Air Act Amendments generally endorsed emissions trading approaches and authorized discharge fees in certain cases. Several states – for example, California and the eight Northeast Regional Greenhouse Gas Initiative jurisdictions – have deployed them more broadly.

After Rule Issuance: Implementation, Permits, Oversight and Enforcement

- Once environmental regulations are issued, they typically trigger implementation activities at federal, state, local and tribal levels. They also

trigger compliance planning by regulated entities that usually participate in these follow-up steps.

- Issued regulations often form the basis for facility-specific requirements called operating permits. Permits are legal documents good for fixed periods (e.g., 5 years). They typically are proposed and subject to public comment before becoming final. They usually include limits on polluting activities or pollution discharges. They also may require monitoring, record-keeping, and reporting to appropriate agencies of exceedances and corrective actions.
- Initial permits generally are based on available reduction technologies or practices. More stringent measures may be required later on if initial provisions fail to achieve required reductions or area-wide clean-air or clean-water standards are not met. While modern regulations often try to avoid such ‘multiple hits,’ needed reductions still must be secured to protect public health and welfare. It usually is up to states, who are closer to the problem, to determine in the first instance how further reductions will be allocated.
- Whatever their form, regulations may have little real-world impact without visible compliance oversight and enforcement. For example, even well-intentioned entities may short-cut compliance if they see their competitors gain advantage by declining to comply. Under most environmental programs, primary implementation has been delegated to state and tribal governments, with varying degrees of oversight by EPA. To help assure national consistency and minimum levels of health protection, EPA may disapprove a state’s program and write its own, though it seldom has had to use that authority.

References

There is a wide range of constantly-expanding literature about modern rulemaking. For further information about the regulatory process:

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3. Andrews, Richard N. L. 1999. *Managing the Environment, Managing Ourselves*. New Haven: Yale University Press. ISBN 0-300-07795-5.
4. Kerwin, Cornelius. *Rulemaking. How Government Agencies Write Law and Make Policy* 1994, ISBN 0-87187-672-6
5. Rosenbaum, Walter. 2014. *Environmental Politics and Policy*. Sage Publications. ISBN 978 1-4833-0163-1
6. Ruckelshaus, William D. 1995. Stopping the Pendulum. *Environmental Forum*. November-December
7. EPA. The Basics of the Regulatory Process. <https://www.epa.gov/laws-regulations/basics-regulatory-process>
8. Office of Management and Budget. 2014 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities. Office of Information and Regulatory Affairs. Washington, D.C. available at: <http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=E0FC30331848430BBF30CE38A57B87BB?doi=10.1.1.698.3498&rep=rep1&type=pdf>. Accessed 2/5/2017.